



Improving healthcare delivery in hospitals by optimized utilization of medicines

A study into 8 European countries

Commissioned by Medicines for Europe

KPMG Advisory N.V.

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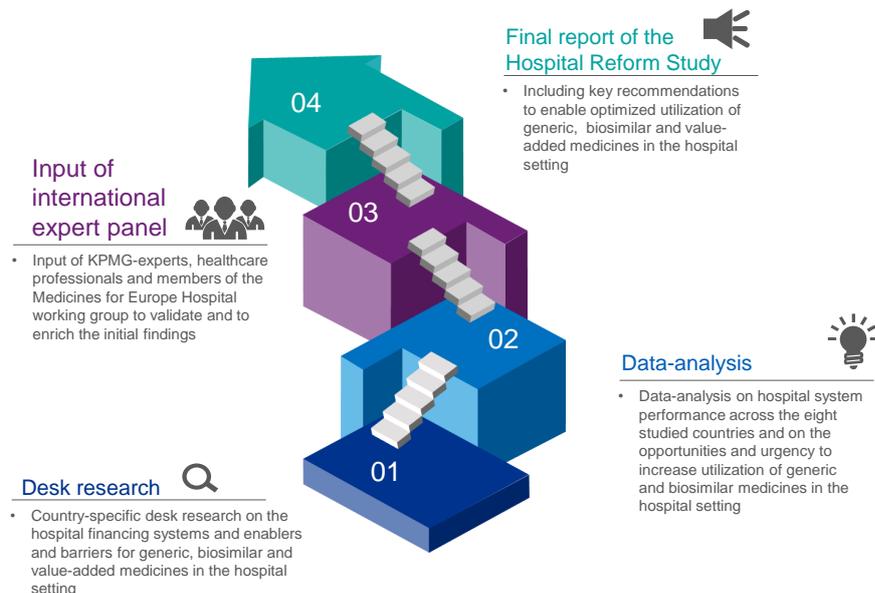
1 Management Summary

Healthcare systems are under significant and increasing budgetary pressure as a result of demand-driven demographic shifts and the growing costs of inputs in the delivery of care. Among European countries, hospitals account for the greatest share of healthcare expenditure and medicines represent a part of the expenditure. Therefore, hospital care presents a chief opportunity to increase healthcare system value (outcome per euro spent) through optimization of efficient and effective delivery of healthcare within the hospital systems. Increased utilization of generic, biosimilar and value added medicines in the hospital systems presents an opportunity to improve healthcare system value by increasing the efficiency of delivery of healthcare within hospital systems.

The objective of this study is to:

- A. Understand the financing of hospital systems;
- B. Create insights in the performance of hospital systems;
- C. Understand the procurement mechanisms of medicines in the hospital setting;
- D. Create insights in the enablers and barriers for increased utilization of generic and biosimilar medicines in hospitals;
- E. Underline the urge to improve the hospital environment to increase the utilization of generic and biosimilar medicines;
- F. Yield key recommendations to enable increased utilization of generic, biosimilar and value added medicines in hospitals.

The 5 most populous European Union (EU) countries (France, Germany, Italy, Spain and the United Kingdom) were selected for this study. In addition, Belgium, Poland and Portugal were selected as countries within the scope. Belgium, Poland and Portugal were added as they were identified to be of special interest with respect to the performance of their hospital systems and/or with respect to the utilization of generic and biosimilar medicines within their respective hospital systems. The figure below gives an overview of the overall project approach.



A. Understand the financing of hospital systems

For each country we have addressed the following two components in order to give an overview and an understanding of the hospital financing systems:

- A high-level overview of the national healthcare system and how the national healthcare system is financed summarized briefly in the table.

A high-level overview of the national healthcare system and how the national healthcare system is financed						
Country	Type of healthcare system	Healthcare expenditures in 2015 as share of GDP (%)	Public funding as share of total healthcare expenditures (%)	Co-payments as share of total healthcare expenditures (%)	Private insurance as share of total healthcare expenditures (%)	Other sources of funding as share of total healthcare expenditures (%)
	Belgium Social insurance	10,50%	77%	17%	4%	2%
	France Social insurance	11,10%	78%	6%	14%	2%
	Germany Social insurance	11,20%	85%	13%	3%	0%
	Italy National Health Service	9,10%	76%	22%	2%	0%
	Poland Social insurance	6,30%	70%	23%	4%	3%
	Portugal National Health Service	9,00%	66%	28%	5%	1%
	Spain National Health Service	9,20%	71%	24%	5%	0%
	United Kingdom National Health Service	9,90%	80%	15%	3%	2%

GDP= Gross domestic product. Main sources for data: The Economist Intelligence Unit 2018 and the Country Health Profiles series by the OECD and the European Observatory on Health Systems and Policies 2017.

- A description of how the hospitals are funded within the national healthcare system, summarized briefly in the table below.

Hospital funding mechanisms and resulting financial incentives for hospitals		
Country	Main payer in the hospital financing system	Main payment mechanisms
	Belgium National Institute for Health and Disability Insurance	Fixed annual prospective budget, Fee-for-service & Sales of Medicines
	France Multiple statutory healthcare insurers	DRG
	Germany Multiple sickness funds	DRG
	Italy Regional Health Authorities (RHAs)	DRG (capped) Global budget for hospitals directly run by RHAs
	Poland 1 national health insurance fund	Global budget (as of October 1st, 2017)
	Portugal Regional Health Authorities	Global budget
	Spain Regional Health Authorities	Global budget
	United Kingdom Clinical commissioning groups (England), Local Health Boards (Northern Ireland, Scotland, Wales)	DRG and global budget (capped)

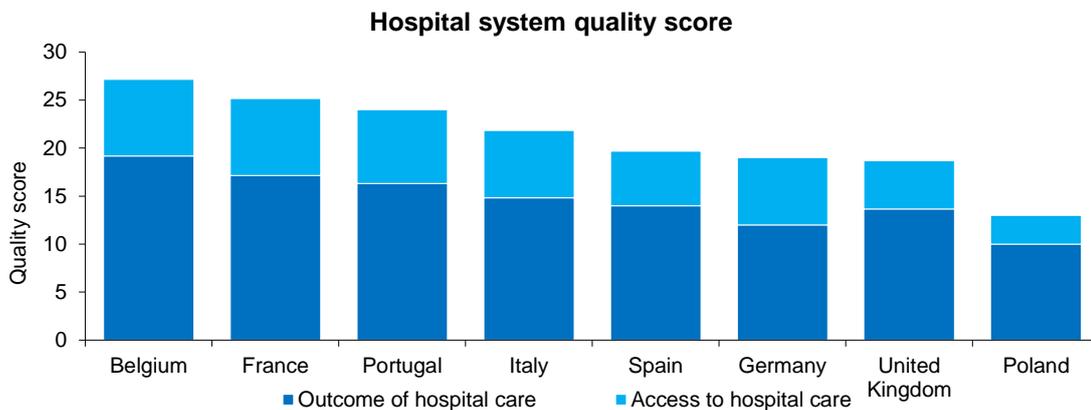
DRG= Diagnosis-related group

B. Create insights in the performance of hospital systems

The hospital system performance per country is assessed by comparing the quality of hospital care and the cost of hospital care.

Quality of hospital care:

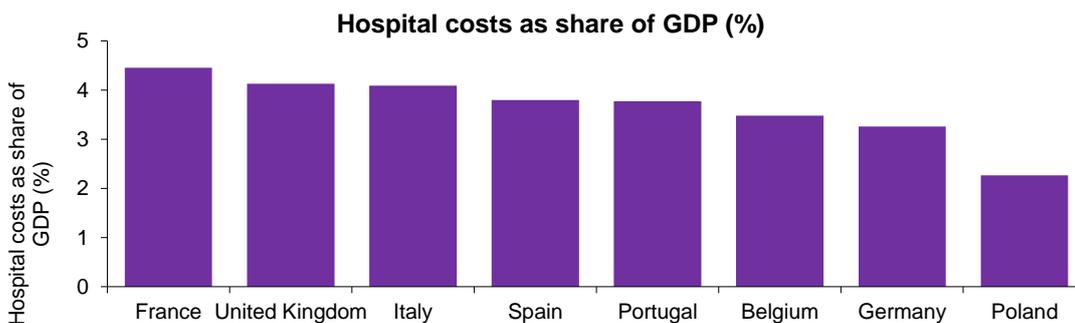
The quality of hospital care is defined as a sum score of available indicators that allow for an international comparison of the eight countries in the scope of this study. These indicators concern outcome and accessibility of hospital care. The indicators originate from the European Health Consumer Index (EHCI; 2017) and Organization for Economic Co-operation and Development (OECD; 2015) databases. Using these two selection criteria, 8 of the 46 indicators of the EHCI and 13 of the 76 indicators of the OECD metrics were selected for the analysis of quality of hospital care.



Belgium has the highest total score on quality of care with 27 out of 42 points on the available indicators. France has the second highest total score (25) and Portugal the third highest total score (24). The average total quality score of hospital care in the eight countries studied is 21.

Costs of hospital care:

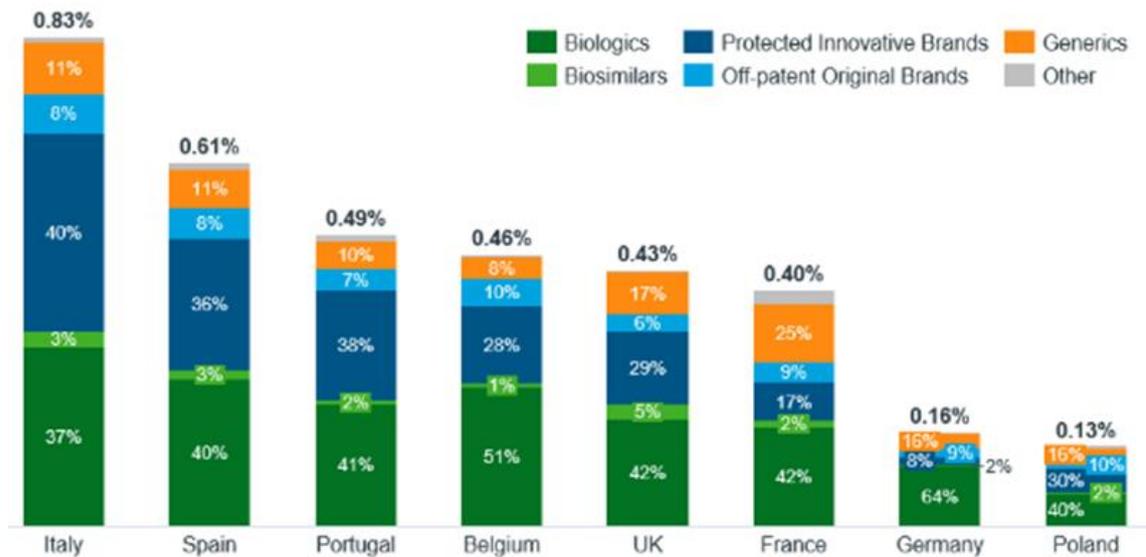
Costs are defined as the hospital costs as a share of GDP and the data concerning hospital costs were extracted from the OECD database (2015).



Source: OECD Database (2015)

The average costs of hospital care as a share of GDP in the eight countries studied is 3.7%. France has the highest percentage of hospital costs as a share of GDP with 4.5% and the United Kingdom (4.1%) and Italy (4.1%) are second and third, respectively. On the other side of the spectrum, Poland has the lowest percentage of hospital costs as a share of GDP with 2.3%, which is a clear drop-off from the second-lowest country (Germany), which has 3.3% hospital costs as a share of GDP.

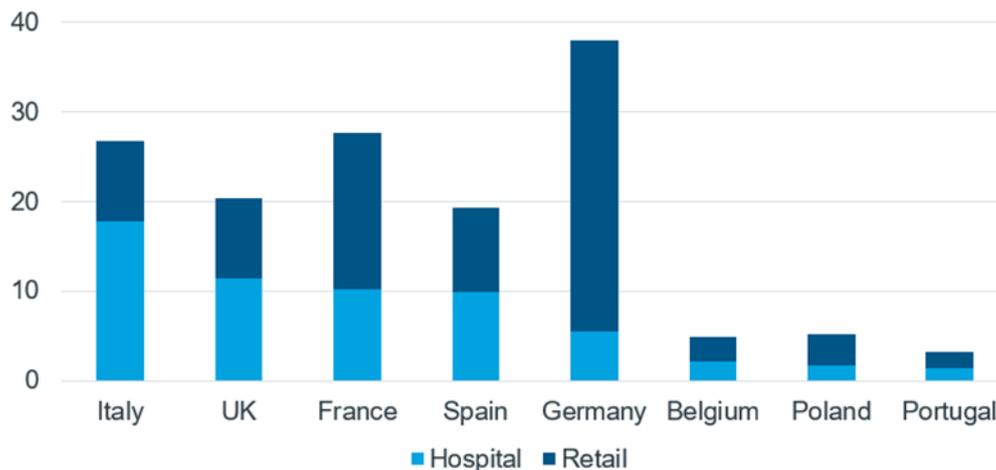
Regarding the expenditure of medicines in the context of cost of hospital care, the figure below showcases the relative hospital expenditure as a % of GDP in the 8 European countries studied. Generic and biosimilar medicines have a relatively low weight on hospital expenditures on medicines. Compared to the overall costs of hospital care, medicines account for relatively a small portion (5-20%).



*Hospital Expenditure on Medicines as a percentage of GDP (List Price¹ USD, 2018).
 Note: Biologics, Generics include Unbranded and Branded Generics
 Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q4 2018.*

¹ Please note that these analyses are based on list prices instead of net prices. Therefore the findings may not fully reflect actual expenditures on medicines and are therefore likely overestimations.

One can observe different dynamics with respect to the relative expenditure of medicines in the hospital versus retail setting, with Germany more retail-based due to its office-based physicians and Italy more hospital-based.



*Hospital and Retail Medicines Expenditure (Billions of Euros; List Price¹; 2018)
Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q4 2018.*

Comparison of hospital system performance

Hospital care presents a chief opportunity to increase healthcare system value (outcome per euro spent) through optimization of efficient and effective delivery of healthcare within the hospital systems. As shown in the analyses above, hospital systems in the eight countries studied show different scores on quality and costs. Although some countries seem to be further than others in realizing optimal hospital system value, all countries show potential to further enhance hospital system value by either increase quality and/or reduce costs (without decreasing quality).

The next sections will show that there is still potential to improve the use of generic, biosimilar and value added medicines in the hospital setting. This presents an ample opportunity to further increase hospital system value in all of the eight studied countries.

Disclaimer: *It is important to note that we gauged hospital performance by using validated (and available) indicators from the EHCI and OECD regarding hospital care. However, it is well known that hospital care as such has a limited influence on outcomes achieved in a healthcare system and that genetics, lifestyle, public health, primary healthcare, etcetera all influence the achieved outcomes as well. Also, it is well known that hospital quality is only partially measured by the available indicators. In addition, we have made a selection of the available information and excluded studies that do not have information on all eight countries in scope. Therefore, the results of this comparative analysis should be viewed as an indication of early insights that warrants further research before making conclusions of relative hospital performance, rather than an exact measure of performance of these eight hospital systems.*

C. Understand the procurement mechanisms of medicines in the hospital setting

The table below gives a high-level overview of the procurement mechanisms of generic and biosimilar medicines in the hospital setting of the 8 studied countries.

Country	Generic medicines					Biosimilar medicines		
	Main procuring entities	Main financial incentive for procuring entities	Main procurement mechanism	Commitment with respect to minimum and maximum volumes by procuring entity?	Prices subject to change during tender duration?	Main procuring entities	Main procurement mechanism	Seperate tenders for naïve patients and patients already undergoing treatment?
 Belgium	(Groups of) hospitals	Low (net) price	Tenders	No	Yes	(Groups of) hospitals	Tenders	Yes, however combination in 1 parcel is promoted
 France	(Groups of) hospitals	Low (net) price	Tenders	Depends on tender	No	(Groups of) hospitals	Tenders	No
 Germany	(Groups of) hospitals	Low (net) price	Tenders	Depends on tender	Yes	(Groups of) hospitals	Direct negotiations	Not applicable
 Italy	Regional health services (LHAs)	Low (net) price	Tenders	No	Yes	Regional health services (LHAs)	Tenders	No
 Poland	(Groups of) hospitals	Low (net) price	Tenders	No	No	(Groups of) hospitals	Tenders	No
 Portugal	SPMS (Groups of) hospitals	Low (net) price	Tenders	Yes	Yes	SPMS (Groups of) hospitals	Tenders	No
 Spain	Regional health services (Groups of) hospitals	Low (net) price	Tenders	No	No	Regional health services (Groups of) hospitals	Tenders and direct negotiations	No
 United Kingdom	Commercial Medicines Unit (CMU) and individual hospitals	Low (net) price	Tenders	No	No*	Commercial Medicines Unit (CMU) and individual hospitals	Tenders	No

*Only in exceptional circumstances (e.g. significant increases in manufacturing costs)

Examples of procurement/hospital tendering principles that improve access to generic or biosimilar medicines

<i>Example</i>	<i>Positive procurement principle</i>
EU Directive on public procurement	<p><i>EU Directive on public procurement from 2014²</i></p> <ul style="list-style-type: none"> • <i>“The most economically advantageous tender from the point of view of the contracting authority shall be identified on the basis of the price or cost, using a cost-effectiveness approach, such as life-cycle costing in accordance with Article 68, and may include the best price-quality ratio, which shall be assessed on the basis of criteria, including qualitative, environmental and/or social aspects, linked to the subject-matter of the public contract in question”</i>
France	<ul style="list-style-type: none"> • Opportunity to have a pre-tender discussion with the relevant hospital stakeholders • Price is not the only criterion to award the winner of the tender
Italy	<p>Italy Procurement law on biosimilar medicines (in force in 2016)³</p> <ul style="list-style-type: none"> • Regional authorities are now obliged to re-open the supply agreements within 60 days after entrance of the biosimilar medicine to the market. • If there are more than 3 competitors on the market, it is mandatory to select 3 preferred products.
Portugal	<p>Enforcement of public procurement law in January 2018</p> <ul style="list-style-type: none"> • Recognition of a dynamic process of procurement when there is the launch of any off-patent medicine (such as generic or biosimilar medicines) in the Portuguese agreement framework (“<i>acordo quadro</i>”)⁴
UK	<ul style="list-style-type: none"> • NHS England drafted in 2017 a document on procurement principles ‘Commissioning framework for biological medicines (including biosimilar medicines)’⁵ • NHS England published in September 2018, the key principle for the tendering strategy of adalimumab to “...ensure plurality of suppliers over the long term...”⁶

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0024> (Article 67; 2)

³ <http://www.gazzettaufficiale.it/eli/id/2016/12/21/16G00242/sg>

⁴ DL111 – B 2017 in force in January of 2018 - Article 17

⁵ <https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf>

⁶ https://www.sps.nhs.uk/wp-content/uploads/2018/09/20180925-Contractual-Commissioning-Intentions-Adalimumab_corporate-template.pdf

D. Create insights in the enablers and barriers for increased utilization of generic and biosimilar medicines in hospitals

The table below gives a summary of the most important enablers and barriers for increased utilization of generic and biosimilar medicines in the hospital setting of the 8 studied countries.

Country	Main enablers for increased utilization of generic and biosimilar medicines	Main barriers for increased utilization of generic and biosimilar medicines
 Belgium	Financial incentives for medicines with lowest (net) prices Quotas for 'low cost' medicines Biosimilar covenant (2016), however non-binding	Additional award criteria in tenders seem to favor originator medicines Tender procedures inefficient (time consuming, low volumes per tender) Physicians and pharmacists have suboptimal confidence in biosimilars Physicians have no prescription quotas to use biosimilars
 France	Financial incentives for biosimilars with lowest (net) prices CAQES contracts stipulate quotas for generics & biosimilars Focus from policy makers to promote generic medicines	Disproportionate penalties in case of supply issues Unrealistic deadlines for tender calls Lack of prescription guidelines for biosimilar medicines Physicians have suboptimal confidence in biosimilars
 Germany	Financial incentives for medicines with lowest (net) prices Immediate pricing and reimbursement of generic medicines Quotas for biosimilar medicines Positive attitude of physicians towards established biosimilars	Disproportionate penalties in case of supply issues 129a SGB-V contracts yield suboptimal financial incentive for biosimilars Originators offering relative low prices in the hospital setting to generate spill over in the outpatient market Reluctant attitude of physicians towards novel biosimilars
 Italy	Financial incentives for medicines with lowest (net) prices Informational campaigns to promote generic medicines New procurement law (2017) for biosimilar medicines	Unfavorable risk/reward balance in tender procedures Payback mechanism for hospital medicines Lack of awareness of benefits of generic medicines Lack of prescription guidelines for biosimilar medicines
 Poland	Financial incentives for medicines with lowest (net) prices Informational campaigns to promote generic medicines Treatment guideline for switching from Infliximab available	Mandatory price cuts on list price for generics and biosimilars Tender procedures inefficient (time consuming, complex) Lack of options in hospital formularies reduces options for substitution Lack of treatment guidelines for most biologicals with respect to switching Physicians have suboptimal confidence in biosimilars
 Portugal	Financial incentives for medicines with lowest (net) prices Informational campaigns to promote generics & biosimilars Fast-track for pricing & reimbursement for generics & biosimilars Minimum quotas of 20% for biosimilar medicines and guidelines on interchangeability/switching of biosimilar medicines	Inclusion of generics and biosimilars in pharmaceutical payback scheme Prices of generics & biosimilars are directly dependent on originator price Single winner tenders Lack of national guidelines for biosimilar treatment switching Lack of implementation of benefit sharing methods for biosimilars
 Spain	Financial incentives for medicines with lowest (net) prices Informational campaigns to promote generics and biosimilars	No list price differentiation between originator and generics Quotas for biosimilar medicines are only present in a few regions Tender procedures inefficient (time consuming, complex) Prescription guidelines do not differ between biosimilar and reference medicines
 United Kingdom	Financial incentives for medicines with lowest (net) prices Immediate pricing and reimbursement of generic medicines Specific guidance on implementing the best value biological medicines in the NHS such as the RMOC briefing on adalimumab	Unfavorable risk/reward balance in tender procedures No commitment to purchase after winning a tender for generic and biosimilar medicines Inconsistent implementation of national guidance between local areas for generic and biosimilar medicines

Please see appendix B for country-specific recommendations for improved access to generic and biosimilar medicines in the hospital setting.

E. Urge to improve the hospital environment to increase the utilization of generic and biosimilar medicines

Before we start this section it is important to state that – in general – higher utilization of generic and biosimilar medicines is associated with cost-efficiency and a similar level of quality of care⁷. Therefore heightening the use of generic and biosimilar medicines is a route to enhance the efficiency (outcome per euro spent) of hospital care. In addition, generic and biosimilar medicines enhance the efficiency of hospital care by increasing competition for branded medicines.

The main objective of this section is to underline the urge to improve the hospital environment to increase utilization of generic and biosimilar medicines by showcasing:

- 1 Differences between countries in the utilization of generic and biosimilar medicines in hospitals, due to diverse hospital environments such as the enablers and barriers for generic and biosimilar medicines as described previously.
- 2 A decrease in market competitiveness due to manufacturers abandoning the market as a result of the barriers as described previously.
- 3 The average lag between the first use of a generic medicine after loss of exclusivity (LOE) of the respective originator and the corresponding hospital opportunity loss.

⁷ See for instance “QuintilesIMS Report. Delivering on the potential of biosimilar medicines. 2016.” In this report Quintiles IMS state that the introduction of biosimilars saved EUR 1.5B in the EU-5 countries alone up until 2016 and that the future potential is way (up to EUR 47 B in the 2016-2020 period) higher. Regarding generic medicines, according to “IMS Health, The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective. 2015”, generic medicines provide an opportunity for European governments to achieve efficiency gains which can be invested in other components of healthcare systems. Without competition from generic medicines, payers in Europe would have had to pay €100BN more in 2014.

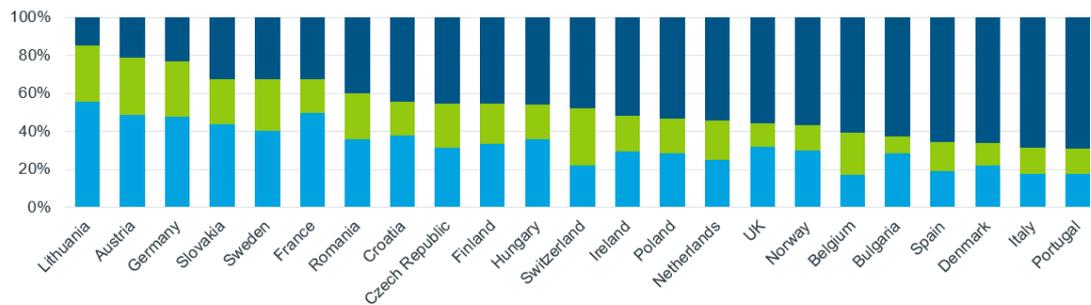
1. Differences between countries in the utilization of generic and biosimilar medicines in hospitals

Generic medicines

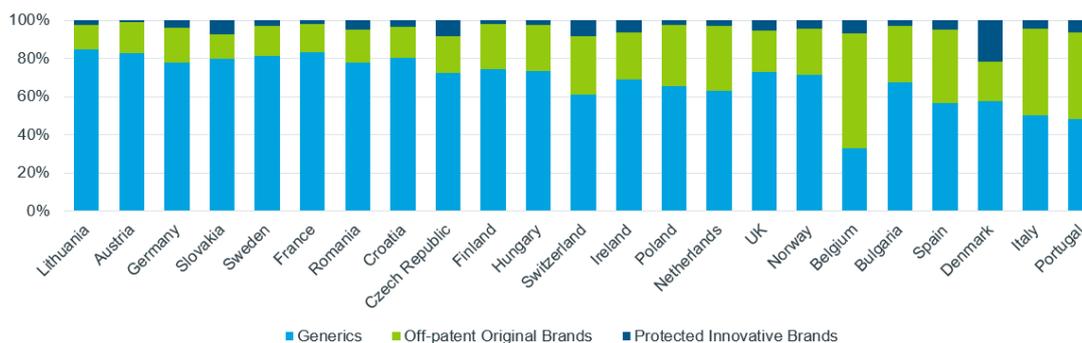
The figure below describes the differences in market shares (value and volume) of generics in the European hospital setting. Comparing value and volume market shares, it is evident that there is an unbalance. Originators and off-patent brands have typically a combined volume market share of <30%, whereas the budgetary impact of originators and off-patent brands typically exceeds 60%.⁸

According to the data presented in the figure below, France and Germany have hospital environments which enable the highest utilization of generic medicines compared to the other countries in scope of this study. On the other side of the spectrum, Belgium shows the most potential to further optimize the hospital environment in order to stimulate higher uptake of generic medicines. Compared to countries such as Lithuania and Austria however, all countries in scope of this study show potential for (further) improving value and volume market shares of generic medicines in the hospital setting.

A Hospital Sales of Small Molecules in 2018, List Price Euros



B Hospital Volume of Small Molecules in 2018, Standard Units



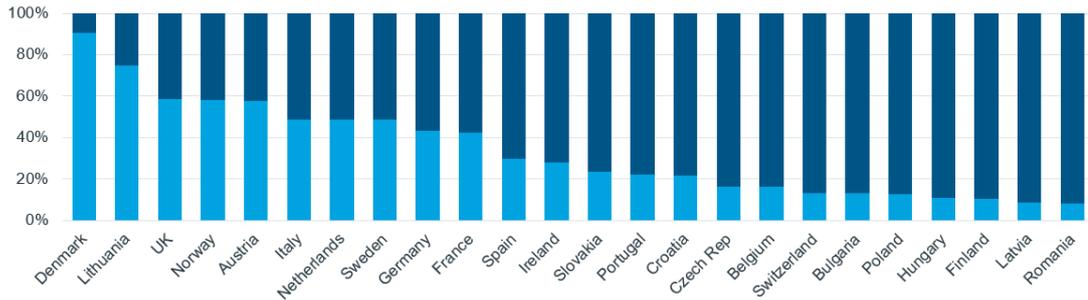
Hospital sales (A) and volume (B) of small molecules in 2018, expressed in Euros (list price) and standard units, respectively. Note: Generics include unbranded and branded generics. Source: IQVIA European Thought Leadership, IQVIA MIDAS FY2018, Innovation Insights, excluding hospital solutions, imaging and other.

⁸ Please note that these analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.

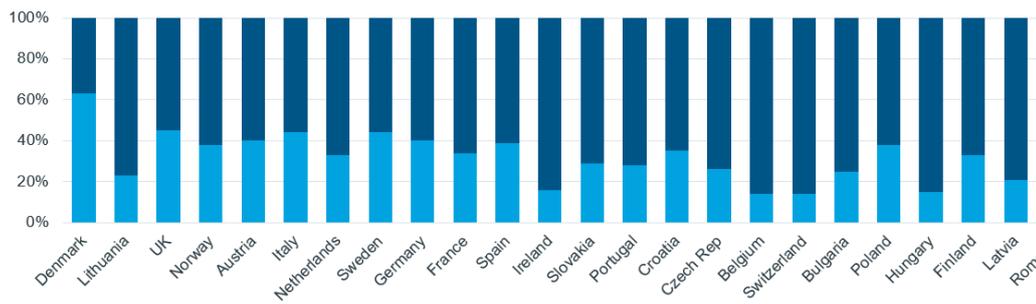
Biosimilar medicines

The differences in market shares (value and volume) of biosimilars in the European hospital setting are shown in the figure below.⁹

A Hospital Sales of Biosimilars in March 2019, List Price Euros



B Simple Average of Hospital Biosimilar Volume in March 2019, Treatment Days



C

		Hospital Biosimilars Volume, Treatment Days, March 2019															
		Simple Average*	Adalimumab	Enoxaparin Sodium	Epoetin	Etanercept	Filgrastim	Follitropin Alfa	Infliximab	Insulin Glargine	Insulin Lispro	Pegfilgrastim	Rituximab	Rituximab IV only	Somatropin	Trastuzumab	Trastuzumab IV only
		6%	48%	9%	3%	0.5%	0.3%	12%	12%	2%	0.5%	2%	2%	2%	2%	2%	2%
EU Weighting		63%	96%	0%	53%	89%	93%	26%	97%	8%	0%	100%	78%	93%	78%	98%	99%
Denmark		63%	96%	0%	53%	89%	93%	26%	97%	8%	0%	100%	78%	93%	78%	98%	99%
UK		45%	39%	53%	6%	81%	96%	52%	93%	16%	0%	12%	79%	90%	22%	32%	81%
Italy		44%	25%	35%	84%	48%	97%	26%	84%	16%	21%	1%	70%	88%	25%	42%	86%
Sweden		44%	55%	0%	81%	65%	98%	16%	81%	33%	50%	21%	22%	58%	2%	43%	80%
Germany		40%	81%	3%	80%	96%	94%	0%	24%	23%	0%	3%	71%	77%	2%	47%	58%
Austria		40%	9%	12%	80%	52%	99%	0%	91%	0%	0%	22%	83%	95%	0%	67%	89%
Spain		39%	12%	41%	77%	39%	94%	85%	59%	24%	0%	2%	43%	59%	20%	17%	40%
Poland		38%	1%	0%	100%	40%	86%	0%	97%	21%	35%	8%	0%	0%	100%	11%	50%
Norway		38%	0%	0%	100%	100%	86%	0%	98%	4%	0%	15%	80%	94%	0%	7%	76%
Croatia		35%	8%	0%	100%	24%	100%	64%	67%	10%	0%	28%	30%	62%	25%	5%	12%
France		34%	28%	0%	42%	49%	99%	0%	61%	47%	0%	13%	62%	78%	0%	36%	80%
Netherlands		33%	25%	0%	19%	22%	39%	0%	82%	30%	0%	15%	96%	97%	16%	80%	99%
Finland		33%	10%	0%	100%	14%	91%	0%	11%	29%	10%	0%	43%	54%	100%	19%	88%
Slovakia		29%	0%	0%	100%	0%	100%	0%	33%	25%	0%	67%	29%	40%	0%	26%	80%
Portugal		28%	4%	0%	96%	29%	93%	0%	61%	0%	0%	3%	51%	78%	12%	13%	35%
Czech Rep.		26%	8%	0%	85%	22%	100%	4%	60%	8%	0%	27%	21%	31%	7%	1%	7%
Bulgaria		25%	0%	0%	100%	0%	100%	0%	100%	0%	0%	0%	19%	21%	0%	0%	1%
Lithuania		23%	0%	0%	0%	0%	100%	92%	0%	2%	0%	0%	0%	0%	0%	100%	100%
Latvia		21%	0%	0%	0%	0%	100%	74%	0%	0%	100%	0%	0%	0%	0%	0%	0%
Romania		17%	0%	0%	100%	0%	100%	0%	0%	17%	0%	2%	7%	7%	0%	0%	0%
Ireland		16%	0%	0%	100%	0%	41%	0%	47%	0%	0%	0%	23%	23%	0%	2%	3%
Hungary		15%	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%	73%	87%	0%	27%	78%
Belgium		14%	0%	0%	14%	0%	32%	47%	33%	6%	0%	0%	2%	4%	40%	2%	5%
Switzerland		14%	0%	0%	21%	23%	83%	0%	24%	1%	0%	0%	14%	15%	11%	0%	0%

Hospital sales (A) and volume (B-C) of biosimilars and biologics in 2018, expressed in Euros (list price) and treatment days, respectively. Note: All biosimilars launched in Europe by March 2019 are in scope. * Simple average calculated including subcutaneous formulation for Rituximab and Trastuzumab. Source: IQVIA European Thought Leadership, IQVIA MIDAS MTH March 2019

⁹ Please note that these analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.

Denmark shows the highest volume market shares of all countries, whereas Central Eastern European countries score typically low, as well as Belgium and Switzerland. The relatively low volume market shares in these countries points towards a lack of access to biosimilar medicines in the hospital setting, and as such limited potential of competition for the originator biologic medicines.

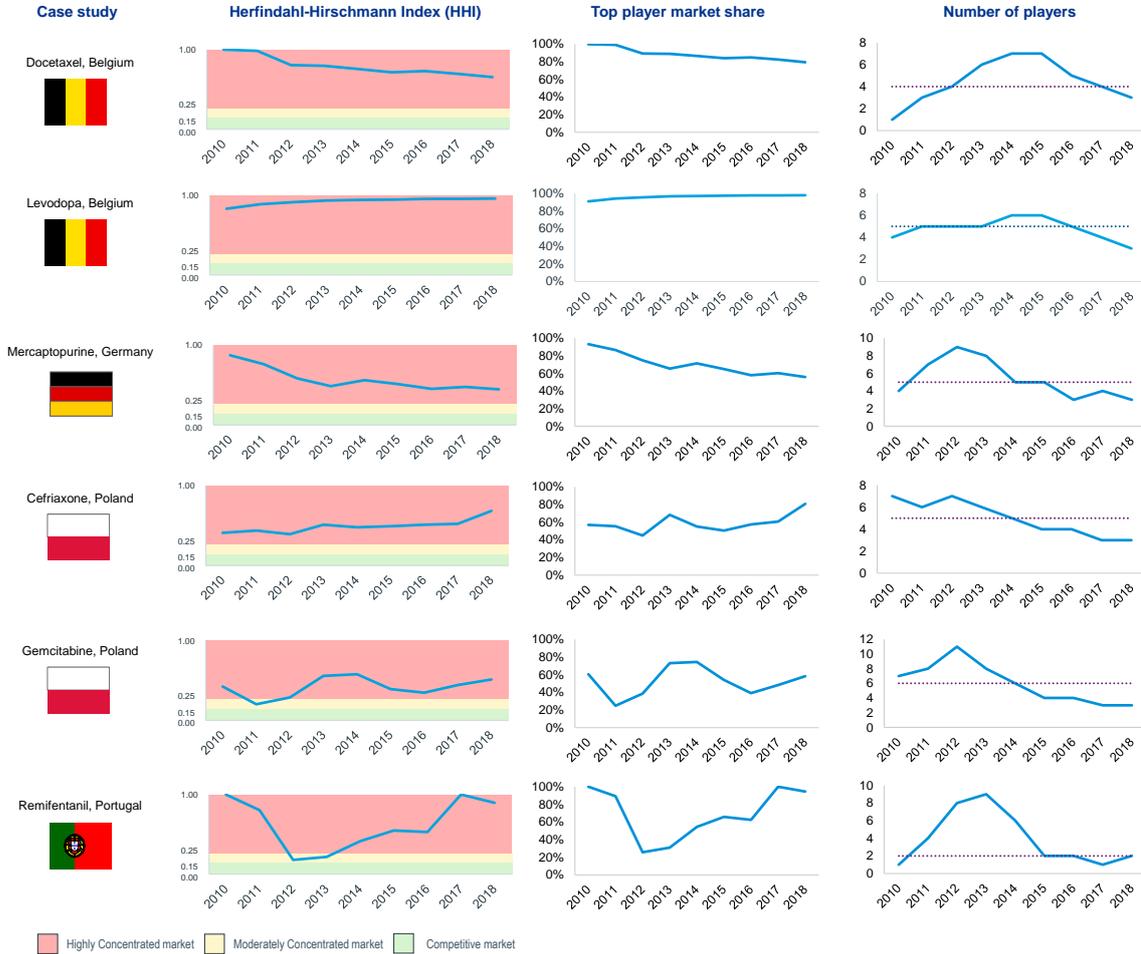
Of the countries within scope of this study, it is the UK which comes closest to the Danish biosimilar volume market shares and it is Belgium that shows most room for improvement in this respect. As none of the countries in scope match Denmark with respect to utilization of biosimilar medicines in the hospital sector, there is still room to further optimize the hospital environment for each of the country within scope of this study.

2. Decrease in market competitiveness due to manufacturers abandoning the market

The figure on the next page displays six case studies into the market competitiveness of small molecules. These case studies show that the market is increasingly getting more concentrated, as manufacturers are abandoning the market.

A good example of this trend are the case studies concerning Ceftriaxone in Poland and Remifentanil in Portugal. Both case studies show a steady decline in the number of players in the market from a situation with more than 6 players in 2012 to a situation with only 2 players in 2018. In addition, in both case studies the top market player has a market share that surpasses 80%, showing that competition in these markets is rather limited. In such cases with a small number of players and a top player which has the vast majority of the market, market effectiveness is rather low (as expressed by a high Herfindahl-Hirschman Index score). This subsequently might lead to de-novo monopolies and unsustainable market characteristics.

Improving healthcare delivery in hospitals by optimized utilization of medicines
KPMG Advisory N.V.



Herfindahl-Hirschman Index (HHI)

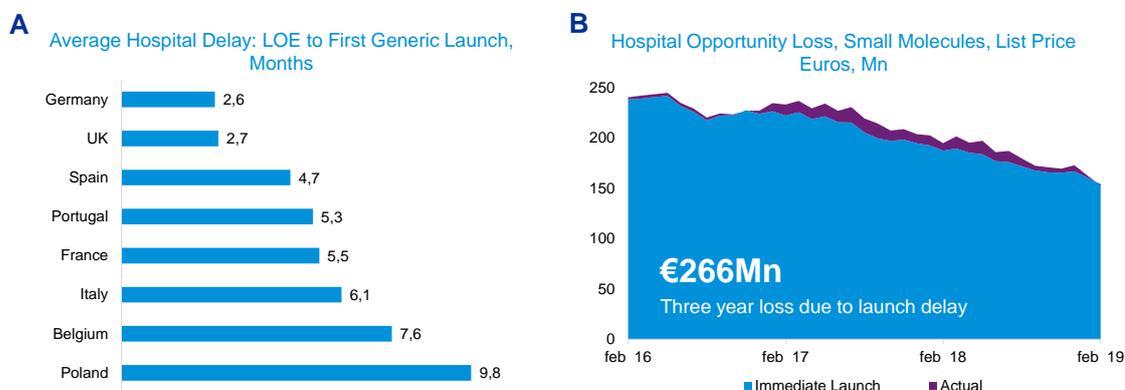
HHI is a common measure of market concentration, and is used to determine market competitiveness. It is calculated by summing the squares of the market shares. Numbers closer to 1.0 are deemed non-competitive (smaller number of players and/or concentrated market share, numbers closer to 0.0 indicate healthier competition (share spread evenly across many players).

	Company A	Company B	Company C		HHI	
Share	98%	1%	1%	$0.98^2 + 0.01^2 + 0.01^2$	0.96	Strong Monopoly
Share	80%	10%	10%	$0.8^2 + 0.1^2 + 0.1^2$	0.66	Weaker Monopoly
Share	33%	33%	33%	$0.33^2 + 0.33^2 + 0.33^2$	0.33	Even share, 3 players
Share	50%	50%		$0.5^2 + 0.5^2$	0.50	Even share, 2 players

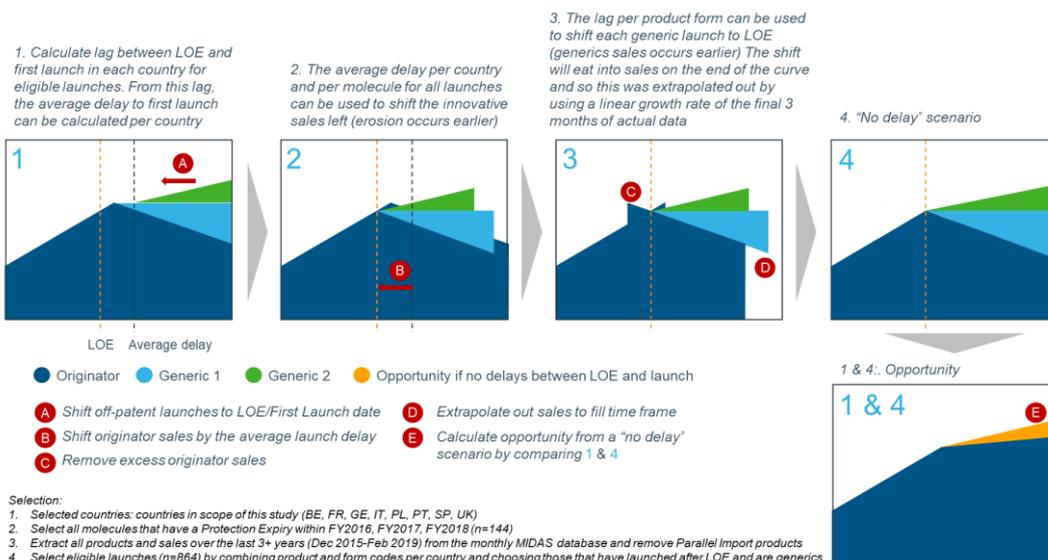
Six case studies into market concentration of selected generic medicines in the hospital sector of selected countries. Source: IQVIA European Thought Leadership

3. Average lag between the first use of a generic medicine after loss of exclusivity of the respective originator and the corresponding hospital opportunity loss

The figure below shows the lag between the first use of a generic medicine after loss of exclusivity (LOE) of the respective originator and the corresponding hospital opportunity loss. From the 8 countries studied, Italy, Belgium and Poland have the longest delay in to access to the first generic medicine post LOE (6, 8 and 10 months, respectively). However, each country studied shows a delay of at least two months, and therefore an opportunity is present for each country to accelerate the utilization of generic medicines in the hospital setting after LOE. This opportunity has amounted up to €266Mn in the last three years.¹⁰ To be able to seize this opportunity, it is crucial that purchasing procedures (e.g. tenders) as well as pricing and reimbursement procedures are streamlined.



C Methodology to calculate average hospital delay and hospital opportunity loss



Average hospital delay (A) and hospital opportunity loss (B) for small molecules after loss of exclusivity and used methodology (C) to calculate average hospital delay and hospital opportunity loss. Notes: Small Molecules only; Calculations are based on list prices. Source: IQVIA European Thought Leadership, IQVIA MIDAS MTH Jan 2019

¹⁰ Please note that these analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.

F. Recommendations to improve access to generic, biosimilar and value added medicines in the hospital setting

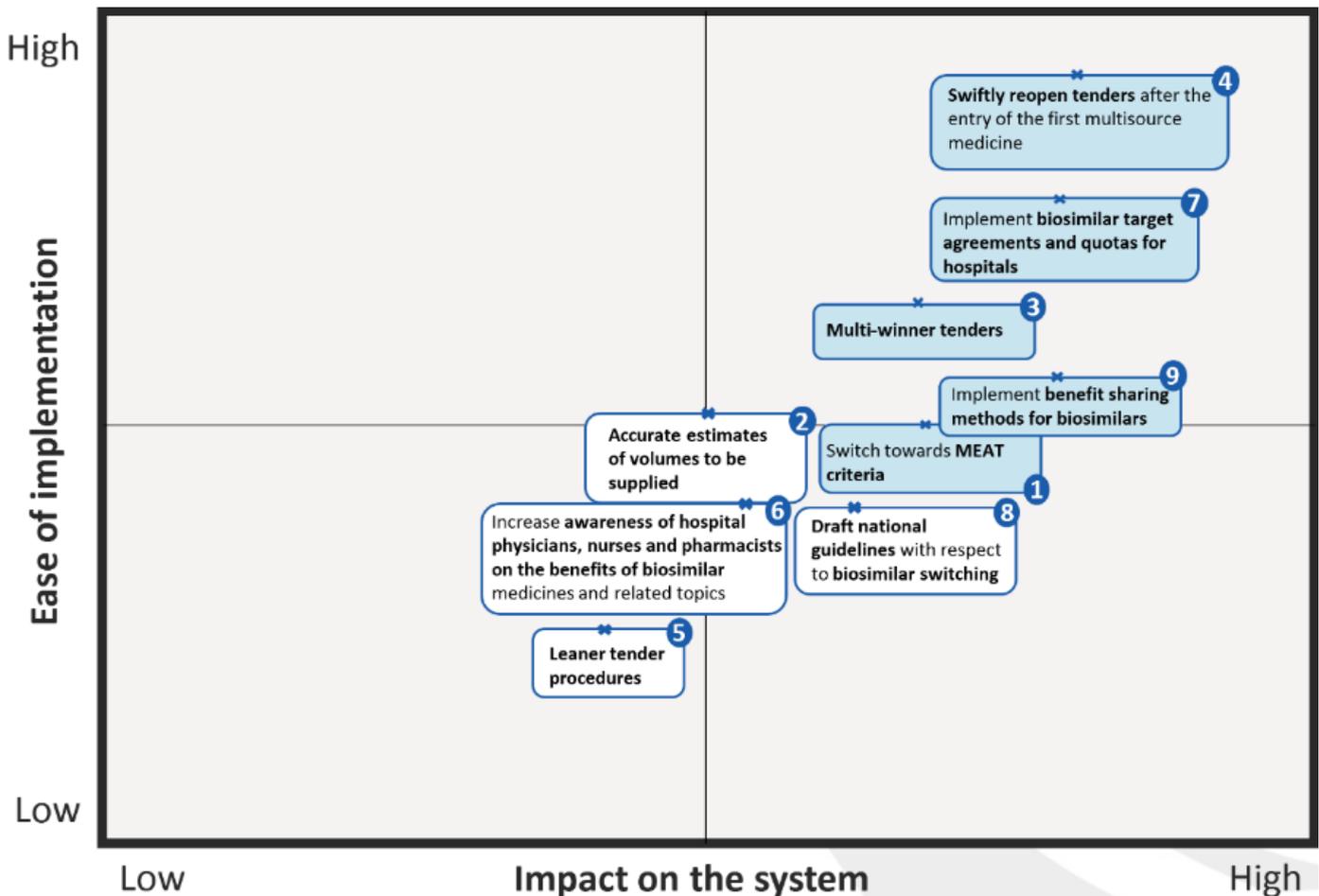
This final section describes a set of overarching recommendations to increase hospital system value by stimulating long-term competition and timely access to generic and biosimilar medicines in the hospital setting. Our recommendations are a synthesis of the findings in this study and are furthermore based on interviews with hospital experts from KPMG and national associations.

With the recommendations as described in this section, a step can be taken in the realization of the potential impact of increased utilization of generic and biosimilar medicines in the hospital market in the eight studied countries. This can have a positive impact on the hospital care system value: costs of hospital care can be lowered or investments can be made to improve the quality of delivered care in the hospital systems. Based on the findings of this study, there is potential as well as urgency for each of the studied countries to improve utilization of generic and biosimilar medicines in the hospital setting in order to increase hospital care system value.

Overarching recommendations for improved access to generic and biosimilar medicines in the hospital setting

This section describes nine key ingredients for a hospital pharmaceutical environment that optimally fosters utilization of generic and biosimilar medicines. Please note that some of the studied countries may already have one or multiple of the key ingredients listed below present in their hospital pharmaceutical market. In addition, some countries require additional country-specific ingredients to optimally foster utilization of generic and biosimilar medicines. Country-specific recommendations for increased utilization of generic and biosimilar medicines in the hospital setting can be found in Appendix B. The figure below shows these nine key ingredients prioritized according to ease of implementation and impact on the system.

9 key ingredients for increased utilization of generic and biosimilar medicines in the hospital setting and prioritisation of these ingredients according to ease of implementation and impact on the hospital system.



✘ Position of the key ingredient

Priority actions

1-9 For more information, on each key ingredient, please consult the recommendations in the section below

1-5 ingredients related to improvement of procurement practices

MEAT – Most Economic Advantageous Tender

Nine key ingredients for increased utilization of generic and biosimilar medicines in the hospital setting

A key ingredient for increased utilization of generic and biosimilar medicines in the hospital setting is a **procurement/purchasing system that stimulates competition**. Competition forms a cornerstone for sustainable market dynamics and creates an opportunity for hospitals to achieve efficiency gains which can be invested in other aspects of hospital care. Many hospital systems choose to conduct procurement/purchasing mechanisms using tendering systems, which can be an efficient mechanism when conducted appropriately. Stimulation of long-term competition can be sustainably achieved by finding the fair spot between risk and reward in the procurement/purchasing system.

In order to stimulate a long-term sustainable competition, we recommend:

- 1 Switch from the frequently employed lowest bid procedure towards a most economically advantageous (MEAT) procedure**, which takes other qualitative elements into account that add value to bids, such as a proven track record of supply reliability on company level. A shift to more 'economically advantageous' procedures may stimulate competition as it creates more opportunities and interest from manufacturers to compete sustainably on more parameters than just price. Actions that ensure the active participation of the manufacturers in the hospital market will stimulate competition and consequently originate efficiency gains that can be invested and benefit the hospital system as a whole. It is important to closely monitor the effects of such additional award-criteria, to ensure that this is well balanced and does not prevent competition, such as in Belgium, where additional award-criteria seem to favour the originator manufacturers (see chapter 4.1.4).
- 2 Set accurate volume estimates to guarantee a continuous supply**. This ingredient raises the interest of manufacturers to compete, as it enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids. The settlement of accurate volumes to be supplied, helps manufacturers to better forecast demand creating predictability and attractiveness to bid which not only stimulates competition and benefits the healthcare system but also reduces the chance of medicine shortages.
- 3 Award tenders to multiple winners¹¹**. Single-winner tenders lead to a risk of reduced competition, as only one manufacturer is active in the market and other manufacturers might choose to discontinue their production. This might lead to a reduced number of manufacturers participating in the next round of tenders, reducing competition. In addition, single-winner tenders might contribute to medicine shortages. In the case of a supply issue of the sole tender winner, other manufacturers might not be able to cope with the sudden demand as they might have significantly reduced or even entirely discontinued their production. Hence, multi-winner tenders with predictability of volumes for each winner not only increase supply reliability that is essential to prevent medicine shortages but also sustain healthier levels of competition in the tendering system, which both benefit the healthcare

¹¹ Except situations/countries where the quantity of medicines tendered is too low and consequently the market volume is too small to create a mature and balanced market.

system as a whole (please see positive examples in Italy and UK chapters, respectively).

- 4 Swiftly reopen tender procedures after the entry of the first multisource medicine.** Reopening tender procedures directly after the entry of the first multisource medicine fosters competition. This enables timely patient access to cost-effective treatments i.e. generics and biosimilars. Timely enhanced competition in tender procedures promotes a better allocation of economic resources which benefits the healthcare system as a whole¹².
- 5 Make the tendering procedure leaner.** The tendering systems in most studied countries are administrative, disharmonious and labour intensive, which may discourage medicine manufacturers from participating in tenders. A concerted effort to make tendering operational procedures harmonious and simpler by requiring submission of essential information for the tender and by fully digitizing the procedure reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in hospital tenders. A leaner tendering incentivizes the participation of multiple manufacturers in the tenders, which stimulates competition in the procedure and benefits the healthcare system as a whole.

Next to the key ingredients 1-5, which biosimilar medicines share with generic medicines, we have identified **four biosimilar-specific key ingredients** for increased utilization in the hospital setting. These four biosimilar-specific key ingredients focus on improving market access of biosimilar medicines by increasing awareness of hospital physicians, nurses and pharmacists, implementing biosimilar target agreements and quotas and by drafting guidelines on treatment switching. In order to increase access of biosimilar medicines in the hospital market and to stimulate competition, we recommend:

- 6 Create guidelines and/or information campaigns to increase awareness of patients and healthcare professionals (including hospital physicians, nurses and pharmacists) regarding the efficacy, quality and safety of biosimilar medicines as well as other important topics such as biosimilar medicines introduction in the clinical practice and physician-led switching.** A general lack of awareness/education on biosimilar medicines still contributes to some resistance among healthcare professionals including hospital physicians, nurses and pharmacists. In order to improve the clinical use of biosimilar medicines by healthcare professionals, and therefore to increase patient access to biologic medicines, it is important for hospitals and other trusted stakeholders to create information campaigns and educational settings to disseminate information on the benefits of biosimilar medicines and relevant biosimilar-related topics such as physician-led switching. In addition, it might be useful to disseminate information about the importance of biosimilar medicines in cost-efficient quality care improvement in the hospital setting not only to healthcare professionals but also to controllers and managers which issue the tenders and often have an incentive to limit pharmaceutical spending (e.g. hospitals, regional health agencies or central procurement agencies). For instance in UK, the update of NICE guidelines after biosimilar filgrastim launch in

¹² Important to take into consideration a balanced re-opening of tenders for biosimilar medicines. Frequent re-opens associated with short duration would be challenging given the extended manufacturing lead time and consequent less predictability.

2008¹³ reflected the improved cost-effectiveness of biosimilar filgrastim vs. alternative treatments. As a result, G-CSF prescribing restrictions were relaxed and usage also recommended for primary prophylaxis of neutropenia versus secondary prophylaxis only. Consequently, this guideline update stimulated an increased use of biosimilar filgrastim and enabled a greater number of patients to access these treatments at an earlier stage of the therapeutic cycle.

- 7 Create incentives for biosimilar use that take into consideration the long-term sustainability of the sector such as the implementation of target agreements and quotas for biosimilar medicine use.** Setting concrete milestones for the use of biosimilar medicines with target agreements for physicians and quotas for hospitals, is acknowledged to stimulate competition, to increase patient access to biologics and to supply physicians with more treatment options. Targets must be accompanied by robust tracking to ensure accurate awareness of progress towards milestones. Regarding target agreements for physicians, there is a concrete example in Germany in the region of Westfalen-Lippe where these target agreements are applied and the physician association plays a major supporting role to physicians by organising information campaigns and by providing reporting to physicians about the progress of the management of the switch.
- 8 Draft national and or local hospital guidelines with respect to treatment changes & medicines exchange.** By drafting national/hospital guidelines on treatment switching, hospital stakeholders are informed on the safe and positive experience of physician-led switching and on the process of exchanging therapeutic alternative medicines (switching from a group of patients already undergoing treatment with an originator biological medicine to a biosimilar). Ample evidence supports the safety of switching to biosimilar medicines and can be incorporated in hospital guidelines and communication to physicians and patients^{14,15}.
- 9 Implement benefit sharing methods.** Benefit sharing models and schemes should be encouraged so that cost-effectiveness gains resulting from the increased use of biosimilar medicines are re-invested into healthcare for the benefit of patients and all the relevant hospital stakeholders. For instance, in the University Hospital Southampton NHS Foundation Trust in the UK , there is an example of a benefit sharing model, where a managed physician-led switching program of biosimilar infliximab for all inflammatory bowel disease patients is available. This switching to biosimilar medicines allowed more patients to be treated and created the opportunity for re-investment in improvements of patients' care, e.g. hiring more nurses to provide targeted support/better care to the patients.

To conclude this report, we take a brief look at a third category of medicines relevant in the context of hospital care delivery efficiency and outcomes: value added medicines. The next section describes value added medicines and their benefits, the current access barriers in the hospital setting and our recommendations for improved access to value added medicines in the hospital setting.

¹³ Simon-Kucher & Partners, IMS Health, MIDAS, IMS Consulting Group, Nov 2015

¹⁴ Kurki P, van Aerts L, Wolff-Holz E, Giezen T, Skibeli V, Weise M.

Interchangeability of Biosimilars: A European Perspective. *BioDrugs*. 2017 Apr; 31(2):83-91.

¹⁵ Ebbers HC, Muenzberg M, Schellekens H. The safety of switching between therapeutic proteins. *Expert Opin Biol Ther*. 2012 Nov;12(11):1473-85.

Value added medicines in the hospital setting and recommendations to improve access to value added medicines

This study shows that optimized utilization of generic and biosimilar medicines in the hospital market can increase quality and efficiency of hospital care. To conclude this report, we took a brief look at a third category of medicines relevant in the context of hospital care delivery efficiency and outcomes: **value added medicines**.

Value added medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers¹⁶. Examples of relevant improvements that value added medicines can achieve are:

- Expand therapeutic use to different indications or populations.
- Optimize administration of medicines and their ease of use;
- Increase of efficacy, safety and/or tolerability of medicines;

Such improvements have the potential to enhance health care delivery and efficiency and can be realized in three different ways (1):

- Reformulation of medicines, such as changing the pharmaceutical formulation, the pharmacokinetic profile, the drug delivery system or route of administration;
 - *E.g. self-injected subcutaneous formulation of a product already available on the market as intravenous formulation administered only at hospital under medical monitoring in a severe inflammatory disease*
- Combination of medicine/medicine or combination of a medicine/medical device.
 - *E.g. New inhaled device to administer genericized products in Chronic Obstructive Pulmonary Disease (COPD) indication with evidence of reducing inhaler errors versus current device used with these active substances*
 - *E.g. Therapeutic drug monitoring device developed in association with a known cancer therapy exhibiting a narrow therapeutic window to potentialise drug efficacy while minimizing toxicity*
 - *E.g. Fixed-dose combination of 2 products already available on the market and used as free dose combination in arterial hypertension to reduce pill burden, improve compliance and avoid intake errors in a highly medicated patient population*
- Repositioning the medicine in order to expand therapeutic use of the medicine;
 - *E.g. repositioning of a well-known product in a rare pediatric indication as an alternative to reference treatments not specifically approved in this indication*

Value added medicines present an opportunity to address the needs of hospital delivery and efficiency. The table on the next page briefly illustrates potential exemplary benefits value added medicines could provide.

¹⁶ Please note that our recommendation only applies to value added medicines, which means that these medicines were improved after patent expiration (and/or developed by a different manufacturer than the originator).

Examples of value added medicines that meet hospital inefficiencies

Examples	Optimization of medical quality and processes	Increase of cost-productivity	Improvement of the commitment treatment-patient and/or treatment-healthcare professional
An extended-release formulation of a product already available on the market for a neurocognitive disease indication, reducing administration regimen from once-weekly injection to 3-monthly injection	Improving the rational use of medicines and hospital resources	Reduce the costs associated with a reduced number of hospitalisations/healthcare professional visits	Improving adherence/convenience to already available therapies
Pre-filled syringes with automatic dosing of an already known product (click-based procedure; 1 click=1 dose)	New and appropriate medicine packaging and/or vial conditioning contributes to limited medicine wastage	Reduced costs associated with medicine wastage and reduced additional steps from healthcare professionals to reconstruct a medicine	Safer-use of medicines for patients and/or healthcare professionals
Electronic-based inhalers in asthma can inform on patient clinical status including alerts when degradation of respiratory function and inform on medication adherence to tailor treatment plans to each patient	Optimise timely treatment monitoring	Combination of a clinical status alert system with a treatment	Improvement of patient adherence to the treatment and improvement of the healthcare professional management of the patient condition

Despite of the benefits that value added medicines present in the hospital setting, during the hospital expert meetings, common barriers to patient access to these medicines were identified in the European hospital landscape:

- Limited involvement of patients and/or relevant hospital functional areas in the decision-making processes in the hospital setting
- Only a few countries present the opportunity for early dialogue between manufacturers and hospital stakeholders (e.g. FR and BE)
- The current purchasing processes are mainly focused on price and do not take into consideration the additional benefits of value added medicines

Recommendations to unlock the potential of value added medicines in the hospital setting

In order to unlock the potential of value added medicines for hospital care delivery and efficiency, **the following could be recommended:**

- 1 Integration of patients and/or other relevant expert areas in identification of key purchasing criteria
 - There is a need for patients and/or relevant hospital actors (healthcare professionals, hospital administrators and purchasing units) to work together to break the silos between clinical/organizational/budgetary aspects in the hospital setting
- 2 Opportunity for an early dialogue between manufacturers and hospital stakeholders
 - Importance for all stakeholders to have the opportunity to discuss the needs being addressed through specific value added medicines in the hospital sector
- 3 Adjustment of purchasing processes that take into consideration additional value dimensions that reward the additional value created.
 - Examples of these dimensions are:
 - *Benefits for patients*, for instance improved quality of life, patient ease-of-use/handling & functionality, reduced treatment duration or more convenient route of administration.
 - *Benefits for healthcare providers*, for instance improved safe-use while handling the medicine, support in monitoring the patient and reduced number of required healthcare activities for the healthcare professionals.
 - *Benefits for caregivers*, for instance reduced travel times and reduced burden for caregivers.
 - *Benefits for the healthcare system as a whole*, for instance reduced long-term costs of treatment and reduced hospitalization rates.
 - *Benefits for the economy as a whole*, for instance fewer missed days at work.

The additional value dimensions would be considered a 'bonus' on top of the price and would likely have different weights according to the different purchasing entities/countries. Enhanced competition stimulates innovation to address the needs in hospital care delivery and efficiency. Therefore purchasing systems have to stimulate innovation and allow its recognition and reward, but cannot be mandatory or descriptive in the benefits accepted and cannot undermine competition

2 Introduction

Healthcare systems are under significant and increasing budgetary pressure as a result of demand-driven demographic shifts (e.g. a growing and ageing population resulting in increasingly more morbidities) and the growing costs of inputs in the delivery of care (e.g. increasing availability of innovative medical technologies and medicines). Among the 35 countries which are part of the Organization for Economic Co-operation and Development (OECD), expenditures on healthcare equaled approximately 9% of the gross domestic product (GDP) in 2016 (2).

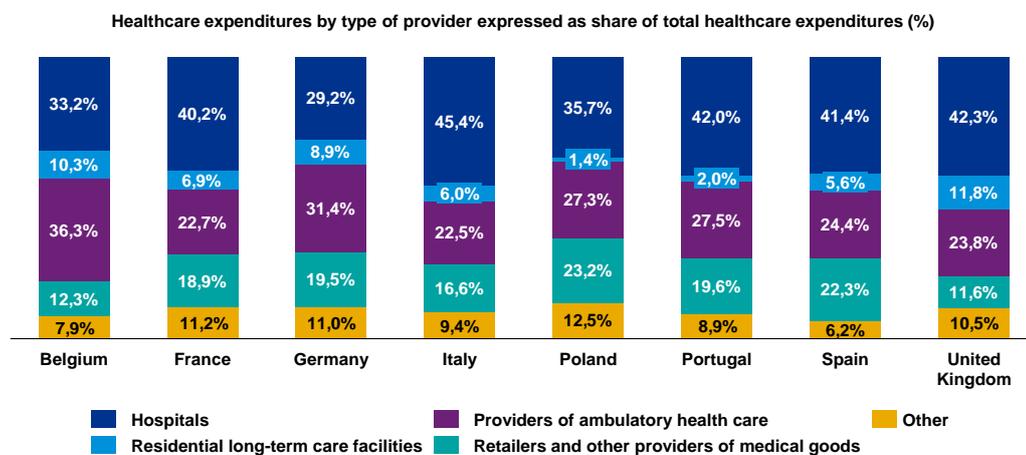


Figure 1: Healthcare expenditures in 2015 by type of provider in the eight studied countries, expressed as a share of total healthcare expenditures (%). Source: OECD (3).

Hospitals typically account for the largest share of healthcare expenditures (2). In addition, hospitals often play a central role in the healthcare system and have therefore a huge influence on the quality and costs of the entire health system. Therefore, hospital care presents a chief opportunity to increase healthcare system value (outcome per euro spent) through optimization of efficient and effective delivery of healthcare within the hospital systems. Increased utilization of generic, biosimilar and value added medicines in the hospital systems presents an opportunity to improve healthcare system value by increasing the efficiency of delivery of healthcare within hospital systems.

The objective of this study is to:

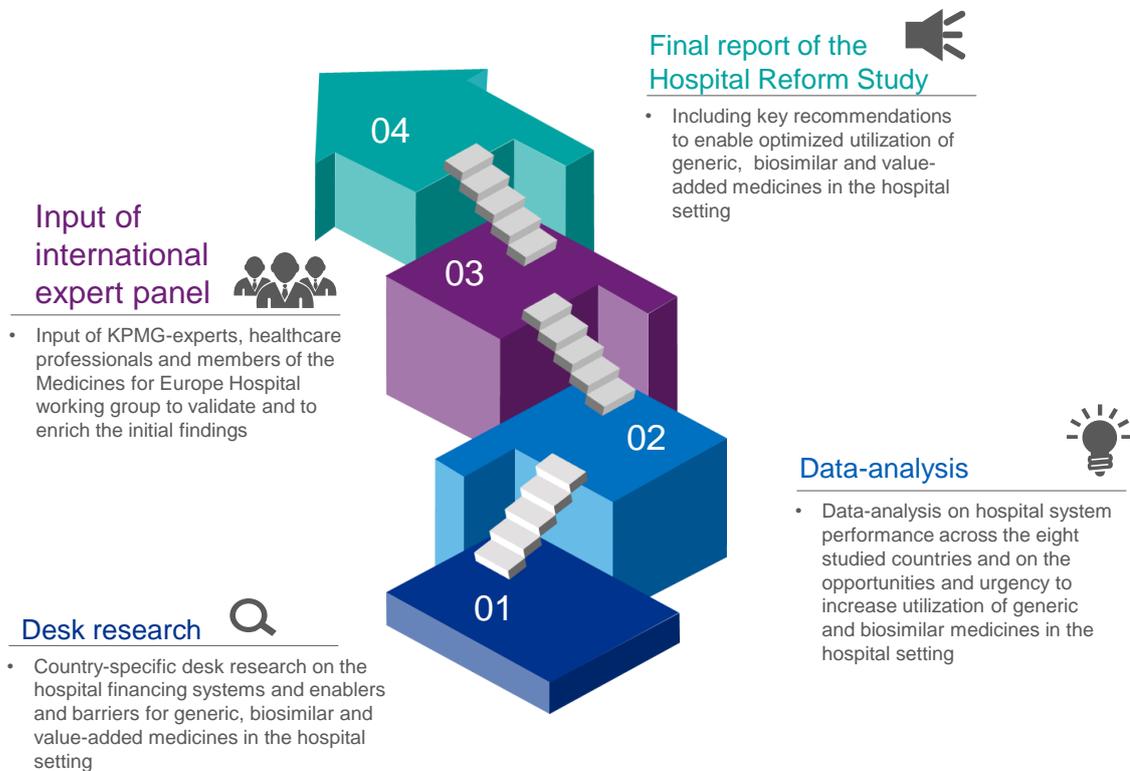
- Understand the financing of hospital systems and its impact on the financial incentives of hospitals;
- Create insights in the performance of hospital systems;
- Understand the procurement mechanisms of medicines in the hospital setting;
- Create insights in the enablers and barriers for increased utilization of generic and biosimilar medicines in hospitals;
- Underline the urge to improve the hospital environment to increase the utilization of generic and biosimilar medicines;
- Yield key recommendations to enable increased utilization of generic, biosimilar and value-added medicines in hospitals.

2.1 Scope of study

The 5 most populous EU countries (France, Germany, Italy, Spain and the United Kingdom) were selected for this study. In addition, Belgium, Poland and Portugal were selected as countries within the scope. Belgium, Poland and Portugal were added as these countries were identified to be of special interest with respect to the performance of their hospital systems and/or with respect to the utilization of generic and biosimilar medicines within their respective hospital systems.

Countries within the scope of the Hospital Reform Study:							
Belgium	France	Germany	Italy	Poland	Portugal	Spain	United Kingdom
							

2.2 Overall project approach



2.3 Outline of this document and reading guide

- **Chapter 1** shows the management summary of this study.
- **Chapter 2** introduces this study.
- **Chapter 3** provides an overview of the hospital financing systems in the eight studied countries. It gives a high-level overview of the national healthcare systems, a description of how these systems are financed and how hospitals are funded in these systems, and what financial incentives this yields for hospitals. In addition, it provides a brief overview of recent reforms in the healthcare and hospital systems and current focus points for improvement.
- **Chapter 4** shows the results of a comparative analysis of the hospital system performance in the eight studied countries. This comparison of hospital systems links back to the findings of the previous chapter as hospital financing systems and incentives in part drive hospital performance. Also it provides the context for the chapters 5 (enablers and barriers for generic and biosimilar medicines) and 6 (showcases underlying the potential and urgency to increase utilization of generic and biosimilar medicines in the hospital setting), where we do a deep dive into the pharmaceutical aspects of the various hospital systems.
- **Chapter 5** provides an overview of the enablers and barriers for generic and biosimilar medicine access in the hospital setting of the eight studied countries. It gives a high-level overview of the national pricing and reimbursement systems for medicines, an overview of the procurement landscape of medicines in the hospital market, and a description of the main enablers and barriers for generic and biosimilar medicines access in the hospital setting. The findings in this chapter form the basis for the recommendations in chapter 7, as this chapter describes the current situation.
- **Chapter 6** underlines the urge to improve the hospital environment to increase the utilization of generic and biosimilar medicines. This chapter links back to the findings of the previous chapter as the enablers and barriers for access to generic and biosimilar medicines in the hospital influence the utilization of generic and biosimilar medicines.
- Increased utilization of generic, biosimilar and value added medicines in the hospital systems presents an opportunity to improve healthcare system value by increasing the efficiency of delivery of healthcare within hospital systems. **Chapter 7** describes our overarching recommendations for improved utilization of generic, biosimilar and value-added medicines in the hospital setting of the eight studied countries. Our recommendations are a synthesis of the previous chapters and are furthermore based on interviews with hospital experts from local KPMG and national associations.
- **Chapter 8** contains the list of references.
- **Appendix A** contains the list of investigated OECD and EHCI quality indicators for hospital care.
- **Appendix B** describes our recommendations for each of the studied countries for improved access of generic and biosimilar medicines in the hospital setting.
- **Appendix C** shows the usage of biosimilar medicines in the hospital setting

3 Hospital Financing Systems

This chapter provides an overview of the hospital financing systems in the eight studied countries. For each country we have addressed the following components in order to give an overview and an understanding of the hospital financing systems:

- 1 A high-level overview of the national healthcare system;
- 2 A description of how the national healthcare system is financed;
- 3 A description of how the hospitals are funded within the national healthcare system and a description of the resulting financial incentives for hospitals within this financing system;
- 4 A brief overview of recent reforms in the healthcare and hospital system and current focus points for improvement of the healthcare and hospital system.

This chapter sets the scene for the further analysis in the report, leading to a set of recommendations in chapter 7. The eight studied countries are ordered alphabetically in this chapter, starting with Belgium and ending with the United Kingdom.

3.1 Belgium

3.1.1 Belgian Healthcare system

The health system in Belgium is based on the principle of solidarity between the rich and the poor, and the healthy and the sick (4). This solidarity is achieved by a compulsory health insurance system, which covers over 99% of the population (5). The compulsory health insurance system is organized through a public association of sickness funds and six private, non-profit associations of sickness funds (4). Patients are free to select the sickness fund through which they wish to be insured (6).

The sickness funds reimburse health service benefits to their members and represent their members in the National Institute for Health and Disability Insurance (RIZIV-INAMI). RIZIV-INAMI is responsible for the organization and financial management of the compulsory health insurance system and is accountable to the Minister of Social Affairs and Public Health (4). The most important tasks of RIZIV-INAMI are:

- Organizing reimbursement of medical costs and replacement income in case of disability;
- Monitoring healthcare spending;
- Informing the different stakeholders in the Belgium healthcare system (care providers, sickness funds and the population) regarding new legislation and ensuring correct implementation of legislation.

The Belgian healthcare system has both private and public characteristics, as most healthcare providers are private and reimbursement of healthcare costs is defined by the state (7). The healthcare system is based on freedom of choice for patients and freedom of therapeutic choice for physicians (4). Patients do not require referrals, however, they may have to pay a higher fee if they see a specialist without a referral (6). Decisions with

respect to healthcare policies in Belgium are often not made top-down, but are rather a result of negotiations between multiple stakeholders, such as representatives of the government, sickness funds, employers, employees and self-employed workers.

Responsibilities for health policies in Belgium are divided between the federal level and federated regions and communities (4). The federal state is responsible for the regulation and financing of compulsory health insurance and the determination of accreditation criteria which stipulate the minimum standards for hospital services. In addition, the federal-state finances hospitals and provides legislation for mandatory qualifications for healthcare professionals. The registration and price control of pharmaceuticals are also managed at the federal level (4).

At the level of the federated regions and communities, governments are responsible for health promotion, prevention and maternity and child health services. In addition, federated regions and communities are responsible for elderly care, home care and coordination and collaboration in primary healthcare and palliative care. The federated regions and communities monitor the implementation of the accreditation standards and are allowed to stipulate additional accreditation criteria for hospitals. Also, the federated regions and communities are responsible for financing of hospital investments (4).

Even though the health system is significantly decentralized in Belgium, there are several national institutions that play an important role in the national health system. Key entities with respect to medicines and/or hospitals are listed below:

- The Federal Agency for Medicines and Health Products (FAGG-AFMPS) is responsible for the quality, effectiveness and safety of medicines. The agency is in charge of the evaluation of the clinical effectiveness of new medicines and of the provision of marketing authorisations for medicines. In addition, the agency supervises advertising on medicines and controls the production, distribution and delivery of medicines (4).
- The National Council for Hospital Supplies is a consultative body which advises the Minister of Social Affairs and Public Health on matters related to hospital financing, accreditation and planning (4). This council is composed of different stakeholders from the hospital sector.
- The Belgian Healthcare Knowledge Centre (KCE) is an independent consultative body which aids healthcare decisions makers by providing scientific support. KCE develops guidelines for good clinical practice, performs health technology assessments and studies topics regarding healthcare organization and financing (4).

3.1.2 Financing of the Belgian healthcare system

Belgium spent approximately 10.5% of its GDP on healthcare in 2015, which is above the EU average of 9.9% (5). Spending on healthcare as a proportion of GDP in Belgium had been rising steadily ever since the 80's, however, the growth relative to GDP has stagnated in the past few years (8).

The Belgian healthcare system is mainly publicly funded, with public funding accounting for approximately 77% of all healthcare expenditures (5). The chief sources of public funding are general taxation and health insurance contributions, of which the latter is

paid by both employers and employees (6). The remaining 23% of healthcare expenditures in Belgium is paid by patients through co-payments, voluntary insurance schemes and non-reimbursed medical procedures and medicines (5). Co-payments are the largest component of such private expenses, accounting for approximately 17% of all healthcare expenditures in Belgium (6). The level of co-payment depends on the type of service provided, income-level and social and health status of the patient, and on the accumulated amount of co-payments already paid during the year (as there is a maximum annual ceiling for co-payments per patient) (5). Patients with low income or who receive social benefits are entitled to preferential reimbursement, which lowers co-payments levels. Patients with chronic diseases are also entitled to the preferential reimbursement status, and usually, do not have to pay co-payments (5).

In the case of medicines, the height of the co-payments is linked to the pharmaceutical category in which the medicine is listed. For medicines which are deemed vital (class A medicines), such as for instance insulin and antiretrovirals, there is no co-payment required. For medicines which are deemed therapeutically significant (class B) and less significant (class C), co-payment levels vary between 25 to 80%. Class D medicines (non-reimbursable medicines) require a 100% co-payment (4). For patients who are hospitalized, co-payments for class A, B and C medicines are replaced by a flat rate charge per day.

Voluntary insurance schemes account only for a small part of the health insurance market (4% of total health spending) (4; 6). Residents can take out voluntary insurance offered by the sickness funds and by for-profit insurance companies. Voluntary insurance in Belgium covers services outside the compulsory health insurance system, such as for instance orthodontics and osteopathy (4). In addition, voluntary insurance may provide improved amenities such as private hospital rooms.

3.1.3 Hospital funding in Belgium

Belgium has approximately 190 hospitals, which are mainly public or private not-for-profit (6; 9). Private not-for-profit hospitals are often run by charities or religious orders. Private for-profit hospitals are rare in Belgium (4; 6). Belgium is characterized by a relatively high number of hospital beds per capita, with 6 beds per thousand citizens, compared to the European Union average of 5 hospital beds per thousand citizens (6). Belgium faces shortages in nursing home beds for the elderly and this may have an impact on the demand for hospital beds.

The hospital financing system in Belgium is depicted in Figure 2. Hospitals have three main sources of funding, which account for almost 90% of the revenue of a typical hospital (4; 7):

- 1 A fixed annual prospective budget (*Budget van Financiële Middelen*) to fund facilities (e.g. nursing units, operating rooms etc.) and nursing activities in day hospitalizations. This budget amounts to approximately 50% of typical hospitals' budget and is determined using a complex set of parameters. Approximately three-quarters of the prospective budget is determined by setting first the national budget and subsequently allocating this national budget to the hospitals using a set of distribution keys. The remaining quarter is determined in the opposite way, as for this

part the hospitals budget is determined per hospital and subsequently aggregated to yield the national budget. Generally speaking, historical costs are used to determine this part of the fixed annual prospective budget.

- 2 Fee-for-service to fund medical services (e.g. consultations, surgeries), laboratory tests, medical imaging procedures and also paramedical services such as physiotherapy. This amounts to approximately 25% of a typical hospitals' budget.
- 3 Sales of pharmaceuticals to both outpatients and inpatients. For inpatient care, hospitals receive a prospective budget for pharmaceutical use. The sales of pharmaceuticals amount to approximately 15% of a typical hospitals' budget.

Next to these three main sources of funding, which amount up to approximately 90% of a typical hospitals' budget, the hospitals receive funding from:

- 4 Lump sum payments per patient for certain ambulatory activities such as day care, rehabilitation and dialysis;
- 5 Subsidies for investment from federated governments; These subsidies vary between the different federated regions in Belgium.
- 6 Supplements charged to patients;
- 7 Non-hospital activities, such as for instance by providing homes for the elderly and hotel-like facilities;
- 8 Private legacy or corporate grants.

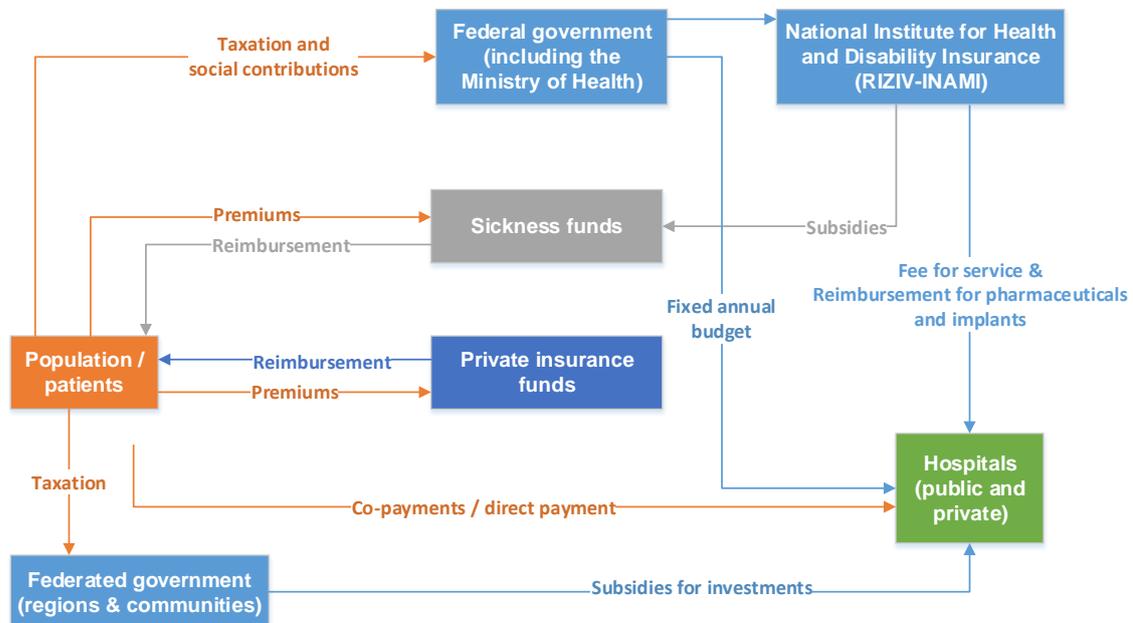


Figure 2: Hospital Financing System in Belgium. Adapted from (4).

In summary, the two main sources of revenue for hospitals come from the Federal Government and RIZIV-INAMI: a fixed annual prospective budget to fund hospital facilities and a fee-for-service arrangement for medical services. A fixed annual budget incentivizes reducing costs, which may lead to underproduction and consequently, waiting lists. However, as the next year's budget is based on the realized volume of the previous year, such cost reduction by reducing volume likely is counterproductive for hospitals with respect to revenue on a longer term.

The main incentive for hospitals in the Belgian hospital financing system appears to be therefore to increase volume. This holds especially for medical services such as consultations, laboratory tests, pharmacy prescriptions and medical imaging procedures, as these medical services are paid for by fee-for-service. Furthermore, doctors in hospitals, most of whom are independent practitioners, are also paid on a fee-for-service basis (6), further incentivizing volume in the hospital system. In addition, an increase in volume might lead to an increase in the fixed prospective budget for the next year. As the Belgian hospital financing system seems to mainly incentivize volume, the productivity of the Belgian hospitals is stimulated. However, this could lead to overproduction and hence larger healthcare expenditures per capita.

3.1.4 Recent reforms and current focus points

Belgium performs relatively well in addressing the healthcare needs of its citizens. The proportion of people who reported unmet needs for medical care was 2.4% in 2015, which was significantly lower than the EU average of 3.2% (5). However, there are large variations in unmet medical needs between different income groups in Belgium, with 7.2% people in the lowest income group reporting unmet medical needs, compared to 0.2% in the highest income group. In order to combat these variations, several measures were taken in 2015 (5):

- Proactive proposing of preferential reimbursement status to patients who are entitled by the sickness funds, in order to remove barriers for patients who are unaware that they are entitled to preferential reimbursement;
- Eliminating co-payments for people with preferential reimbursement status (with exception of general practitioner consultations)

Like many healthcare systems in the EU, the Belgian healthcare system faces budget pressures due to an ageing population. Long-term care spending as a share of GDP is projected to grow by almost 2 percentage points in the next 40 years, mainly due to ageing (10). In order to keep the Belgian healthcare system financially sustainable, reforms to the hospital sector, including hospital funding arrangements, were announced by Health Minister Maggie De Block in 2015 and are still on the agenda. These proposed reforms, which are broad in scope, are designed to improve efficiency whilst remodelling provision to reflect the changing needs of the population (for example, increasing numbers of patients who are elderly and increased prevalence of chronic diseases).

De Block has indicated that the existing complex hospital funding model would be overhauled and simplified as part of the reforms. Accordingly, De Block has proposed a tripartite funding model which would allow for variations in the cost of care. Thus, elements of care would be assigned to one of three funding "clusters":

- Cluster 1: “standard” procedures for which there is little/no variation in cost between hospitals. A set fee would apply in all hospitals nationwide.
- Cluster 2: procedures which are likely to vary due to for instance co-morbidities and complications, meaning that the cost of treatment can vary (moderately). A fixed budget would be set at the national level for this cluster, with each hospital reimbursed according to the number of patients and any complications.
- Cluster 3: highly complex treatments/procedures. These would be reimbursed according to the actual cost of treatment.

It is understood that separate, and more transparent, funding arrangements would meanwhile be introduced for emergency care and for teaching activities in university hospitals. However, no further details of the planned changes have been made public yet and the planned changes have yet to be implemented.

3.2 France

3.2.1 French healthcare system

The French healthcare system is based on social insurance (*sécurité sociale*), a concept which was introduced in France shortly after World War Two (11). It is built on the foundations of the philosophy of national solidarity, which emphasizes the combination of civil rights and civil responsibilities (12). As of 2016, the social insurance system provides universal coverage for all legal residents in France (13).

The management of the healthcare system is divided between the Ministry of Health and Social Affairs and the statutory healthcare insurers (SHIs) (14). There are several SHIs in France. SHIs do not compete as they cater to different segments of the labour market. This means that individuals cannot choose through which SHI they wish to be insured. The main healthcare insurance fund (*Caisse Nationale d'Assurance Maladie*) covers over 90% of the population in France, including people without a job (14; 11).

Compared with most healthcare systems based on social insurance, the French state has a relatively strong role within the system (14). The Ministry of Health and Social Affairs is responsible for the overall health system in France and sets the national strategy (15). In addition, the Ministry allocates budgets among the different healthcare sectors (e.g. mental healthcare, hospital healthcare etc.) and for the hospital sector, it divides the budget between regions (13). The ministry is represented regionally by the regional health agencies (*Agences régionale de santé*, ARSs). The ARSs are subsidiaries of the state and in charge of healthcare (including hospital care), social security and care for elderly and disabled people in the regions (11). ARSs are autonomous bodies and have extended autonomy regarding regional capacity planning and management of the budgets of the SHIs.

The Ministry of Health and Social Affairs and the SHIs jointly determine the benefit package of the national social insurance system and set prices for medicines and for healthcare providers (including DRG-fees and co-payments). Healthcare planning and regulation usually involves negotiations among the Ministry, SHIs and provider representatives. Subsequently, the results of these negotiations are converted into laws passed by the parliament (13). The parliament wields final control over the healthcare system (11).

Next to the national government, the ARSs and SHIs there are multiple other key entities in the French healthcare system. Key entities with respect to medicines and/or hospitals are listed below:

- The National Health Authority (*Haute Autorité de Santé*, HAS) is an independent public entity and is responsible for the assessment of drugs, medical devices and medical procedures, for publishing guidelines, and for accreditation of healthcare organizations and medical doctors (11; 13).
- The National Agency for Safety of Medicines and Health Products (*Agence Nationale de sécurité du médicament et des produits de santé*, ANSM) is responsible for the safety of medicines and other health products. This responsibility covers the entire span from manufacturing to marketing (11; 13).

- The National Agency to Support the Performance of Healthcare and Social Care Institutions (*Agence nationale d'appui à la performance des établissements de santé et médico-sociaux*, ANAP) has two main functions. 1) It provides advice to healthcare and social care organizations on strategic and financial issues. 2) It supports the ARSs and the Ministry of Health and Social Affairs in monitoring the performance of healthcare and social care organizations (11).
- The General Directorate of Care Supply (*Direction générale de l'Offre de soins*, DGOS) is part of the French Ministry of Health and Social Affairs. It is in charge to ensure quality and proximity of care and functions as a liaison between care providers and the Ministry of Health and Social Affairs.

The French healthcare system has two key ingredients: free choice for patients and clinical freedom for medical doctors (12). Free choice of patients refers to the direct payments that patients make to doctors in France, a practice that is deemed to protect the patient's freedom to choose a doctor. As such, individuals are free to refer themselves to either a general practitioner or a medical specialist, although recent policies are aiming to position the general practitioner more as a gatekeeper of the healthcare system (12). To facilitate the direct payments of patients to healthcare providers, the *carte vitale* was introduced in 1998. It gives patients a direct settlement of the payment to the provider and (partial) reimbursement of this payment by the SHIs (12).

3.2.2 Financing of the French healthcare system

France spent approximately 11,6% of its GDP on healthcare in 2017 (15). This is the second highest spending as a share of GDP in Europe, with only Sweden spending more of its GDP on healthcare. The ratio of healthcare expenditures to GDP did rise considerably in France during the financial crisis and has subsequently been fairly stable since 2014 (15). For a system that is based on the philosophy of national solidarity, it is worthwhile to note that the social insurance system only accounts for approximately 78% of total healthcare spending, with the remainder accounted for by private healthcare insurance and co-payments (12; 15). The social insurance system is mainly funded by income-based contributions from employers and employees, with additional funding coming from taxes levied on alcohol, tobacco and medicines (14).

Public expenditures as a share of total healthcare expenditures have been fairly constant for the past decade. The ratio of public and private expenditure on healthcare is a direct result of the benefit package, which is broad but often does not reimburse 100% of the healthcare costs (14). For instance, the coverage rate for hospital care is generally 80%. For outpatient care, the coverage rate ranges from 70% of the predetermined tariff for consultations with medical specialists and dentists, to 60% for laboratory tests. To position the general practitioner as a gatekeeper, coverage rates for patients who directly access medical specialists (without a referral from their general practitioner) drop to 30% (14). The coverage rate of medicines is generally 65%, but can range from 15% for drugs that have been assessed as having low effectiveness to 100% for drugs that are deemed highly effective and/or non-substitutable (13; 14). Exemptions from co-payments apply in most cases for people with chronic conditions, pregnant women, disabled children, victims of work accidents and pensioners (13; 11). There are no exemptions on economic

grounds, however people with low incomes receive free public complementary voluntary healthcare insurance by the CMU-fund, effectively providing a full exemption on co-payments (11).

Next to co-payments, flat-rate deductibles are present for most types of care, such as visits to physicians, laboratory tests, hospital stays and medicines. These deductibles generate additional revenue for the SHIs and furthermore aim to promote “responsible” healthcare consumption by individuals (11). Similar to the co-payment systems, exemptions for deductibles exists, such as for instance for people with low incomes, children and pregnant women.

Private healthcare expenditures are mainly paid through private healthcare insurance schemes (ca. 70% of all private expenditure). The remainder of private healthcare expenditures (30%) is paid by direct co-payments of patients. This translates into a 6% share of co-payments with respect to total healthcare expenditures in France, which is significantly lower than the European Union average of 14% (15).

Voluntary coverage may be purchased by individuals or by firms for their employees. The main role of voluntary private healthcare insurance in France is to provide complementary coverage for co-payments and other user charges (11). The depth of coverage varies significantly, however, all contracts cover the difference between the reimbursement rate of the social healthcare insurance and the statutory service fee. In addition, the excess that healthcare providers can charge on top of the statutory service fee (‘balance billing’) is usually also covered up to a certain multitude of the statutory service fee (13). Voluntary private healthcare insurance in France does not provide a wider access to healthcare providers and it also does not reduce waiting times. Next to complementary coverage, voluntary private healthcare insurance may also offer supplementary coverage, for instance for private amenities such as private hospital rooms that are not included in the social healthcare insurance system.

The private voluntary healthcare insurance market is fragmented, with more than 600 insurers present on the market (11). Most insurance companies operate on a non-profit basis (82% of insurers, combining a 55% market share) and try to avoid differentiation in premiums to achieve solidarity. These insurers offer generally only complementary insurance and not supplementary insurance. For-profit insurers have approximately 29% market-share and do actively use premium differentiation methods. The final and smallest group of insurers are provident institutions which are not-for-profit and specialize in mandatory group contracts (11).

The population covered by voluntary private healthcare schemes has risen steadily and now exceeds 90%, including the free complementary healthcare insurance by the CMU-fund for people with low incomes (11). The rise in voluntary healthcare insurance can be explained by the reduced depth of coverage of the social insurance system due to budgetary pressures for the SHIs. Reduced coverage of the social insurance system increases the required level of co-payments and therefore incentivizes the enrolment in complementary voluntary insurance schemes (11). Similar trends can be identified in other European countries, but the unique aspect of the healthcare system in France is that the majority of the healthcare expenditures are covered by a system that does not provide free choice with respect to insurers (SHIs) and is then ‘topped up’ by free choice of voluntary insurance (12).

3.2.3 Hospital funding in France

France has approximately 3,000 hospitals, of which approximately a third is privately owned and for-profit, a fifth is privately owned and not-for-profit, and the remainder is publicly owned (15; 12). Patients are free to choose between public and private institutions as insurance usually covers both segments. Unlike some other European countries, public and private hospitals are expected to deliver the same quality of care, as the French system promotes choice over the competition (12).

France is characterized by a relatively high number of hospital beds per capita, with 6 hospital beds per thousand citizens compared to the European Union average of 5 hospital beds per thousand citizens (14). However, the number of hospital beds has declined by more than 15% since 2000, reflecting policies that promote less reliance on the inpatient hospital system. Long-term care beds in hospitals showed the largest decline during this period (-60%), as efforts to move such long-term care beds to nursing homes were rather successful.

Publicly owned hospitals account for approximately 60% of the hospital beds. Generally, large teaching hospitals are publicly owned and private hospitals focus mainly on elective care (12). In 2016, 1,100 of the public hospitals were organised in approximately 150 territorial hospital groups (*groupements hospitalier de territoire*), encouraging more optimal planning of hospital care capacity and more efficient procurement (15). In addition, a trend of consolidation is ongoing in the private hospital sector, spurred by relative low profitability within the sector (15). There is still room for further consolidation, as even the largest group of private healthcare clinics, Ramsay Healthcare, has a relatively low market share of 13%.

The hospital financing system in France is depicted in Figure 3. Hospitals are mainly funded through the French DRG-system (*groupes homogènes de séjours*; GHS), which applies to both inpatient and outpatient care (13). The GHS-system covers all hospitals: public, private not-for-profit and private for-profit. Each hospital patient is allocated to one of the circa 2,200 DRGs and to one of the associated GHSs (11). Each GHS yields a lump-sum tariff, which is determined annually. Medicines for inpatients are included in the GHS-tariffs, with the exception of innovative, expensive drugs. For public and not-for-profit private hospitals, salaries of medical specialists are covered by the GHS-system (11). For for-profit private hospitals, services of medical specialists are not covered by the GHS-system, but are paid separately. GHS-tariffs are usually lower for for-profit private hospitals, a disparity which is mainly justified by differences in case-mix (13). DRG-systems essentially function as fee-for-service. This means that productivity of public and private hospitals in France is stimulated, but that also maximization of volume is incentivized, which leads to a risk of overproduction, and hence larger health expenditures per capita.

Next to GHSs, hospitals in France receive activity-based funding for emergency care visits and for employment of expensive medical technologies, procedures and medicines (11). This additional activity-based funding on top of GHS-system aims to reduce potential economic barriers for hospitals for employment of such expensive treatments. In addition to these supplementary activity-based funding fees, public and not-for-profit hospitals receive block grants for functions such as organ transplantation, psychiatry, long-term care and emergency care (11).

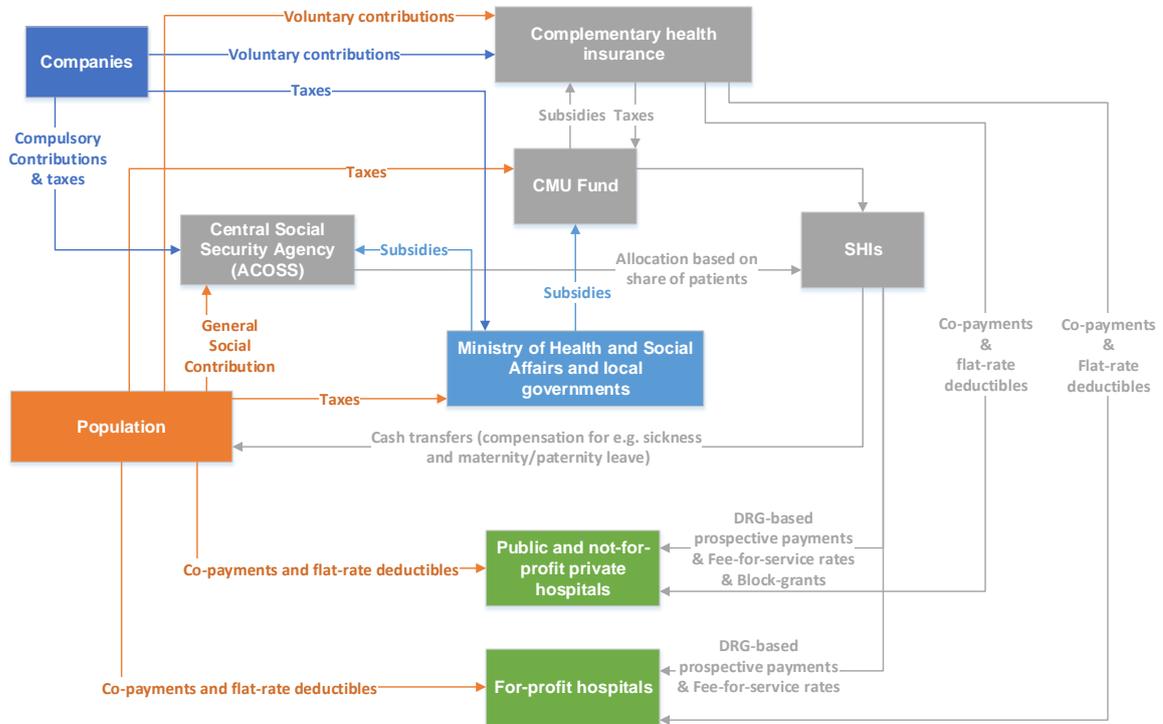


Figure 3: Hospital Financing System in France. Adapted from (11).

Self-employed medical specialists in private hospitals are paid on a fee-for-service basis. The fees are predetermined, however, doctors are in some cases allowed to bill more than the statutory tariffs (balance billing) (12). Medical specialists working in public hospitals are generally salaried employees and are usually allowed to see private patients. For these private patients, the medical specialists receive a fee-for-service, however, they must pay a percentage of this fee to the hospital (13).

3.2.4 Recent reforms and current focus points

The relative high spending on healthcare in France compared to GDP (second highest in EU) is a threat to the sustainability of the French healthcare system (12). The new government, which was installed in 2017, aims to further increase health spending by 2.3% per year. However, as the GDP is expected to grow at a similar rate, the health spending relative to GDP is forecasted to remain fairly stable (15). Still, this means that France likely will remain one of the countries with the highest spending on healthcare compared to GDP in the EU.

SHIs have recorded significant deficits over the past two decades. However, the magnitude of the deficits has decreased from over € 10 billion in 2005 to almost break-even in 2018, due wide-ranging cost-reduction policies (13). Examples of these policies are a reduction in the number of acute-care hospital beds and a reduction of the statutory tariffs for self-employed radiologists and diagnostic laboratories. In addition, cost-

reduction policies have been aimed at medicines, as over 600 medicines have been withdrawn from public reimbursement, prices of generic medicines have been reduced and prescription of generic medicines has been further encouraged (16).

Furthermore, care delivery in hospitals has been a focus of cost-reductions, with policies aiming to reduce the average length of stay, to increase the share of outpatient surgeries, to reduce duplicate diagnostic testing and to prevent avoidable hospital admissions (13). Also, the route toward hospital care is being addressed by cost-reduction policies, as the general practitioner is increasingly being positioned as the gatekeeper of the healthcare system.

Next to cost-containment, a clear focus point for the French healthcare system is the large health inequalities between regions and social classes, especially for men (12). Life expectancy for men in lower social classes is more than six years shorter than life expectancy for men in higher social classes (14). Two major reforms were proposed in 2016 to reduce such health inequalities. One reform, which has already been fully implemented, is implementing universal access to the social insurance system (13). The other reform proposed the introduction of a general third-party payment system at the point of use, which replaces the upfront fees that patients have to pay to healthcare providers. Such upfront fees can be a barrier for patients with low income to access the healthcare system and therefore contribute to health inequalities. In the proposed system, doctors have to claim the fees from insurers instead. This reform was greeted with heavy protests by doctors as they deemed that the reform transferred too much financial risk to them. The reform has subsequently been postponed (15).

Regional inequalities in healthcare can (partly) be attributed to disparities in the distribution of doctors and other healthcare professionals between regions. To combat these regional inequalities, the Ministry of Health has launched “Health Territory Pacts” in 2012 and 2015 (14). These pacts promote recruitment and retention of doctors and other healthcare professionals to underserved regions. In addition, medical students receive a monthly allowance during their education, if they commit to serving underserved regions after graduation (14).

3.3 Germany

3.3.1 German healthcare system

Germany was the first country in the world to introduce social healthcare insurance funds (sickness funds). Solidarity, subsidiarity and corporatism are the founding principles of these sickness funds, which were established by Otto von Bismarck. These principles still define today's German healthcare system, where the 16 states (*Bundesländer*) are largely responsible for healthcare and powers are delegated to membership-based self-regulated organizations of payers (sickness funds), providers and physician associations ('corporatist bodies') (12; 17; 13). The various levels of government in Germany have no direct role in the financing or delivery of healthcare. The Germany healthcare system is characterized by multiple payers (sickness funds) and a co-existence of statutory health insurance and substitutive private health insurance (18).

In Germany, it is mandatory for all residents to have either statutory or private health insurance. 87% of the population is covered by sickness funds in the statutory health insurance system (*Gesetzliche Krankenversicherung*), which is, with few exceptions, mandatory for everyone in employment with a gross annual income of less than € 59.400 (19). The number of sickness funds has steadily been declining due to consolidation. Currently, there are 110 funds, down from 267 in 2005 and down from 1.147 in 1990 (20). The six biggest funds have a market share of more than 50%. This trend of consolidation is expected to continue (19; 21).

The remainder of the population is covered by private health insurance (ca. 11%) or free healthcare provided by the state (less than 3%), which is, for instance, applicable for soldiers and policemen (17). Next to substitutive private health insurance, private health insurance also can be contracted to serve as a supplement on top of the statutory health insurance, e.g. for treatment by chief physicians or for special services like single-bed-rooms in hospitals or dental supplementary insurance. In total, ca. 37% of the Germans have either full-cover private health insurance, which replaces the statutory health insurance, or a supplementary private health insurance, which is in addition to the statutory health insurance (19).

The statutory healthcare insurance system covers a wide range of services, including, amongst others, inpatient and outpatient hospital care, prescription medicines, preventive medicine, physical therapy, dental care, mental healthcare and sick leave compensation (13). All prescription medicines are covered, with exception of certain medicines that have failed the benefit assessment, medicines that have been excluded by law (so-called lifestyle medicines such as for instance medicines for hair loss) and certain over-the-counter medicines (17).

The German health system has a complex structure, with the federal government responsible for providing the legal framework for the healthcare system and the Federal Joint Committee (*Gemeinsame Bundesausschuss*, G-BA) responsible for specification of the regulatory details, determination of the benefits in the statutory health insurance system and quality assurance (18). The G-BA consists of representatives of associations of sickness funds, hospitals, physicians, dentists and patients. The *Bundesländer* supervise the corporatist bodies at the state level and are responsible for the planning of hospital capacity, for investments in hospitals and for medical education (18).

Next to the various levels of government, the G-BA and the corporatist bodies, there are other key entities in the German healthcare system. Key entities with respect to medicines and/or hospitals are listed below:

- The Federal Institute for Pharmaceuticals and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, BfArM) is responsible for marketing authorization and safety of medicines and medical devices (17).
- The Paul Erlich Institute (Federal Institute for Vaccines and Biomedicines) is responsible for licensing vaccines, blood products and sera (17).
- The Institute for Quality and Efficiency (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWiG) is an independent foundation which is responsible for the evaluation of the cost-effectiveness of drugs with added therapeutic benefits (13).
- The Institute for Quality and Transparency (*Institut für Qualitätssicherung und Transparenz im Gesundheitswesen*, IQTiG), is an independent foundation which is responsible for intersectoral quality insurance in the German healthcare system (13). IQTiG defines the quality indicators which hospitals are obliged to publish in order to allow for hospital comparisons.

3.3.2 Financing of the German healthcare system

Germany spent approximately 11.2% of its GDP on healthcare in 2015, which is the highest in the EU (18). Healthcare expenditures fell in absolute terms during the economic crisis. Subsequently, healthcare expenditures have risen annually by approximately 3% in the period 2012-2017, due to an ageing population, new medical technologies, policy reforms, increasing prevalence of chronic diseases and an inflow of migrants (19).

Approximately 85% of the total healthcare expenditures are publicly funded in Germany, which is the highest public spending share in the EU and well above the EU average of 79% (18). The share of public spending on total healthcare expenditures has increased significantly over the past decade, from 76% in 2005 (19). The public healthcare system (via sickness funds) is primarily financed by payroll contributions, with the remainder from government subsidies. With few exceptions, employee and employer have to pay in total 14.6% of the worker's salary (each 7.3%) and the employee has to pay a supplementary fee depending on the efficiency of his or her sickness fund (average over all 110 sickness funds in 2018: 1.0%). Family members (children, non-working wife/husband) are also included in the sickness funds for free and have also the same insurance benefits. Policymakers are currently exploring whether employers should also contribute 50% of the supplementary fee, as a way to reduce the financial burden of the insured individuals (22).

The share of private healthcare spending on total health expenditure was about 16% in 2015, including 13% of out-of-pocket spending by patients (19). This share of out-of-pocket spending is well below the EU-average of 15% and ranks amongst the lowest in the EU (18). 37% of all out-of-pocket spending is related to medical goods such as over-the-counter medicines and medical aids such as eye-glasses and hearing aids. Long-term care and dental care are two other major components of out-of-pocket spending in Germany: 33% and 15%, respectively (18). Another category of out-of-pocket spending

are the so-called ambulatory individual health services provided by physicians. Such health services are not reimbursed in the statutory health insurance system, as the therapeutic benefit has not (yet) been proven. The 10 euro co-payment per first physician visit per 3 months was abolished in 2013 (19).

3.3.3 Hospital funding in Germany

Germany has close to 2.000 hospitals, of which approximately one third is public (for instance owned by the municipality), one third is private not-for-profit (for instance owned by a religious institution) and one third is private for-profit (for instance owned by a private investor) (19). Germany is characterized by a relatively large hospital sector, with 8 beds per thousand citizens, a ratio which is the highest in the EU and significantly higher than the EU average of 5 beds per thousand citizens (18). Public hospitals have the largest share of hospital beds in Germany (ca. 48%), followed by private not-for-profit hospitals (ca. 35%) and private-for-profit hospitals (ca. 17%) (17). The share of hospitals beds in private-for-profit hospitals has increased significantly over the past decades, whereas the share of hospital beds in public hospitals has shown a sharp decrease (17).

Hospitals in Germany provide the vast majority of their services to inpatients, as they are only allowed to provide limited and exactly defined services for outpatients (12). This is the result of a clear separation in the German healthcare system between ambulatory care and hospital care. Examples of services that hospitals are allowed to deliver to outpatients are highly specialized procedures, treatments of rare diseases and treatment of severe progressive diseases (13).

The hospital financing system in Germany is depicted in Figure 4 and shows that hospitals are funded through dual financing. The federal and state governments finance investment costs and the sickness and private insurance funds pay the running costs (12; 17). In order to be eligible for financing of investments by the government, public, not-for-profit and for-profit private hospitals have to be listed in the hospital requirement state plans (16 plans – 1 for each state) and the investments need to contribute towards the realisation of these state plans.

Sickness funds are the major financing source for running costs such as personnel, medical goods and assets with an average economic life up to three years (17). Sickness funds and hospitals determine the level of funding for operating costs by negotiation and payment takes place per admission through the German diagnosis-related group (G-DRG) system.

The German DRG Institute (InEK GmbH), which is funded by corporatist bodies, maintains and further develops the G-DRG system. In contrast to most DRG systems in other countries, the G-DRG system is centred around medical procedures. A G-DRG is determined first by procedure and subsequently by clinical severity and comorbidity (17). This grouping process, as well as the entire G-DRG system, is annually revised by the German DRG Institute. Next to DRGs, hospitals may receive supplementary fees and additional surcharges for innovative diagnostics and treatment procedures (17). Regional social healthcare insurance medical review boards are responsible for auditing the DRG registrations of the hospitals. These review boards focus especially on “upcoding”, a known threat to DRG-systems.

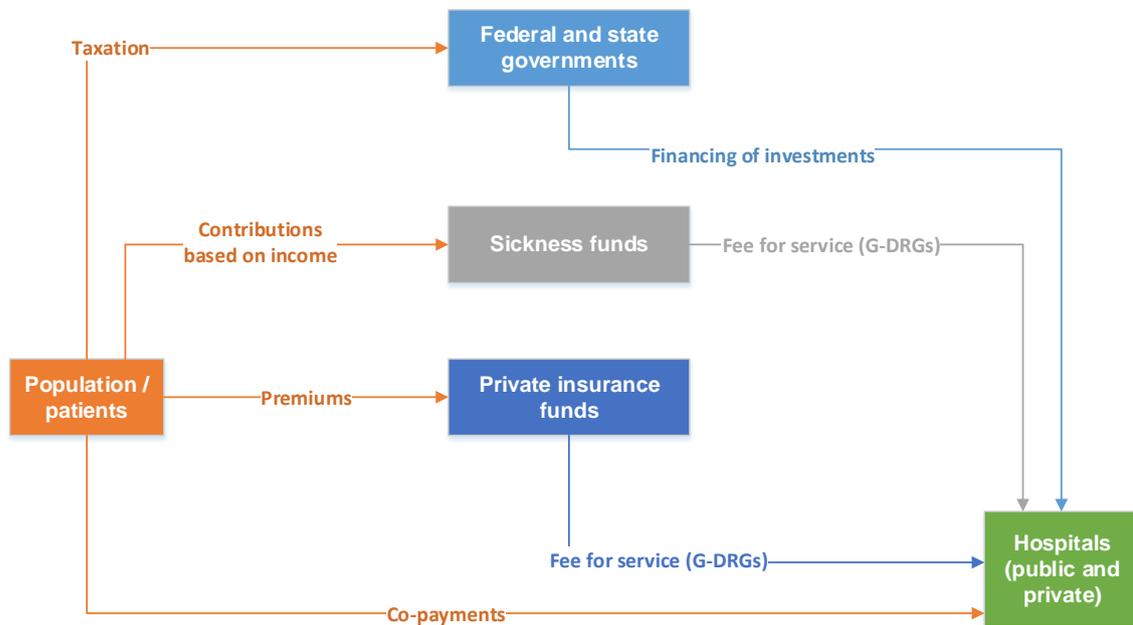


Figure 4: Hospital Financing System in Germany. Adapted from (17).

DRG-systems essentially function as fee-for-service. This means that the productivity of the hospitals is stimulated, but that also maximization of the volume is incentivized, which leads to a risk of overproduction, and hence larger healthcare expenditures per capita. In order to counter this incentive, German policies stipulate that hospitals have to pay back 65% of the revenue which exceeds the agreed revenue hospital budget and that hospitals receive 25% of the shortfall where the actual revenue is less than agreed (to finance hospital's fixed costs) (17). In order to reduce the ongoing increase of costs for hospitals, recent hospital reforms have established further instruments that also bring in parameters regarding quality in the hospital financing system (pay for value) and bring quality parameters in the paying process (pay for performance). These reforms are currently begin implemented.

3.3.4 Recent reforms and current focus points

Germany performs relatively well in addressing the healthcare needs of its citizens. The proportion of people who reported unmet needs for medical care due to costs, distance and waiting lists was 0.5% in 2015, among the lowest in Europe and significantly lower than the EU average of 3.2% (18). Compared to many other EU countries, there is little variation in reported unmet medical needs between people with low annual incomes and people with high annual incomes. The major source of reported unmet medical need is perceived discrimination (e.g. longer waiting times or not having private health insurance) (23).

The new German government, which was installed on March 14th 2018, is expected to focus on a few, but highly pressing, areas with respect to healthcare, such as increasing the capacities in long-term care and a reform of the working conditions and the

remuneration of the healthcare workforce (22). The likelihood of major systemic healthcare policy reforms in Germany by the new government is rather low (19).

Professor Michael Porter of Harvard Business University summarized aptly the current state of the German healthcare system: *“Germans receive more care than citizens in many parts of the world, but not necessarily better care or the highest value care”*. Michael Porter has proposed a range of structural changes for the German healthcare system. Two of the most important proposed changes regarding the hospital financing system are dissolving the division between inpatient and outpatient services and consolidating the provider market to reduce overcapacity, oversupply and variation (24).

3.4 Italy

3.4.1 Italian healthcare system

The Italian National Health Service (*Servizio Sanitario Nazionale*, SSN) is based on the principles of solidarity and universal coverage and was set up in 1978 (13). The health system in Italy is significantly decentralized (12). This results in different organizational models (and outcomes) across the 19 different regions and two autonomous provinces in Italy (25). At the national level, the government retains overall responsibility, distributes the tax-financed health budget, and defines the national benefits package (*livelli essenziali di assistenza*) that is guaranteed for all citizens and foreign residents. Regions are responsible for the organisation and delivery of healthcare through local health authorities (LHAs) (25; 26). LHAs deliver hospital care, primary care, public healthcare and social care (26). These LHAs are managed by general managers appointed by the regional government and therefore are under local political democratic control (12). Several regions have merged LHAs since 2016, with the goal to increase efficiency and quality of care through economies of scale and better organizational integration (25).

The SSN covers all citizens and (legal) foreign residents, and coverage is automatic and universal (13). In Italy, inpatient care and primary care are free at the point of use. There are both positive and negative lists, which define which services are offered, or not offered, to all residents (13). Examples of positive lists services are pharmaceuticals and inpatient care. Cosmetic surgery is a negative list example. Regions can offer services which are not included in the national benefits package, however, they must finance these services themselves.

Even though the health system is significantly decentralized in Italy, there are several national institutions that play an important role in the national health system. Key entities with respect to medicines and/or hospitals are listed below:

- The National Agency for Regional Health Services (*Agenzia Nazionale per i Servizi Sanitari Regionali*, AGENAS) is responsible for comparative-effectiveness analyses and is accountable both to the Ministry of Health as well to the regions (13). In addition, it supports the Ministry of Health and the regions in planning and implementation of organizational reforms (26).
- The National Pharmaceutical Agency (*L'Agenzia Italiana del Farmaco*, AIFA) is responsible for matters related to medicines, including reimbursement policies, prescription medicine pricing and authorization of clinical trials (26).

3.4.2 Financing of the Italian healthcare system

Italy spent approximately 9.1% of its GDP on healthcare in 2015, which is below the EU average of 9.9% (25). Expenditures on healthcare as a proportion of GDP have remained stable in the past decade (27). However, absolute spending on healthcare fell in 2011-2013 due to the economic recession, and only recently absolute spending on healthcare has recovered to pre-economic crisis levels (27). It is estimated that healthcare expenditures as a proportion of GDP will rise moderately to 9.4% in 2021, driven by an ageing population and advances in medical technologies (27).

The SSN is mainly funded through national and regional taxation. These taxes account for 76% of the total health budget and can roughly be divided in corporate taxation and national value-added tax revenues (13; 25). Funding of the Italian healthcare system is supplemented by co-payments of patients for outpatient pharmaceuticals and outpatient care (ca. 21-23% of the total health budget), and by voluntary private insurance (ca. 1-3% of the total health budget) (26; 27). People under age 6 and over age 65, people with a household gross income of less than ca. €36.000 and people with severe disabilities are exempted from co-payments. In addition, people with chronic or rare diseases and pregnant women are exempt from co-payments related to their conditions (13). Policymakers have been increasing co-payment levels for medicines in order to contain regional public spending and to achieve more sensible and appropriate levels of medicine prescriptions (25).

Most private health insurance is provided by not-for-profit insurance companies. Private insurance in Italy is complementary and supplementary to the SSN and not a substitution for the SSN, as the government does not allow people to opt out of the national system to only seek private care (13). Voluntary health insurance is taken to reduce co-payments, to obtain faster access to treatments and to cover services not included in the SSN, such as dental care. In addition, voluntary health insurance gives a wider choice of private and public providers and a higher standard of comfort and privacy in hospital facilities (25). Approximately 11 million people in Italy were covered by voluntary health insurance in 2015 (28). In recent years, the government has introduced tax benefits to stimulate complementary voluntary private insurance (25).

3.4.3 Hospital funding in Italy

Italy has approximately 1.100 hospitals serving the population of 61 million citizens. Consolidation is an ongoing trend in the Italian hospital sector, with numbers of hospitals falling consistently over the past decade, from ca. 1.250 hospitals in 2008 (27). The number of hospital beds also shows a decrease, from ca. 5 beds per 1.000 citizens in 2000 to 3 beds per 1.000 citizens in 2017, due to the aforementioned consolidation, but also due to shorter hospital stays, a shift of care to outpatient settings and budget constraints (27).

Approximately 56% of the hospitals are private for-profit institutions, 41% of the hospitals are publicly owned and 3% are owned by private not-for-profit institutions, such as religious orders (27). Public hospitals account for the majority of hospital beds (ca. 80%) (13). Private hospitals that are accredited by the LHAs are allowed to provide services paid for by the state. Public hospitals are usually managed by the LHAs or by semi-independent public enterprises (13).

The hospital financing system in Italy is depicted in Figure 5. Throughout the country, the majority of the hospitals funding is operated via a DRG-prospective payment system. Rates include payment for ordinary and day hospital treatments and include the salary of the physicians. DRG tariffs are set at the national level, based on average production costs, and subsequently, the regions can modify the tariffs (26), which leads to a considerable variation in the hospital financing system between regions. The DRG-system is usually not applied to hospitals which are run directly by the LHAs. Instead, these hospitals generally are funded using a global budget (13).

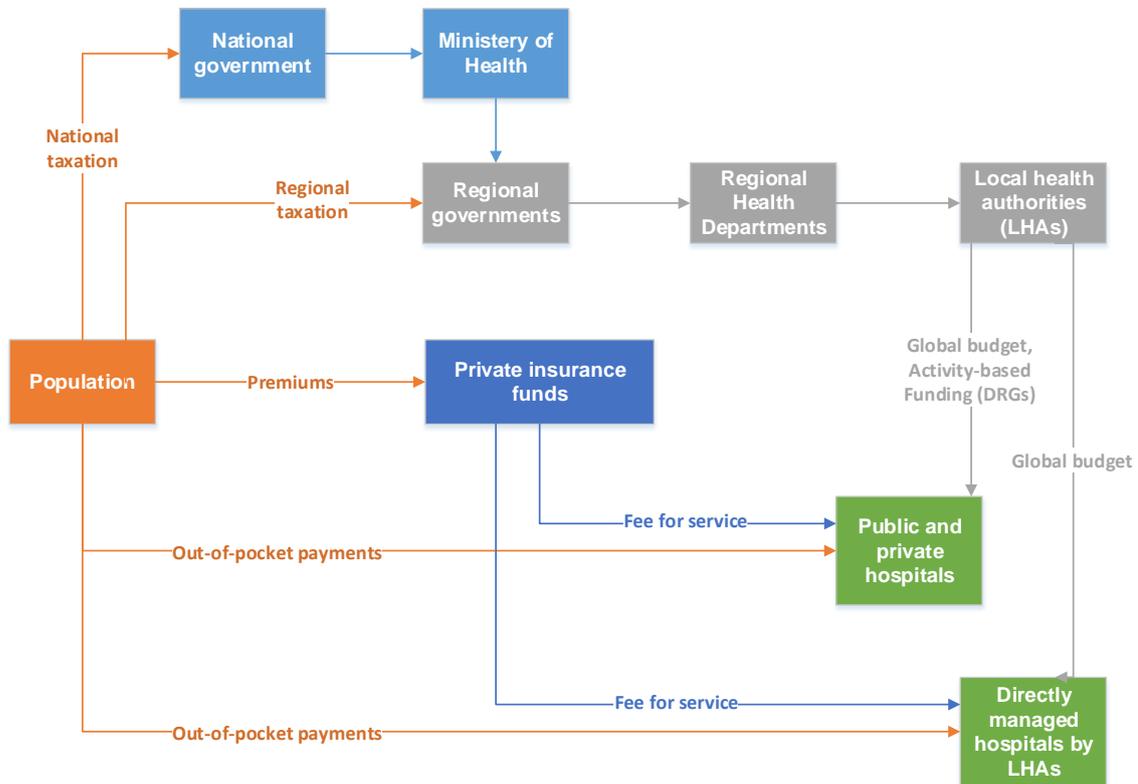


Figure 5: Hospital Financing System in Italy. Adapted from (26).

In addition to the prospective payment system, block-grants are employed for specific functions such as teaching programs, emergency departments, organ transplants and blood and tissue banks (13; 26). Physicians working in hospitals are salaried employees. Physicians working in public hospitals are prohibited to also work in private hospitals and have to pay a portion of their additional earnings from private patients seen in a public setting to the hospital (13).

Outpatient specialist care, diagnostic tests and medical imaging procedures are based on standardized tariffs (26). Outpatient specialist care is mainly provided by LHAs or subcontracted by the LHAs to public and private hospitals (13). Once a patient has been referred, the patient has free choice of hospitals, however, the patient is not given a choice of specialist.

In summary, the main financial source for both private hospitals and public hospitals not directly managed by LHAs are DRGs. However, all regions employ mechanisms for cutting hospital budgets once a certain spending threshold is reached (13). Therefore, private hospitals and public hospitals not directly managed by LHAs are effectively funded via a global budget, similarly to public hospitals directly managed by LHAs. An

annual budget incentivizes reducing costs, which may lead to underproduction, and consequently, waiting lists.

3.4.4 Recent reforms and current focus points

Italy was heavily impacted by the economic crisis. As part of the EU's Stability and Growth Pact, Italy's 2016 Stability Law aims to improve healthcare efficiency by introducing deficit-reduction plans for hospitals and by centralizing purchasing procedures (27). The goal of the law is to create approximately € 2 billion in savings in healthcare expenditure. In addition, regions are no longer covered by the central government for their health spending deficits, spurring regions to make considerable progress in reducing their healthcare expenditures (27).

In addition to cost savings, regional differences in the quality of healthcare are a focus point for improvement of the Italian healthcare system. Generally speaking, southern regions have lower capacity, less access to advanced technologies, less developed community care services and worse perceived quality of care than the northern and central region (25; 13). This results in a flow of patients from the south to the north to obtain high-quality care. Estimations from the Ministry of Health show that the southern regions of Campania, Calabria and Sicily lose at least 30.000 patients a year to the more northern regions (25).

Seven percent of Italians report unmet needs for medical care. This is significantly higher than the EU average (less than 4%) and this percentage has grown in recent years (25). Most of this unmet need is attributable to care being too expensive. This is particularly reflected in the proportion of people in the lowest income group reporting unmet needs for medical care, which is 15%. In contrast, less than 2% of Italians in the highest income group report unmet needs with respect to medical care. Next to care being too expensive, waiting lists and geographic barriers (travel time) attribute to unmet needs for medical care of Italians (25).

3.5 Poland

3.5.1 Polish healthcare system

After the collapse of communism in Poland in 1989, the strongly centralized and hierarchical Soviet model of healthcare was discarded for a more decentralized healthcare system (29). This resulted in the introduction of a decentralized compulsory social health insurance system in 1999 (30). The compulsory social health insurance system covers approximately 98% of the population in Poland and offers a broad range of healthcare services (29; 30).

In the initial version of the social health insurance system, sixteen regional insurance funds were responsible for contracting healthcare providers, one for each of the 16 regions (*voivodeships*). In 2003, the 16 insurance funds were subsequently merged into a single national health insurance fund (*Narodowy Fundusz Zdrowia*, NFZ) (31). The NFZ has ever since been the sole distributor of social security healthcare funds, which are mainly collected from social insurance contributions (29). The NFZ is responsible for contracting healthcare services for the insured population from providers, which can either be public or private (29). The NFZ is not allowed to engage in commercial activities and is not allowed to own or operate healthcare institutions. Financially, the NFZ has struggled with significant debts. However, the financial position of the NFZ has improved since 2013 due to enforcement of more stringent reimbursement rules (31).

The NFZ shares the responsibility for the Polish healthcare system with the Ministry of Health, the Ministry of Finance and local governments (territorial self-governments). The Ministry of Health supervises the operations of the NFZ and is responsible for setting the national health policy, and for financing of highly specialized medical services, public health programs, major capital investments and medical education and science (29). The Ministry of Finance is responsible for supervision of the finances of the NFZ. The NFZ has limited regulatory powers, as these are mostly held by the Ministry of Health.

Local governments are responsible for health promotion, management of public healthcare institutions and planning of health services delivery (29). Generally speaking, the local governments of the *voivodeships* are responsible for planning of health services delivery and emergency care. *Voivodeships* own the larger, complex healthcare facilities in the region, whereas *powiats* (districts within a *voivodeship*) own the general hospitals. *Gmina* (municipalities within *powiats*) are responsible for health promotion. In certain municipalities such as larger cities, the municipalities can own hospitals and out-patient care as well.

Next to the NFZ, the national government and the territorial self-governments, there are multiple other key entities in the Polish healthcare system. Key entities with respect to medicines and/or hospitals are listed below:

- The Agency for Health Technology Assessment and Tariffication (*Agencja Oceny Technologii Medycznych i Taryfikacji*; AOTMiT) is a state-financed HTA agency that functions as an advisory body to the Ministry of Health (29). The main activity of AOTMiT is providing the Ministry of Health with recommendations regarding the inclusion of medicines on the reimbursement list. In order to do so, AOTMiT analyses the clinical effectiveness, cost-effectiveness and budget impact of new medicines.

- The Office for Registration of Medicinal Products, Medical Devices and Biocides (*Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*, URPL-WMiPB) is a government agency directly subordinated to the Ministry of Health and is responsible for the evaluation of safety and efficacy of medicines, medical devices and biocides (29). Next to issuing marketing authorizations, URPL-WMiPD also can withdraw previously granted marketing authorizations in the case of safety concerns or lack of therapeutic effect.
- The Chief Sanitary Inspectorate (*Główny Inspektorat Sanitarny*) is a government agency directly subordinated to the Ministry of Health and is responsible for monitoring safety and sanitary conditions in healthcare institutions and hygiene in various other areas such as food quality (29).

3.5.2 Financing of the Polish healthcare system

Poland spent approximately 6.3% of its GDP on healthcare in 2015, which is significantly below the EU average of 9.9% and the lowest of all eight countries studied in this report (30). It is estimated that healthcare expenditures as a proportion of GDP will rise marginally in the next few years to approximately 6.6% in 2022 (31).

Public sources account for approximately 70% of all healthcare spending in Poland (31). The remaining 30% is accounted for by private sources, with out-of-pocket payments representing the majority of these private sources (23% of all healthcare spending) (30). This level of out-of-pocket payments is significantly higher than the European Union average of 15% and also translates into a relatively high percentage of the population (8%) for which the out-of-pocket payment level is deemed 'catastrophic'. Out-of-pocket payments are defined as catastrophic if these payments exceed more than 40% of a yearly total household spending on basic needs such as food and housing (30).

The majority of out-of-pocket payments in Poland are spent on medicines in ambulatory care, for which coverage is rather narrow in the compulsory social health insurance system (30). This is reflected in the fact that Poland has the fourth highest share of out-of-pocket expenditure on medicines (60%) within the European Union. Recently, a new policy has been enforced which stipulates that a greater number of medicines are fully reimbursed for people of age 75 or older. This measure will likely reduce the out-of-pocket payment level for the elderly population significantly (30). Medicines dispensed by hospitals for inpatient treatments are exempt from copayments in Poland (29).

The private insurance market is rather limited in Poland (approximately 4% of all healthcare spending) and the term 'private health insurance' has not been legally defined (31). Private insurance generally is limited to supplementary insurance and is offered in two forms (29):

- 1 Medical subscriptions, which cover mostly outpatient health services and is the most common form of private health insurance in Poland. These medical subscriptions are generally speaking offered by employers to their employees.
- 2 Health insurance policies, which are offered by insurance companies and include reimbursement or direct payment of for instance certain hospital treatments.

3.5.3 Hospital funding in Poland

The number of hospitals in Poland has risen from 800 to approximately 1.100 between 2000 and 2015 (31; 32). This increase is mainly due to new hospitals which generally have a limited amount of hospital beds. Approximately two-thirds of the hospitals are publicly owned, and one third is owned by private institutions. The share of private hospitals has been increasing (31). Most outpatient and ambulatory care in Poland is delivered by private providers (30). Generally speaking, the hospital infrastructure in Poland is quite dated, with ageing equipment and the urgent need for renovation. Many public hospitals have been unable to adequately invest in infrastructure due to debt-related issues (31).

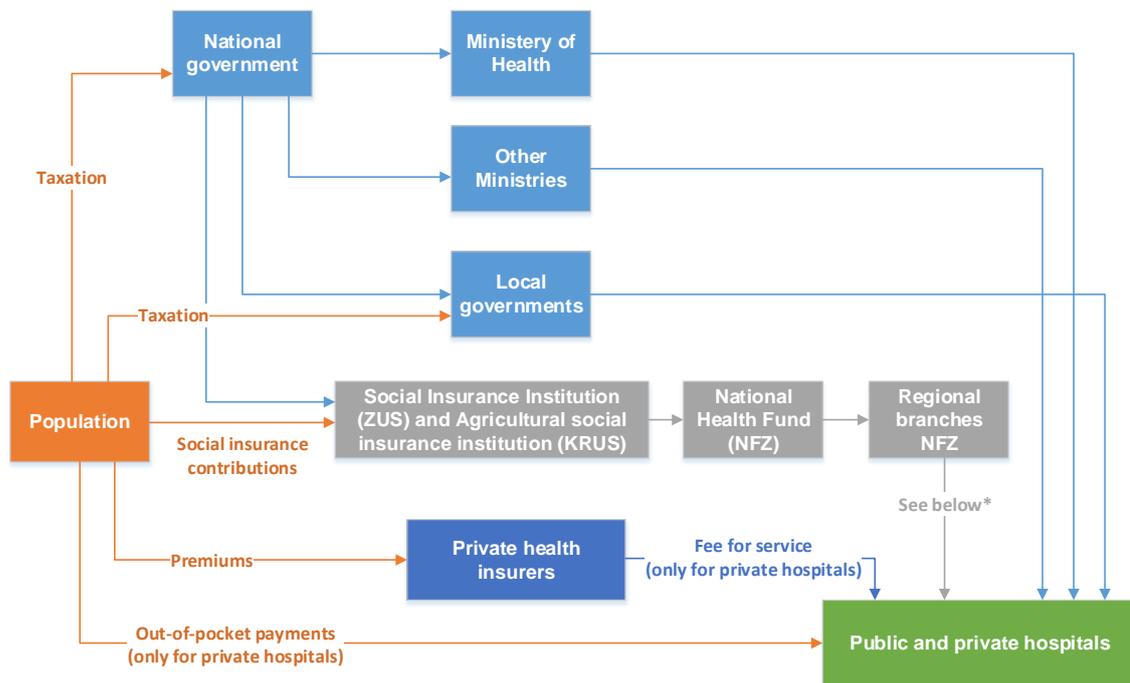
The hospital financing system in Poland is depicted in Figure 6. The Social Insurance Institution (ZUS) and Agricultural Social Insurance Institution (KRUS) collect social healthcare insurance contributions and transfer them to the NFZ. The collection rate of health insurance contributions in Poland is typically high (>97%), which supports the solidarity of the healthcare system (29). Subsequently, the NFZ head office divides the centrally collected contributions between the local NFZ branches (1 for each *voivodeship*) according to an allocation formula. The regional branches of the NFZ are responsible for procurement of healthcare services for its population within the available budget and are the largest source of revenue for hospitals (29). Contracts can be awarded by the NFZ local branches by means of a competitive tender or negotiations.

Hospital financing by the NFZ goes mainly through the Polish DRG-system (JGP), which was introduced in 2008 (29). This system applies to all hospital patients (including hospital emergency care), with exception of highly complex procedures such as for instance transplant surgery, for which the Polish state provides funding. The JGP system is supposed to fully cover all hospital expenses, with exception of major investment costs and expensive medicines. Since 2011, the DRG-system also applies to specialist ambulatory care (29). The goal of the introduction of DRGs in the ambulatory care is to incentivize a shift from inpatient care to daycare for non-complex cases. Other revenue streams of hospitals in Poland include revenues from state and local governments. Private hospitals also have additional revenue streams from out-of-pocket and private healthcare insurance payments. Furthermore, since the European Union membership in 2004, EU subsidies have covered a major part of the investments in hospital buildings, facilities and equipment.

Poland is characterized by a relatively high number of hospital beds per capita, with 7 hospital beds per thousand citizens compared to the European Union average of 5 hospital beds per thousand citizens (30). This is likely a remnant of the previous Soviet-based healthcare system, where hospitals were put at the centre of the system (31). In addition, a shortage of (affordable) long-term care beds and elderly care beds contributes to the relatively high number of hospital beds in Poland. The number of hospital beds has not changed significantly since the early 2000s and overcapacity of acute care beds remains an issue (30). However, the capacity is unevenly distributed, resulting in capacity problems in some areas in Poland.

The relatively high number of hospital beds in Poland is in stark contrast to the availability of elective hospital services in Poland, such as cataract and joint replacement surgery (30). Poland has the longest waiting times for this kind of procedures in the European Union. The long waiting times can (partly) be attributed to underfunding of the hospital

system, inefficiency within the hospital system and to the scarcity of healthcare professionals in Poland. Another cause for these waiting lists are the incentives of medical specialists, which can benefit from creating waiting lists as these boost demand for their own private services (30). Such private services are paid out-of-pocket by patients. Double employment of medical specialists in both public hospitals as well as private practice is common in Poland and poorly regulated.



* As of October 2017:

Block grants for hospitals included in the national hospital network. 91% of total national hospital budget is allocated to these block grants. The excluded hospitals can compete in tenders to receive funds from the remaining 9% of the national hospital budget.

Figure 6: Hospital Financing System in Poland. Adapted from (29).

3.5.4 Recent reforms and current focus points

As of October 1st 2017, the Polish hospital system has been changed significantly (33). A national hospital network, called System of Fundamental Hospital Care Coverage, has been introduced. 515 public and 82 private hospitals have been included in the network, and the remaining 16 public and 320 private hospitals have been excluded (34). The included hospitals will be financed by block grants assigned by the NFZ. 91% of the total hospital care budget will be allocated to fund these block grants for included hospitals. Excluded hospitals may apply for contracts with the NFZ to compete for the remaining 9% of the hospital care budget. With these reforms, the Polish government has effectively switched the majority of the hospital care funding from activity-based funding towards prospective annual budgets (30). Previous maximum contractual limits that capped activity-based funding revenues are now replaced by minimum volumes that hospitals will have to meet to be eligible for receiving block grant funding.

Generally speaking, block grant funding incentivizes hospitals to reduce costs in order to create a positive bottom-line result. Such an incentive may lead to the risk of underproduction, and consequently waiting lists. In order to tackle this potential risk, the government has defined minimum volume targets for hospitals within the new national hospital network.

Two other major changes in the hospital system that are enforced as of October 1st 2017 are a ban on acquisition of more than 51% of public hospital shares by private investors and the de-privatization of emergency care, effectively prohibiting private companies to deliver emergency care.

These changes in the hospital system are a part of a larger set of healthcare reforms which are proposed by the Polish government (30). These reforms are aimed at improving access to care and efficiency of the Polish healthcare system. The reforms are accompanied by a pledge of the government to increase state health spending from 5% to 6% of the GDP (31). A portion of this increase is allocated to increase the salaries of medical staff in Poland, as there is scarcity in medical personnel due to workforce migration to other European countries, which provide better remuneration of healthcare professionals (30). This is currently a hot topic, with junior doctors having participated in strikes in 2017 to protest against the level of remuneration and against working conditions (31).

Within these reforms, it is also planned to replace the NFZ with a new funding system controlled by the central government. This new system will abolish the social insurance model and will be financed out of tax revenues instead (31). The aim of this reform is to consolidate funding and to reduce overhead. Another goal of the reform is to bring more citizens in the social healthcare system, as currently temporary workers are not obliged to pay for insurance. However, the plans for the replacement of the NFZ are likely to be delayed due to cost concerns (31).

Citizens of Poland currently report the fifth highest unmet medical care needs in the European Union (30). Cost and waiting times are the major causes for unmet needs in Poland. As waiting times can be avoided by opting for (more expensive) private care, the high-income households report significantly lower unmet medical care needs (4%) than people in the lowest income brackets (10%) (30). It remains to be seen whether the proposed set of reforms can contribute to a more efficient hospital system, with a reduced number of hospital beds, lower waiting times and better access for citizens with a low level of income.

3.6 Portugal

3.6.1 Portuguese healthcare system

The Portuguese health system consists of three (overlapping) systems:

- 1 **The National Health Service** (*Serviço Nacional de Saúde*, SNS) provides universal coverage and is (almost) free at the point of delivery (35; 36; 37). Coverage is comprehensive, including primary care and hospital care. Dental care, however, is mostly excluded from the SNS. The SNS is the largest employer and provider of healthcare in Portugal (12).

The Ministry of Health is responsible for regulation and planning of the SNS and for the definition of benefit package within the SNS. Management of the SNS is performed at the regional level, with 5 regional health administrations (RHAs) being responsible for management of population health and primary care (35). In addition, the RHAs supervise hospitals and are in charge of the implementation of national health policies. Boards of the RHAs are accountable to the Minister of Health. The autonomy of RHAs with respect to the budget setting is limited to primary care, as hospital budgets are being set by the Ministry of Health (35).

- 2 **Health subsystems** are special health insurance schemes for particular professions or sectors to which both employers and employees contribute, with employers paying the majority (36). These schemes can be considered as the remnants of the social welfare system which existed prior to the foundation of the SNS (35). Health subsystems can be either public (e.g. for civil servants) or private (e.g. for bankers) and are supplementary to the SNS (35; 37). Subsystems mainly provide diagnostic and therapeutic care as well as dental services, however, subsystems also provide some in- and outpatient hospital care and rehabilitation care (35). Healthcare within the subsystems is provided either directly by the health subsystem, or via contracts with public and/or private providers. Access to health subsystems is generally limited to people with a specific profession and their families. Approximately 16% of the population is covered by a health subsystem. The largest health subsystem is the subsystem for civil servants, which covers more than 10% of the entire Portuguese population (35).
- 3 **Private voluntary health insurance** is supplementary (12). It increases the choice of providers and reduces waiting times for elective hospital treatments and outpatient clinical consultations. Only rarely does voluntary health insurance cover services which are excluded from the SNS. Approximately 2.6 million people (26% of the population) were covered by individual or group voluntary health insurance in 2015, with the majority covered through corporate group policies (35; 36).
- 4 **Shared Services of Ministry of Health (SPMS):**
SPMS is a public enterprise created in 2010 (Decree-Law 19/2010 of 22 March), functioning under the guardianship of the Ministries of Health and Finance. Its aim is to provide shared services – in the areas of purchasing and logistics, financial services, human resources and information and communications systems and technologies – to organisations operating specifically in the area of health, in order

to “centralise, optimise and rationalise” the procurement of goods and services within the NHS.

Areas of intervention:

- a) Cooperation with the health services in innovation and change management;
- b) Promoting knowledge sharing for strengthening the reform of the health sector;
- c) Provision of shared services in several areas such as financial management, accounting, high-efficiency human resources, purchasing and logistics services and information and communications systems and technologies, keeping in mind the needs and responsibilities of the services of the NHS network;
- d) Functioning as a purchasing agency for procuring goods and services for the health sector, obtaining economic gains through economies of scale and trading in competitive dialogue with suppliers;**
- e) Contributing as an Operating Unit of the Ministry of Health for the promotion of modernisation and innovation in operating procedures of Hospitals and Healthcare Centres, through the proper integration of information and communications technologies, in perfect coordination with national and regional policies.

Even though the health system is quite decentralized in Portugal, with RHAs being responsible for management of primary care and supervision of hospital care, there are several national institutions that play an important role in the national health system. Key entities with respect to medicines and/or hospitals are listed below:

- The National Authority on Drugs and Health Products (*Autoridade Nacional do Medicamento e Produtos de Saúde*, INFARMED) regulates the pharmaceutical and health product markets in Portugal (35). INFARMED is responsible for approving reimbursement for medicines and for suggesting co-payment levels to the Ministry of Health. In addition, INFARMED is responsible for quality and safety of medicines and therefore supervises R&D, clinical trials, production, distribution and sales of medicines.
- The Central Administration of the Health System (*Administração Central do Sistema de Saúde*, ACSS) is responsible for managing financial and human resources within the SNS (35). In addition, it is in charge of the information technology within the SNS (including the DRG-system) and is together with the RHAs responsible for health service contracting.
- General Direction of Health (*Direção Geral de Saúde – DGS*) responsible by public policies and public health, which represents the WHO locally. It is responsible for vaccination programs, HIV/AIDS, among other health programs. DGS works closed with SPMS and Infarmed.
- The Health Regulatory Agency (*Entidade Reguladora de Saúde*, ERS) is an independent entity which is responsible for the supervision of the healthcare sector

(35). ERS supervises healthcare institutions with respect to operational requirements, patient rights, quality of provided care and competition rules. In addition, ERS is in charge of ensuring that there is sufficient competition among healthcare providers.

— The SPMS as referred above.

3.6.2 Financing of the Portuguese healthcare system

Portugal spent approximately 9.0% of its GDP on healthcare in 2015, which is significantly below the EU average of 9.9% (37). GDP is also much lower than average of European countries (belonging to OECD), and the health expenditure/capita of Portugal in 2017 was 2 066 while the average of EU28 was 2 773 Euro PPP). Due to the economic crisis, expenditures on healthcare fell in absolute terms in the period 2011-2013. Subsequently, health spending has recovered and it is forecasted that health spending will continue to increase to approximately 9.7% of the Portuguese GDP in 2021 (36). Approximately 66% of healthcare expenditures in Portugal are publicly funded, which is well below the EU average of 79% and down from the peak prior to the economic crisis (36). The SNS is mainly funded from general taxation. The public health services in Portugal are tendentiously free.

Private expenditures on healthcare in Portugal are chiefly represented by co-payments of patients, with 28% of all healthcare spending being co-payments in 2015, which is significantly higher than the EU average of 15% (37). Another indicator which shows that co-payments in Portugal are relatively high is the share of co-payments in total household consumption, which is 3.8% in Portugal, compared to the EU average of 2.3% (37). The relatively high level of co-payments can be (partly) related to the cost-containment policies in reaction to the economic crisis which severely impacted Portugal (12).

Patients are required to make co-payments for a wide range of SNS services, such as prescription drugs, diagnostic tests, emergency hospital visits, home visits, primary care visits and outpatient specialist visits. Hospital stays are exempted from co-payments. In 2016, emergency services, primary care visits and outpatient visits also became exempt, but only if the patient has a proper referral from for instance the *Saúde 24* call centre or from a general practitioner (35). Several population groups are also exempted from co-payments, such as people with low income, pregnant women, children under 18, firemen, permanently disabled people, blood donors and people with certain medical conditions (37; 36). This results in a fairly large share of the population (60%) that is exempted from co-payments, with low income being the main reason for exemption (35). The size of the required co-payment for most services is typically small compared to the actual costs of the received services, with an exception for medicines, for which different levels of co-payment are applied according to their therapeutic value (37). There are no co-payments for medicines dispensed by hospitals to inpatients.

Voluntary private healthcare insurance has been growing over the past years and currently accounts for approximately 5% of overall health expenditures in Portugal, which is similar to the EU average (36). Affordability is a major restraining factor in the further uptake of voluntary health insurance (36). The private healthcare insurance market has been consolidating in the past few years, with approximately 25 insurers remaining.

There are currently two market leaders, *Fidelidade* and *Ocidental Seguros*, which together have a market share of over 50% (35).

3.6.3 Hospital funding in Portugal

Portugal has 225 hospitals, of which 111 are private and 114 belong to the NHS, with four NHS hospitals participating in public-private partnerships (36). Portugal is characterized by a relatively low number of hospital beds per capita, with 3 beds per thousand citizens compared to the EU average of 5 hospital beds per thousand citizens (36). Private hospitals increased their market share by 22% during the period 2005-2015, amounting to approximately a total of 11.000 beds in private hospitals in 2015. During the same period, the number of hospital beds in public hospitals decreased by 21%, amounting to approximately a total of 22.000 beds in public hospitals in 2015.

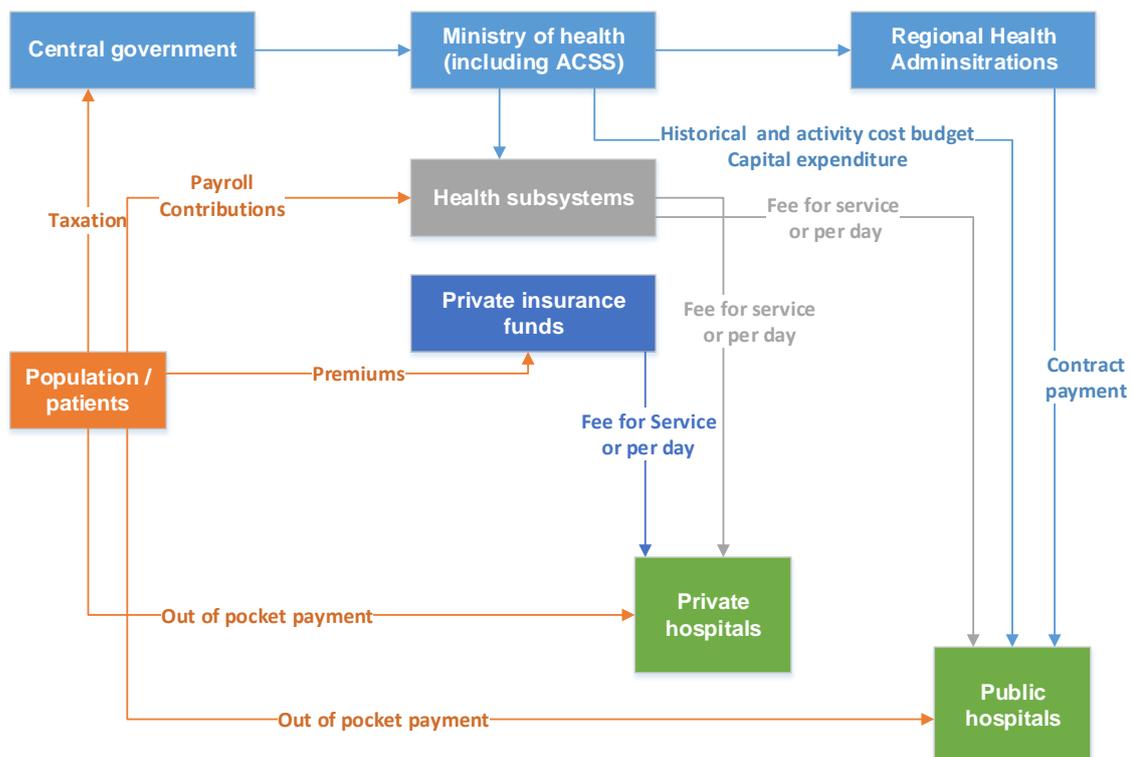


Figure 7: Hospital Financing System in Portugal. Adapted from (35).

The hospital financing system in Portugal is depicted in Figure 7. Both public and private hospitals are financed by multiple payers. Public hospitals are allocated global budgets based on program contracts signed with the Ministry of Health and are paid on the basis of diagnosis-related groups (DRGs). Funding through DRGs represents around 80% of NHS hospitals' inpatient budget; the remainder is funded by third-party payers, such as health subsystems and private insurance funds (35). The DRGs are used to set the budget given to the hospital, not to define a fee for service per episode. All NHS hospitals use a minimum basic data set (*Folha de Admissão e Alta*) to support the DRG system. The ACSS runs the process of adjusting prospective budgets for case-mix and other

hospital specificities. Health subsystems reimburse NHS hospitals on a case-by-case basis for inpatient care and ambulatory surgery, using a DRG price list (35). For ambulatory services, health subsystems reimburse on a fee-for-service basis. Private insurers use different modes of reimbursement.

The public hospital financing system is therefore rather complex, with multiple payers (both private and public) and with multiple types of contracts. Therefore the incentives for public hospitals are also mixed. As the main source of funding is budget based, the main incentive appears to be reducing costs in order to have a positive bottom-line result. This could lead to the risk of underproduction and consequently, waiting lists.

For private hospitals, the main payers are private insurance funds and health subsystems. Both payers pay on a fee for service or fee per day basis (35). This stimulates the productivity of the private hospitals, but also incentivizes hospitals to maximize the volume of delivered care which leads to the risk of overproduction and hence higher healthcare expenditures per capita.

3.6.4 Recent reforms and current focus points

Portugal performs relatively average in addressing the healthcare needs of its citizens. The proportion of people who reported unmet needs for medical care in 2015 due to costs, waiting lists or distance was equal to the EU average of 3% (37). However, there are large disparities in Portugal when it comes to unmet healthcare needs among the different income groups. The highest income group in Portugal reported an unmet healthcare need of 0.6% in 2015, among the lowest in the EU. In contrast, 6% of the people in the lowest income group reported unmet medical needs, which ranks above the EU-average for people in the lowest income groups. This perhaps also is the explanation for the relatively low score of Portugal with respect to self-reported health, with Portugal in the bottom 3 of the EU (37). Approximately 60% of people with high income in Portugal reported being in good health in 2015, compared to 37% in the lowest income group. In order to create more equitable access to healthcare among income groups, the Portuguese government expanded the groups eligible for exemptions of co-payments in 2016, as described in section 3.6.2.

The most important barrier to accessing healthcare in Portugal are waiting times (37). Long waiting times can (partly) be attributed to the uneven distribution of healthcare resources across the country, with the coastal areas of Lisbon and Oporto having the majority of healthcare facilities and healthcare workforce. People living in the interior parts of the country are more at risk of poverty and face more distance barriers to timely access to health services (37). Another reason for the issues with respect to waiting times in Portugal is workforce shortages. Portugal decreased the salaries of most healthcare workers in the public sector as a response to the financial crisis. Although most of the salary reductions are currently being reversed, healthcare personnel in SNS is paid less than in the private sector. This is particularly an issue for physicians and nurses, who are incentivized by higher salaries to move out of the SNS to work in the private sector, or abroad (37).

In addition to the efforts to increase equitable access and to reduce waiting times, a major focus point likely remains containment of SNS expenditures. The SNS is projected to continue to struggle with budget constraints and high debt levels, while demand for

healthcare will keep rising (36). At the end of 2017, hospitals had approximately 1 billion euros in overdue payments, which is twice as high as in 2016. A key focus point for policies to contain costs within the SNS is to enhance the position of primary care as the gatekeeper of the SNS. Currently, primary care is generally still perceived as a low value and inaccessible provider, which increases demand for (more expensive) secondary care.

Next to strengthening primary care, curbing the rising costs of the public hospital sector is an important aim in order to keep the SNS within the budget constraints. The SNS has formulated the following aims in order to decrease public hospital expenditures (38):

- Establish hospital management with autonomy, accountability and application of performance-related incentives;
- Optimize contracting and financing procedures, in order to attain an efficient adaptation of the resources to the needs;
- Deepen the articulation and integration of the healthcare services (primary care, inter-hospital, etc.);
- Minimize seasonal overcrowding and the role of hospital emergency as a priority access door;
- Strengthen outpatient care;
- Optimize human resource planning;
- Improve the Electronic Health Record and Information Systems for decision support and hospital governance;
- Contain costs of medicines and medical devices by virtuous innovation;
- Optimize volumes of complementary diagnostic and therapeutic services for rational use.

3.7 Spain

3.7.1 Spanish healthcare system

The Spanish healthcare system (*Sistema Nacional de Salud, SNS*) provides universal coverage to all citizens of Spain. Civil servants are allowed to opt out of the SNS in order to fully switch to private insurance. In 2014, 99.1% of the population was covered by the SNS, 0.8% of the population chose to fully opt for private insurance and 0,1% was not covered by the SNS or private insurance (39).

Spain has a relative young parliamentary democracy, which was instituted after the death of General Franco in 1975. Political devolution has ever since been incrementally implemented, leading to 17 highly autonomous regions (*Comunidades Autónomas, CAs*), with each an individual government and parliament (40). This political devolution has also impacted the Spanish healthcare system, as the primary jurisdiction over the management of health services has been transferred from the central government to the 17 regional health ministries (39).

Due to this devolution of the healthcare system, the Ministry of Health, Social Services and Equality (MHSSE) of the Spanish government is vested with a relatively limited set of powers (40). In essence, MHSSE is the central coordinator of the 17 largely autonomous regional health systems within the SNS. The main responsibilities of MHSSE are:

- Monitoring of the health system performance;
- Wielding authority over pharmaceutical legislation;
- Setting the minimum standards for quality;
- Setting the minimum expenditure level of the CAs on health;

The highest body of coordination within the SNS is the Inter-territorial Council of the SNS (CISNS), which consist of the national and regional ministers of Health (39). The main purpose of the CISNS is to coordinate the SNS, to discuss the impact of new state laws on the CAs and to plan national responses to epidemics. As the CISNS mainly covers matters that have been transferred to the autonomous regions, the CISNS does not play a role of regulator, and decisions by the CISNS have the status of recommendations instead of obligations (40).

The regional governments of the 17 CAs are responsible for the purchaser, provider and insurer function within the regional healthcare systems. A typical structure of a health system within a CA is a regional ministry holding responsibility for healthcare policy, regulation and organization, and a regional health service which functions as a provider (40). However, there are also CAs which have split the purchaser and provider functions and in that case the regional health service functions as the purchaser. A frequent model employed by the regional Ministries of Health is to split the organisation of primary care and specialist care (including hospital care) into two different functions.

The regional Ministry of Health is the principal insurer of the population with the CA. The minimum benefits package is nationally set by the CISNS to ensure health equity across Spain. The current minimum benefit package includes three types of services (39):

- 1 Basic services such as emergency transport, prevention, diagnostic tests and treatment and rehabilitation services. These basic services are fully covered within the SNS.
- 2 Supplementary services, such as medicines, orthopaedic services and non-urgent transport. These supplementary services are partly covered by the SNS and thus subject to cost-sharing.
- 3 Ancillary services. This part of the package remains to be defined.

The minimum benefit package is rather comprehensive, however certain services such as dental care are only marginally included. The regional Ministry of Health of a CA may add additional benefits in the regional benefits package at its own discretion. Such additional benefits have to be funded by the region itself (40). Examples of additional benefits included by certain CAs are fertility treatments and sex reassignment surgeries.

Even though the health system is significantly decentralized in Spain, there are several national institutions that play an important role in the national health system. Key entities with respect to medicines and/or hospitals are listed below:

- The Spanish Agency of Drugs and Medical Products (*Agencia Española de Medicamentos y Productos Sanitarios*; AEMPS) is responsible for the quality, safety and clinical efficacy of medicines. The agency is in charge of the evaluation of the clinical effectiveness of new medicines and of the provision of marketing authorisations for medicines (40).
- The General Directorate of Pharmacy and Health Products (*Dirección General Cartera Básica de Servicios y Farmacia*, DGCF) is part of the national Ministry of Health and determines which medicines are co-financed by the SNS. In addition, the DGCF plays an important role in the setting the price of medicines (40).

3.7.2 Financing of the Spanish healthcare system

Spain spent approximately 9.0% of its GDP on healthcare in 2016, which is below the EU average of 9.9% (39; 2). It is estimated that this proportion remained similar in 2017 and will remain stable in the next few years (41). Prior to 2016, healthcare expenditures as a proportion of GDP rose significantly in 2009 and 2010 due to the economic recession. Subsequently, healthcare expenditures as a proportion of GDP declined again, due to cost-containment policies which were partly stipulated by the conditions provided in the Stability Program of the Kingdom of Spain (41). There are substantial variations in the health spending per citizen across the different regions in Spain, with differences up to 30% (39).

Approximately 71% of healthcare expenditures in Spain are publicly funded, which is well below the EU average of 79% and down from a peak prior to the economic crisis of 76% (39; 41). The SNS is mainly funded from taxation and is mostly free at the point of use, except for medicines and some supplementary services. Regional governments have the option to raise additional taxes to cover health expenditures.

Private expenditures on healthcare in Spain are chiefly represented by co-payments of patients, with 82% of all private healthcare expenditures being co-payments in 2014 (41). This translates into a 24% share of out-of-pocket spending as a percentage of the total

health expenditures in Spain, which is significantly higher than the 15% average in the European Union. This increase in the share of out-of-pocket spending can be partly related to the cost-containment policies in reaction to the economic crisis. One of the major cost-containment measures that impacted the share of co-payments was the establishment of new co-payment thresholds for medicines and common supplementary and ancillary services in 2012 (39). Co-payments for medicines are the major category of co-payments in Spain and were increased from 40% to 50% for people with annual income between €18,000 and €100,000 and increased to 60% for people with an annual income in excess of €100,000, with some limits¹⁷. In addition, people over 65 are not exempted anymore from co-payments and now face co-payment levels of 10% for annual incomes below €100,000 and 60% for annual incomes above €100,000. People who are long-term unemployed and non-contributory pensioners remain exempt from co-payments. Also, medicines which are dispensed for inpatients in hospitals remain exempt from co-payments (39). In addition to higher co-payments, increased waiting times in the health system due to the economic crisis led to an increase in the share of out-of-pocket spending in Spain, as more people turned to the private healthcare sector to circumvent the waiting lists.

Voluntary private insurance accounts for approximately 5% of overall health expenditures in Spain (39). Around 20% of the population holds private health insurance (42). Private health insurance mainly functions as a supplement to the SNS, providing more choice of providers, improved amenities such as private hospital rooms and faster access to certain healthcare services. For civil servants who choose to fully opt-out of the public health insurance system, private health insurance functions as a substitute of the public health insurance system. Demand for voluntary private health insurance is expected to grow gradually in the coming years due to better economic circumstances and continuing budgetary pressure on the public system (41).

The private health insurance market has been consolidating in the past few years. There are three market leaders, of which two companies (*Adeslas* and *Asisa*) have a high market share among civil servants who opt out of the public health system. The third market leader is *Sanitas*, which focusses more on individuals and companies as customers.

3.7.3 Hospital funding in Spain

Spain has 765 hospitals, of which approximately 50% are publicly owned (2015 data) (41). Most publicly owned hospitals are directly run by the SNS. Approximately two-thirds of all hospital beds are located in public hospitals. A move to outsource some public hospitals in 2014 was greeted with heavy protest and subsequently, the plans were put on hold (41).

Spain is characterized by a relatively low number of hospital beds per capita, with 3 beds per thousand citizens compared to the European Union average of 5 hospital beds per thousand citizens (41). The number of hospital beds per thousand citizens has come down from a high of 4 in the early 90's and has been stable for the past few years.

¹⁷ For lowest incomes, - the ones that are exempted from submitting the income tax return (less than 18,000 euros per year), co-payments are limited to eight euros per month. The rest up to 100,000 euros per year, has a limit of 18 euros per month and the wealthiest with higher incomes have a maximum level of co-payments of 60 euros per month.

The hospital financing system in Spain is depicted in Figure 8. For most CA's, the regional Ministry of Health negotiates global annual budgets with the regional health service, which is the main provider of health services. In turn, the regional health service negotiates global annual contracts with its integrated hospitals (40). The regional health services also contract private providers, usually with the aim to reduce waiting lists for surgical and medical imaging procedures. In some CAs, most notably Catalonia, private (not-for-profit) hospitals are more fundamentally part of the public network of providers, and in this case the regional health service functions more like a payer instead of a provider of healthcare (40).

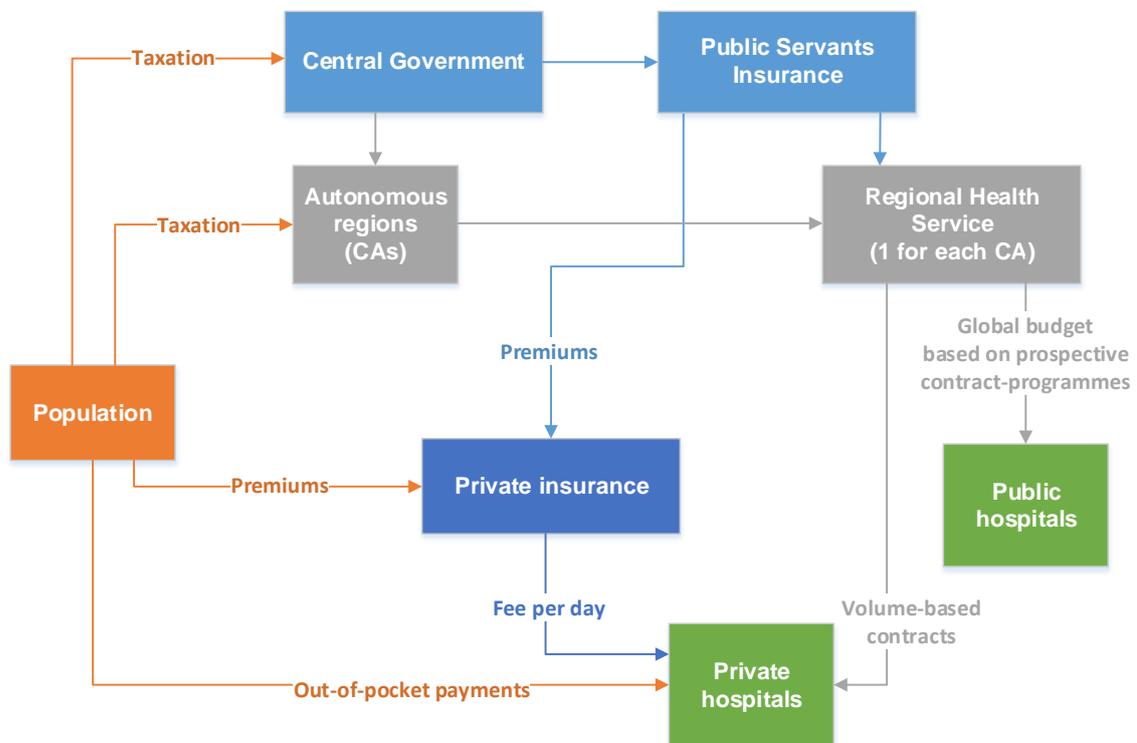


Figure 8: Hospital Financing System in Spain. Adapted from (40).

Funding of public hospitals generally is based on prospective contract-programmes between the hospital and the regional health service (40). Such contract-programmes attach financing to objectives set out in the programme. Typical examples of objectives in these contract-programmes are reducing waiting lists and creating a shift from inpatient to outpatient care. The degree of sophistication of the contract-programmes differs significantly across CAs (40). Since the 90's, Spain has been developing a DRG-like system. The use of DRGs for analytic and evaluation purposes is quite advanced, however, DRGs are not used in a standardized way in the contract-programmes. Funding of private hospitals typically is based on prospective volume-contracts, with usually some ex-post correction clauses (40).

Medical specialists working in public hospitals are salaried employees. The base salary is set by the national government and CAs have the autonomy to change some

components of the salary structure (40). It is prohibited for medical specialists working in public hospitals to generate additional income by increasing the bills to patients. Salaries of medical specialists working in private hospitals are determined by the market (40).

In summary, the main source of income from public hospitals is a global budget. Generally speaking, this incentivizes reducing costs in order to create a positive bottom-line result to contain the expenditure raise. Such an incentive may lead to the risk of underproduction, and consequently waiting lists. Regional health services try to mitigate this risk by attaching funding to certain predetermined objectives, such a reduction of waiting times.

For private hospitals, the main source of income are volume-based contracts, which generally incentivize productivity but also lead to a risk of overproduction as private hospitals have the incentive to maximize volume. This could subsequently result in larger healthcare expenditures per capita. To try to mitigate this risk, regional health services apply ex-post correction clauses in their contracts with private hospitals.

3.7.4 Recent reforms and current focus points

Spain performs relatively well in addressing the healthcare needs of its citizens. The proportion of people who report unmet needs for medical care is among the lowest of the European Union (39). People who do report unmet healthcare needs generally cite long waiting times as the main reason. For services that have low coverage in the SNS, such as dental care, higher rates of unmet medical need are present in Spain. In addition, the increased co-payments for medicines appear to lead to unmet medical need, with ca. 4% of the population in Spain reporting to have stopped taking prescribed medicines as they are deemed too expensive (39).

Waiting times, especially for elective procedures, have been a long-lasting issue for the SNS. Efforts were made prior to the economic crisis to reduce waiting times, however, due to budget reductions during the economic crisis, waiting times for elective surgeries rose again (39). In addition, waiting times show large regional variation, with people from regions like Catalonia and Castilla-La Mancha waiting on average more than 160 days for elective surgery, whereas people based in the region of Madrid and in the Basque country typically have elective surgery within 60 days (39). Policies to decrease waiting times are focussed on increasing the capacity for surgical procedures, for instance by extension of the fee-for-service working time for surgeons and by increasing the available funding for medical equipment. However, the effect of these policies seems to be outmatched by the growing demand for elective procedures. The Health Barometer of the MHSSE shows a significant increase in the proportion of people who think that waiting times are increasing: from 12% in 2010 to 28% in 2016 (43). In addition, the barometer shows that more people have the perception that healthcare is not equally offered across all Spanish regions: from 56% in 2010 to 62% in 2016. Hence, reducing waiting times will probably remain an important focus point for the SNS in the coming years.

In addition to reducing waiting lists, recent reforms have focused on curbing the costs of the hospital sector, which was accountable for more a quarter of all healthcare expenditures in 2014 (39). Next to a reduction of hospital beds, a reduction of the average length of hospital stay was realised, from 9 days in 2000 to 7 days 2014 (39).

This reduction was enabled by shifting inpatient care to outpatient care and by introducing early discharge programmes. Another initiative to curb hospital costs was to map unwarranted variations in hospital care volumes. For instance, rates of knee replacements were found to vary more than five-fold across different Spanish regions (39). These insights were subsequently used to reduce such unwarranted variations. A good example of the potential of this initiative is the reduction of unwarranted variation of caesarean sections in public hospitals. This reduction was enabled through the implementation of clinical guidelines that were developed by a group of stakeholders. However, due to the decentralization of the Spanish healthcare system, it remains a challenge to extend such approaches to all regions and hospitals (39). The focus to curb costs of the hospital sector does also have some adverse effects, with for instance a high strain on the emergency care capacity in Spain (41).

3.8 The United Kingdom

3.8.1 Healthcare system in the UK

The National Health Service (NHS) was the first universal healthcare system developed after World War Two and was founded in 1948 (12). The founding principle of the NHS is free universal care for everyone at the point of use, irrespective of one's age, health, race, religion or the ability to pay. The NHS is seen in the United Kingdom (UK) as a great achievement that symbolizes fairness and equity.

The Department of Health and Social Care is responsible for the overall health system in the UK. Each of the UK's countries (England, Northern Ireland, Scotland, Wales) has its own health system and sets their own health policies, although the core principle of the NHS applies to all four countries (44). The UK government collects and pools funds at the UK level. Subsequently, the Department of Health allocates funding in England and gives block grants to the other countries in the UK in order to allow their administrations to allocate the funds independently (45).

The day-to-day responsibility for running the NHS in England, which contains over 80% of the United Kingdom's population, is in the hands of NHS England, a separate public body. NHS England together with NHS Wales are responsible for (13):

- Ensuring that the objectives of the NHS are met;
- Managing the NHS budget;
- Setting Healthcare Resource Group (HRG) rates (HRGs are the UK version of DRGs);
- Overseeing the local Clinical Commissioning Groups (CCGs). CCGs are steered by primary care professionals (local GPs are part of the board) and procure hospital care and mental and community health services (44). CCGs control two-thirds of the total NHS England budget.
- Commissioning of primary care, tertiary care ('specialised commissioning') and national immunization and screening programs (13).

Next to NHS England, there are several national institutions that play an important role in the national health system in the UK. Key entities with respect to medicines and/or hospitals are listed below:

- The Medicines and Healthcare products Regulatory Agency (MHRA) is the responsible body for the regulation of medicines and medical devices in the UK (45). It authorizes clinical trials, monitors the safety and the quality of medicines and has the mandate to remove underperforming medicines from the market.
- The National Institute for Health and Clinical Excellence (NICE) assesses new health technologies for their cost-effectiveness and sets guidelines for clinically effective treatments. NICE is a non-departmental public body working within the English NHS, however, its services are also employed in various ways in Northern Ireland, Scotland and Wales (45). Scotland and Wales have their own HTA authorities and decision autonomy (NICE data may be used in these assessments).

The Care and Quality Commission (CQC) sets standards of safety and quality through provider registration and monitors these standards (13). Results of inspections by the CQC are publicly accessible.

3.8.2 Financing of the healthcare system in the UK

The NHS develops a long-term planning document¹⁸ which is used to negotiate and agree the funding settlement from UK government. This typically has a 5-year horizon.

The United Kingdom spent approximately 9.9% of its GDP on healthcare in 2015, which is close to the EU average (44). Healthcare expenditures as a proportion of GDP have been decreasing since the peak of 9.8% in 2009, when the economy contracted due to the economic crisis. It is estimated that healthcare expenditures as a proportion of GDP will rise moderately to 9.6% by 2022, driven by an ageing population, advances in medical technologies and Brexit (46).

Health services are mainly funded through general taxation (80%), with the remainder coming from national insurance and payroll tax (ca. 18%) and a small number of out-of-pocket payments (45; 13). Most services are provided free of charge to patients, however, some services such as dental care and pharmaceuticals involve prescription taxes. In England, patients have to pay a fixed charge for prescription medicines (£8,80), however, medicines prescribed in NHS hospitals are free, except for outpatients (46). There are several exemptions to the prescription charge in England, such as for children, people older than 60, people with cancer and people with low income. This means that about 90% of all prescriptions in England are dispensed free of charge (13). People who are not exempt and who do require large amounts of prescription medicines can buy prepayment certificates that ensure no further charges for the duration of the certificate.

Approximately 10% of the population in the UK has private voluntary health insurance, which speeds up access to care, especially for elective hospital procedures (13). The private health insurance market is relatively small, only accounting for ca. 3% of total health spending (46). This is due to the fact that many private insurance policies do not cover services such as mental health, maternity services and emergency care. According to the Competition and Markets Authority, four private insurance companies account for almost 90% of the private insurance market (13).

3.8.3 Hospital funding in the UK

Publicly owned hospitals in England are organized either as NHS trusts, which are directly accountable to the Department of Health, or as foundations trusts, which are regulated by NHS England (13). Many of these trusts operate multiple hospitals. Patients have the right to choose where to receive treatment, however, this choice is often not proactively offered to the patients by their GP's (47). In addition to the right to choose where to receive treatment, the government also has introduced a right to choose for a particular specialist within a hospital. However, this has not yet been fully implemented (13).

¹⁸ Please find more information [here](#).

The hospital financing system in the United Kingdom is depicted in Figure 9. In England, both NHS trusts and foundation trust hospitals contract with local CCGs to provide services and are primarily funded through a mix of HRGs and block payments where the maximum budget is fixed. Other sources of revenues for hospitals are mental health, education and research funds (13). In the other three countries of the UK, other purchasing mechanisms are employed (45).

Nearly all medical specialists in NHS hospitals are salaried employees. Specialists have the option to engage in private practice within designated wards in NHS hospitals or in private hospitals. In the most recent estimate (2006), 55% of medical specialists performed private work (48).

Approximately 550 private hospitals and 550 private clinics in the UK offer a range of services, including treatments either unavailable in the NHS system or treatments that are subject to long waiting times in the NHS system, such as bariatric surgery and fertility treatments (13). Private hospitals and clinics generally do not have emergency or intensive care functions. These private hospitals and clinics must be registered with the CQC and with NHS England. The fees that the private hospitals and clinics charge to private clients are not regulated and there are no public subsidies for these private providers. NHS use of private hospitals and clinics remains low (approximately 4% of overall spending by CCGs on hospital services) (49).

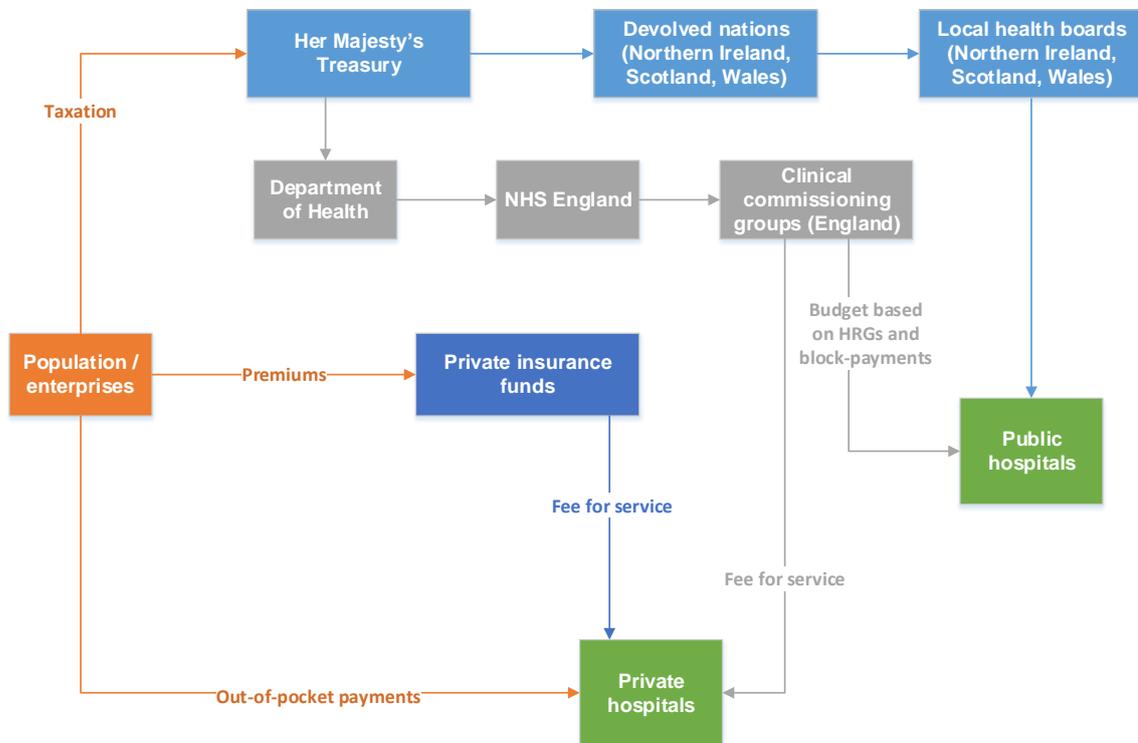


Figure 9 Hospital Financing System in the United Kingdom. Adapted from (45).

In summary, the main financial sources for public hospitals are HRG's and block-payments, with a maximum budget ceiling often in place. A maximum budget ceiling incentivizes hospitals to reduce costs in order to stay below the ceiling level. This may lead to underproduction, and consequently, waiting lists. The majority of public hospitals are currently running budget deficits of about 1 billion pound¹⁹. Private hospitals have different financial incentives, as private hospitals receive fee-for-service. Fee-for-service stimulates productivity, which could lead to overproduction and hence larger healthcare expenditures per capita.

3.8.4 Recent reforms and current focus points

The UK performs relatively well in addressing the healthcare needs of its citizens. The proportion of people who reported unmet needs for medical care due to cost, distance and waiting lists was 2.8% in 2015, which was significantly lower than the EU average of 3.2% (44). Compared to many other EU countries, there is little variation in reported unmet medical needs between people with low annual incomes and people with high annual incomes.

The NHS faces serious budget pressure going forward. In 2015 and 2016, NHS hospitals and other providers recorded a deficit of approximately £4 billion. Forecasts for 2020 and 2021 project that the deficit will increase to ca. £6 billion, even if hospitals are able to realize efficiencies of 2% per year (50). The financial pressure on the NHS is leading to an increase in waiting times (13). For instance, the target to see 95% of the patients reporting to accident and emergency departments within four hours has not been reached (46). In addition, the waiting time targets for elective surgical procedures were abandoned in 2017. Several strategies are being employed to contain costs, such as reducing HRG rates, reducing administration costs and focus on generic and biosimilar medicine prescription and dispensing. To stimulate these costs-savings strategies, NHS England helps hospitals to generate savings through the more efficient use of medical staff, optimized management of real estate and more cost-effective procurement of medicines and medical equipment (13).

In addition, the NHS makes special financial and operational plans for each winter season when there are peak demands on the system²⁰.

Next to budget pressure, the NHS faces issues due to lack of integration of health services, such as separation of primary and secondary care, and the separation of health and social care (12). The policy paper *Next Steps on the Five Year Forward View NHS England*, which was published in 2017, seeks to break down the barriers between GP's and hospitals and between health and social care. It de-emphasises the role of markets and competition and put emphasis on new models that foster regional collaboration, such as primary and acute care systems, similar to accountable care organisations in the US, and new multispecialty community providers (integrated GPs, secondary and social services delivering out-of-hospital care) (44; 12). The main delivery structure for this is called Sustainability and Transformation Partnership (STPs), and also Integrated Care Systems (ICSs).

¹⁹ Please find more information [here](#).

²⁰ Please find more information [here](#) and [here](#).

4 Hospital system performance

The previous chapter described the hospital financing systems of the eight countries included in this study. Next to yielding an understanding of the hospital financing system and the incentives for hospitals within these financing systems, this study aims to compare the performance of the hospital systems in the eight studied countries. This comparison of hospital systems links back to the findings of the previous chapter as hospital financing systems and incentives in part drive hospital performance. Also it provides the context for the chapters 5 (enablers and barriers for generic and biosimilar medicines) and 6 (showcases underlying the potential and urgency to increase utilization of generic and biosimilar medicines in the hospital setting), where we do a deep dive into the pharmaceutical aspects of the various hospital systems.

This chapter provides a comparative analysis of the hospital system performance in the eight studied countries. First, this chapter describes the conceptual framework used to gauge hospital performance. Subsequently, the results of the comparative analysis of the hospital system performance in the eight countries are presented.

4.1 Conceptual framework

The conceptual framework that was used in this study to gauge hospital system performance is depicted in the figure below:

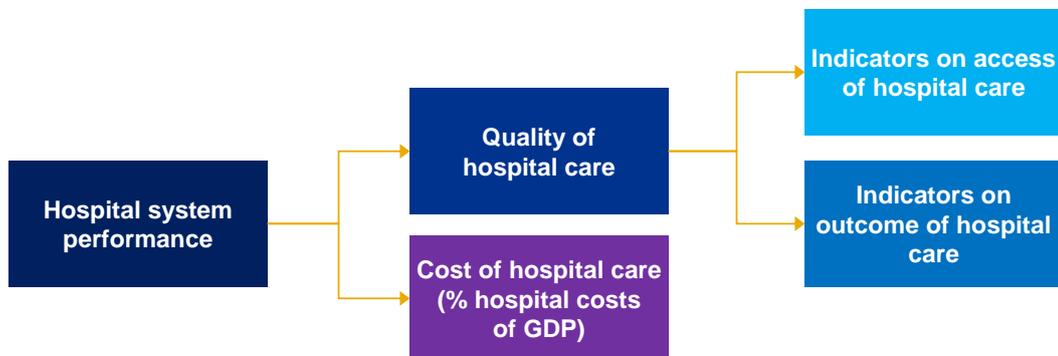


Figure 10: Conceptual framework hospital system performance per country

The hospital system performance per country is assessed by comparing the quality of hospital care and the cost of hospital care in the eight countries studied in this report. The quality of hospital care is defined as a sum score of available indicators that allow for an international comparison of the eight countries in the scope of this study. These indicators concern outcome and accessibility of hospital care. The indicators originate from the European Health Consumer Index (EHCI) and Organization for Economic Co-operation and Development (OECD) databases (51; 2). Costs are defined as the hospital costs as a share of GDP and the data concerning hospital costs were extracted from the OECD database (3). Both the quality of hospital care and the cost of hospital care are discussed in more detail below.

Quality of hospital care

The score on quality of hospital care is based on a selection of available indicators regarding the quality of hospital care in the eight studied countries. The score on quality of care is defined as a sum of relevant indicators of the EHCI and OECD metrics on quality of hospital care. These indicators are based on available EHCI and OECD data and were included in this study if they meet both of the following two inclusion criteria:

- 1 Does the indicator refer to hospital care?
- 2 Does the indicator refer to quality of care? Please note that both outcome of care as well as accessibility to care are viewed as measures of quality.

Using these two selection criteria, 8 of the 46 indicators of the EHCI and 13 of the 76 indicators of the OECD metrics were selected for the analysis of quality of hospital care (other indicators refer to health system performance or measure inputs instead of outcomes of hospital care). In Appendix A an overview of all indicators and the outcome of the selection procedure is given. Some of the selected indicators are likely correlated to each other (for instance waiting times for acute care likely affects life expectancy). However, we feel that the selected indicators (as shown on the next page) are not overly correlated, and therefore we have opted to use all of the indicators in our analysis which match the two inclusion criteria. Please note that indicators of the International Profiles of Healthcare Systems of the Commonwealth Fund are not used in this research, as not all eight countries in the scope of this study are included in the research of the Commonwealth Fund.

The selected indicators of the EHCI and OECD were scored individually and summed up to a total score. In the EHCI, indicators receive 0, 1 or 2 points, depending on the three-point scale outcome of the indicators. In order to match with the EHCI methodology using a three-point scale, the indicators of the OECD also received 0, 1 or 2 points per country. To fit the OECD indicators to a three-point scale, the average score of the (available) outcomes per selected indicator is first calculated. Second, it is determined whether a higher or lower indicator score corresponds to a better quality of hospital care. For example, for waiting times a lower score is marked positive, for survival rates a higher score is marked as positive. For indicators where a high score is positive, countries receive 2 points if the country score is above the average score plus 10%. 1 point is given when the score is between the average score of $\pm 10\%$. 1 point is also given if a score is not available. If the score is below the average score of minus 10%, the country receives 0 points. For indicators where a low score is positive, the scoring system is reversed. As stated above our way of rating and weighing (where every indicator has the same importance in the overall score) has self-evident implications in our scoring of performance. Whilst one may not always agree that each indicator should weigh the same, nor that one may always agree that a 3 point score scaling does justice to the given absolute differences per indicator.

The methodology as described above results in a maximum quality score of 42 and a minimum quality score of 0 points per country.

Cost of hospital care

The score on the cost of hospital care per country is defined as the hospital costs as a share of GDP. By expressing hospital costs as a share of GDP, the relative burden of the hospital costs on the national budget can be compared between countries.

Disclaimer

It is important to note that we gauged hospital performance by using validated (and available) indicators from the EHCI and OECD regarding hospital care. However, it is well known that hospital care as such has a limited influence on outcomes achieved in a healthcare system and that genetics, lifestyle, public health, primary healthcare, etcetera all influence the achieved outcomes as well. Also, it is well known that hospital quality is only partially measured by the available indicators. In addition, we have made a selection of the available information and excluded studies that do not have information on all eight countries in scope. Therefore, the results of this comparative analysis should be viewed as an indication of early insights that warrants further research before making conclusions of relative hospital performance, rather than an exact measure of performance of these eight hospital systems.

4.2 Quality of hospital care

In this section, the scores on quality of hospital care among the eight studied countries are presented. The scores on quality of hospital care are presented in Figure 11. Two categories of hospital care scores can be observed in the figure: scores from indicators which concern the accessibility of the hospital system, and scores from indicators which concern the outcome of hospital care.²¹ The total score on quality of hospital care is the sum of the outcome score and the accessibility score.

Belgium has the highest total score on quality of care with 27 out of 42 points on the available indicators. Compared to the other countries, Belgium scores particularly well mostly on non-medicines related indicators, such as: surgical complications, waiting time for CT scans, caesarean sections per 1.000 live births and screening, survival and mortality for colorectal cancer. France has the second highest total score (25) and Portugal the third highest total score (24). The average total quality score of hospital care in the eight countries studied is 21. The country with the lowest total score on quality of hospital care is Poland, with a score of 13 out of 42.

²¹ See appendix A for more information regarding the selected indicators.

Indicators related to outcome of hospital care: life expectancy at birth; patient experience with ambulatory care; avoidable hospital admissions; mortality following ischaemic stroke; mortality following acute myocardial infarction; surgical complications; obstetric trauma; screening, survival and mortality for breast cancer; survival and mortality for colorectal cancer; survival and mortality for leukaemia in children; life expectancy and healthy life expectancy at age 65; infant deaths per 1.000 live births; cancer survival; MRSA infections; caesarean sections per 1.000 live births (good prenatal care leads to lower amount of required caesarean sections).

Indicators related to access to hospital care: waiting times for elective surgery, waiting times for hip fracture surgery, waiting time for cancer therapy, waiting time for CT scan, waiting time for major elective surgery, waiting time for acute and emergency care.

Taking a more specific look at the ratio between outcome and access scores, it can be observed that the United Kingdom and Poland score relatively low on access in comparison to the outcome. For Germany, this is the other way around, with a relatively high score on access and a relatively low score on outcome (such as for instance avoidable hospital admissions and surgical complications).

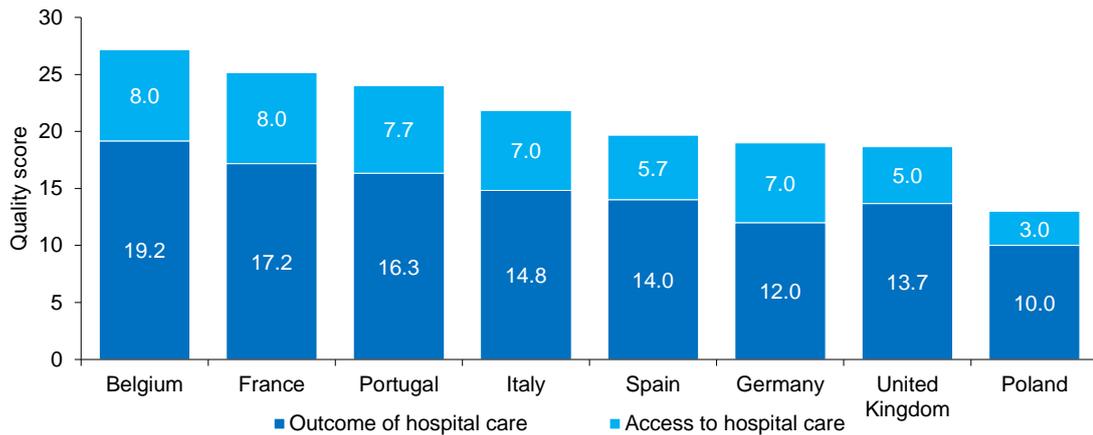


Figure 11: Total score of quality of hospital care

4.3 Cost of hospital care

In this section, the costs of hospital care are presented. The cost of hospital care is expressed as the total hospital costs as a share of GDP and is shown in Figure 12.

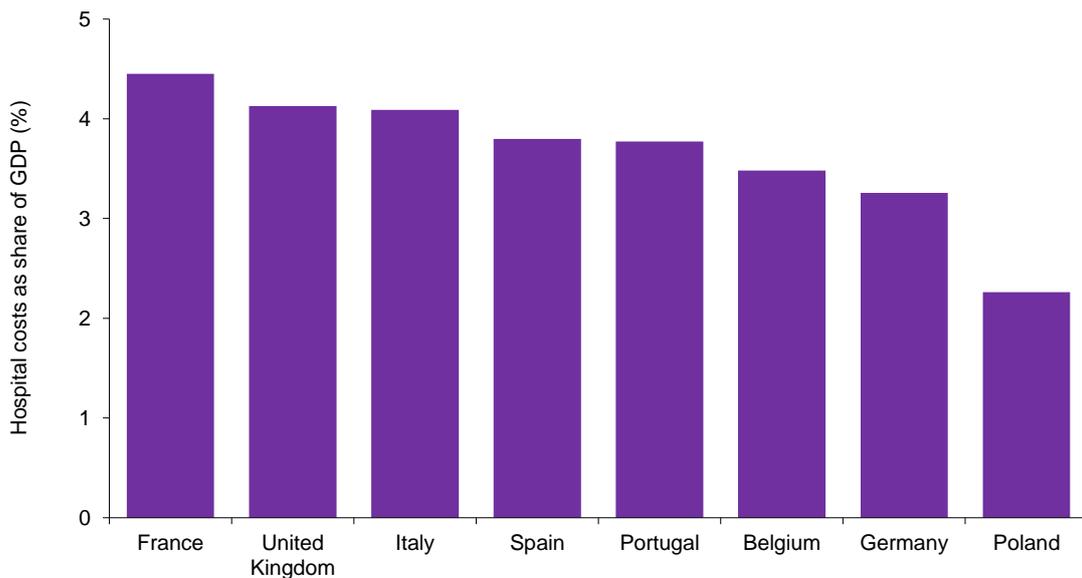


Figure 12: Hospital costs as a share of GDP (source: OECD database 2015).

The average costs of hospital care as a share of GDP in the eight countries studied is 3.7%. France has the highest percentage of hospital costs as a share of GDP with 4.5% and the United Kingdom (4.1%) and Italy (4.1%) are second and third, respectively. On the other side of the spectrum, Poland has the lowest percentage of hospital costs as a share of GDP with 2.3%, which is a clear drop-off from the second-lowest country (Germany), which has 3.3% hospital costs as a share of GDP.

Regarding the expenditure of medicines in the context of cost of hospital care, Figure 13 showcases the relative hospital expenditure as a % of GDP in the 8 European countries studied. Generic and biosimilar medicines have a relatively low weight on hospital expenditures on medicines. Compared to the overall costs of hospital care (see Figure 12), medicines account for relatively a small portion (5-20%).

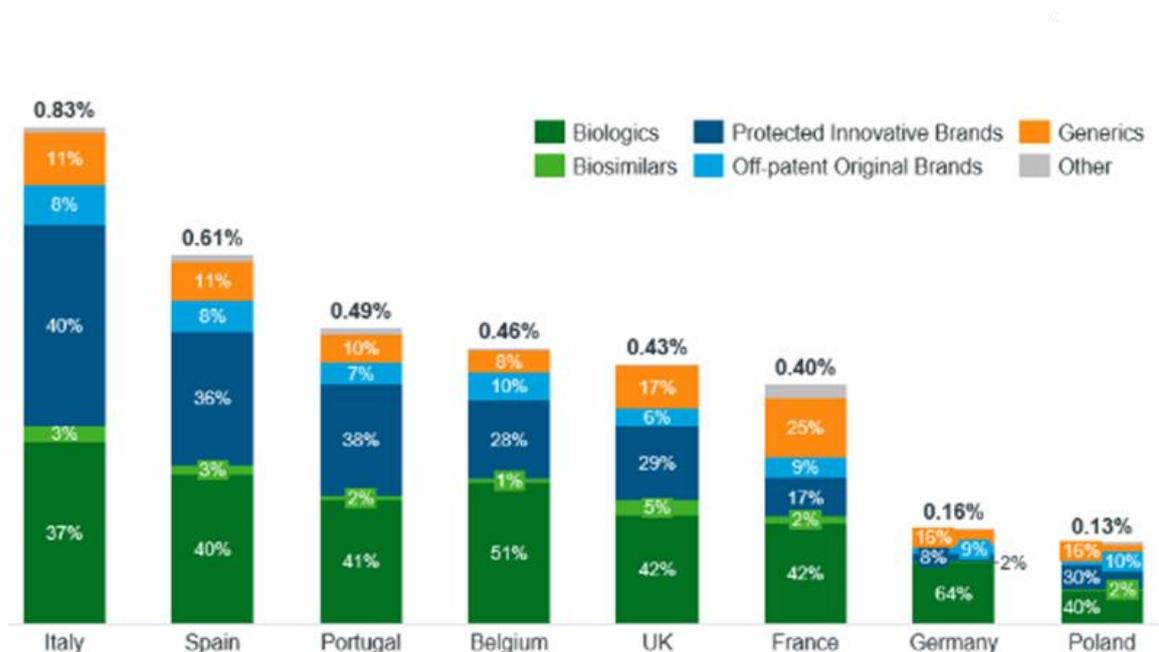


Figure 13: Hospital Expenditure on Medicines as a percentage of GDP (List Price²² USD, 2018).
Note: Biologics, Generics include Unbranded and Branded Generics
Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q4 2018.

Figure 14 displays the relative expenditure of medicines in the hospital versus retail setting in the 8 European countries studied. One can observe different dynamics, with Germany more retail-based due to its office-based physicians and Italy more hospital-based.

²² Please note that these analyses are based on list prices instead of net prices. Therefore the findings may not fully reflect actual expenditures on medicines and are therefore likely overestimations.

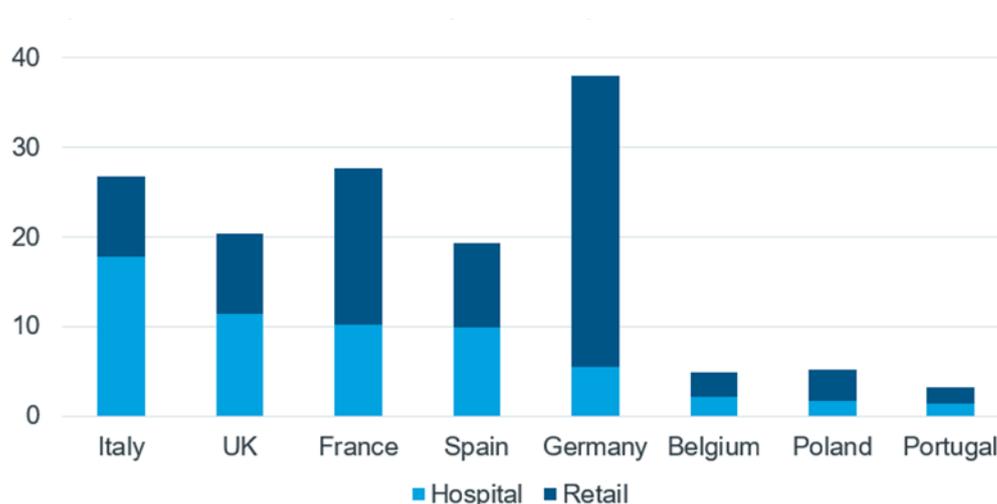


Figure 14: Hospital and Retail Medicines Expenditure (Billions of Euros; List Price²²; 2018)
Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q4 2018.

4.4 Comparison of hospital system performance

Hospital care presents a chief opportunity to increase healthcare system value (outcome per euro spent) through optimization of efficient and effective delivery of healthcare within the hospital systems. As this chapter shows, hospital systems in the eight countries studied show different scores on quality and costs. Although some countries seem to be further than others in realizing optimal hospital system value, all countries show potential to further enhance hospital system value by either increase quality and/or reduce costs (without decreasing quality).

The following chapters will show that there is still potential to improve the use of generic, biosimilar and value added medicines in the hospital setting. This presents an ample opportunity to further increase hospital system value in all of the eight studied countries.

5 Enabler and Barriers for generic and biosimilar medicine access in the hospital setting

This chapter provides an overview of the enablers and barriers for generic and biosimilar medicine access in the hospital setting of the eight studied countries. For each country we have addressed the following components in order to give an overview and understanding of the access mechanisms of generic and biosimilar medicines in the hospital setting:

- 1 A high-level overview of the national pricing and reimbursement system for medicines;
- 2 A high-level overview of the procurement landscape of medicines in the hospital setting, with specific attention for generic and biosimilar medicines;
- 3 A description of the main enablers for generic and biosimilar medicine access in the hospital setting.
- 4 A description of the main barriers for generic and biosimilar medicine access in the hospital setting.

The findings in this chapter form the basis for the recommendations in chapter 7, as this chapter describes the current state of affairs. The eight studied countries are ordered alphabetically in this chapter, starting with Belgium and ending with the United Kingdom.

5.1 Belgium

5.1.1 Pricing and reimbursement of medicines in Belgium

Regulation of the pharmaceutical market is a responsibility of the national government in Belgium. When marketing authorisation is granted by the European Medicines Agency or the FAGG-AFMPs, the pricing and reimbursement process can be initiated. Belgium has a relatively long time to market compared to other European Union countries with 11 months (52). However, introduction of a new procedure in September 2018 will likely reduce the time to market for biosimilar medicines with approximately 3 months. Pricing and reimbursement procedures run in parallel in Belgium (4). The Minister of Economic Affairs is responsible for setting the maximum price of medicines, both in retail and hospital settings (6; 53). The Pricing Committee for Pharmaceuticals advises the Minister of Economic Affairs on this matter. The maximum prices for generic medicines are usually set at 54-60% below the originator price, depending on the reimbursement category (54). For biosimilar medicines, the maximum price is set via external price referencing and by setting a mandatory discount of 7,5% compared to the price of the originator medicine. In practice, prices are subsequently also negotiated, leading to price decreases up to more than 30% compared to the initial price of the originator (55).

The Minister of Social Affairs and Public Health determines whether a new medicine should be reimbursed in the compulsory health insurance system (52). The Commission for the Reimbursement of Pharmaceuticals (CRP) of RIZIV-INAMI advises the Minister of Social Affairs and Public Health on this matter. The CRP consists of 30 representatives of sickness funds, physicians, pharmaceutical companies, pharmacist, government and

academics. The CRP employs a two-step procedure in order to draft the advice to the Minister of Social Affairs and Public Health:

- 1 Examination of the therapeutic added value compared to existing medicines. This examination takes into account the efficacy, effectiveness, safety, convenience of use and applicability of the medicine (4). Based on this examination, the medicine is classified either as a medicine with added therapeutic benefit (class 1), a medicine with comparable therapeutic benefit (class 2), or as a generic medicine (class 3) (52). So far, all biosimilar medicines in Belgium have been categorized as class 2 medicines (56).
- 2 Issuing a proposal to the Minister of Social Affairs and Public Health, taking into account the determined therapeutic value, cost-efficiency and budget impact of the medicine. However, the Minister of Social Affairs may deviate from the recommendations of the CRP, and usually does so as a result of budgetary or societal pressures (52).

Reimbursement decisions of medicines are usually reviewed within a period of 1,5 year to 3 years after admission, but also can be initiated ad hoc by request of the government or the CRP (52). Pricing decisions are also subject to periodical and ad hoc revisions.

Like many countries, Belgium has focussed on decreasing expenditures on medicines. Examples of policies that have been implemented to curb the rising costs of medicines are:

- Price freezes and cuts in reimbursement rates (6);
- Increasing the use of health technology assessments to make coverage decisions on medicines (5);
- Stimulation of the use of “low-costs”-medicines, as discussed later in this chapter.

In 2015, the Belgian pharmaceutical industry has signed a ‘Pact for the future’ with the Minister of Social Affairs and Public Health. The agreement provides a framework that combines cost containment measures and improved access to innovative therapies (5).

5.1.2 Procurement landscape of medicines for hospitals in Belgium

Hospitals have been incentivized to decrease expenditures on medicines by policies such as determining realistic budget targets, using a prospective budget for inpatients determined by case mix and DRGs (4). This leads to a clear incentive for hospitals to procure medicines at low (net) prices. As noted in chapter 2, the hospital system in Belgium is currently being reformed. It is unclear at the moment whether the new hospital system will alter the incentives of hospitals with respect to the procurement of medicines.

Procurement of medicines for the hospital market in Belgium is usually performed by (groups of) hospitals. If the value of the procured medicines is above the European publicity threshold, hospitals are required to procure medicines via public tenders (57). Tenders are usually defined on the basis of INN and manufacturers are allowed to offer discounts in the tender procedure. Frequently, price is the award-winning criterion, however an increasing number of tenders are including other award-criteria that are not related to price. Below the European publicity threshold, hospitals may also opt for direct

negotiations, however they are obliged to explore at least three different manufacturers in this process.

Generic medicines:

Tender contracts for generic medicines in the Belgian hospital market are awarded by active substance and the duration of the tender contracts may vary from tender to tender (54). There are no commitments from the issuing party with respect to the minimum or maximum volume that is associated with the tenders for generic medicines. Prices are subject to change during the tender contract duration. As described above, the main incentive for hospitals is to procure medicines for low (net) prices and this also holds for generic medicines. Therefore, price is often the main award-winning criterion in the tenders for generic medicines for the Belgian hospital market. However, more and more tenders are including other award-criteria as well.

Biosimilar medicines:

For biosimilar medicines, the tenders are also performed by hospitals. Tenders may be issued separately for on-treatment patients and naïve patients, however, the Ministry of Social Affairs and Public Health promotes tenders that place both on-treatment patients and naïve patients in the same parcel (55). Tenders for biosimilar medicines in Belgium have an average duration of 18 months and usually have 1 winner. Tender contracts legally have to be reopened once a biosimilar medicine enters the market. However, this is not current practice. Therefore the Minister of Health recently has urged hospitals to start the tender process as quickly as possible after the patent expiry of the originator biological (55).

5.1.3 Enablers for generic and biosimilar medicines in the hospital setting in Belgium

Depending on their medical speciality, doctors have a quota for prescription of medicines that are labelled as 'low cost'. Three groups of medicines have been defined as low-cost medicines: 1) generic and biosimilar medicines, 2) originator medicines that decreased their price to the same price as generic medicines and 3) medicines that are prescribed by international non-proprietary name of the active component (INN) (4). While INN is possible, this is used in less than 10% of pharmaceuticals due to lack in promotion of this policy (4; 54). Hospitals have approximately a 70% target regarding low-cost medicines, however, this policy does not appear to be strictly enforced.

Another enabler for generic medicines in Belgium is the reference pricing system, which can be enforced two months after the introduction of a generic medicine (58). The reference pricing system sets the maximum reimbursement price of all medicines within the reference group to approximately 40% of the original originator price for all medicines labelled as class A and 46% for all medicines labelled as class B. The reference price system, therefore, stimulates the use of all low-cost medicines: generic medicines, but also originator medicines that have decreased their price to the reference price level.

The Belgian government, hospitals and pharmaceutical industry signed an agreement in 2016 with the aim to stimulate the utilization of biosimilar medicines in the hospital setting

(59). However, this agreement is non-binding. Overall, incentives for utilization of biosimilar medicines in the Belgian hospital setting seem lacking.

5.1.4 Barriers for generic and biosimilar medicines in the hospital setting in Belgium

The Belgian generic medicines market remains relatively small by European standards despite the government's determination to balance its healthcare budgets and the capacity of generic medicines to create savings for healthcare systems (6; 5). A possible reason for the low penetration of generic medicines relates to the fact that there is no real policy or long-term vision to incentivize the use of generic medicines specifically, as opposed to the encouragement of low-cost therapies (which include generic medicines, but also originator medicines that have a reduced price).

Next to a lack of policies focussing on generic medicines, the tendering system in Belgium appears to be an important barrier for generic (and also biosimilar) medicines market uptake. Generally speaking, generic and biosimilar medicines compete well on price with off-patent originators. However, more and more tenders are including increasing numbers of other award-criteria that are not related to price, but which serve as a proxy for quality instead or asking for scientific studies, trainings, etc. Examples of such proxies are the distance to the manufacturing plant, speed of delivery and single dose packaging. Often, these additional criteria are more favourable to the originator medicines. Based on our interviews, it may be hypothesized that physicians might have an incentive to add these originator-favouring award-criteria to the tender procedures, as the outcome of the tender may affect their personal grants and personal sponsorships from the manufacturers which produce the originator medicines.²³ On June 21st the Belgian Federal Agency for Medicines and Health Products (FAMHP) has issued an administrative circular (nr 646) clarifying the conditions in which healthcare institutions may request and companies may provide gifts, advantages and benefits in the context of public tenders taking place in Belgium²⁴. This trend requires the manufacturers of generic medicines to propose a significantly lower price than the originator medicine in order to still be able to win the tender. Consequently, this might lead to price erosion of generic medicines, which could lead to countermeasures by the producers of generic medicines that may not be beneficial to patients. For instance, pharmaceutical companies may opt to not keep an emergency stock available, as it is economically not feasible to do so. This could potentially lead to medicine shortages.

Furthermore, based on our interview, we gathered that pharmaceutical companies feel that the current tendering system in Belgium is inefficient as each hospital may tender individually and hospitals seem to favour to contract multiple suppliers for the same medicine category, leading to rather low volumes per tender. As tenders in Belgium are usually quite time-consuming due to a high amount of required input, the balance between volume and required effort seems to be tilted, which may reduce the appetite of producers of generic and biosimilar medicines to compete in the Belgian market. In addition, the low volumes per tender also may contribute to medicines shortages in

²³ Since 2017, the Belgian Sunshine act stipulates that pharmaceutical companies register benefits given to medical specialists and medical organisations. These benefits are published annually on the [website](#) of the Belgian Transparency Register.

²⁴ <https://www.fagg.be/sites/default/files/content/DC-CT/20190625151700.pdf>

Belgium, as in the case of stock emergencies, contracts with larger volumes in other countries are likely to be prioritized by pharmaceutical companies.

For biosimilar medicines in Belgium, an additional barrier is the preference of physicians and pharmacists to use originator biologicals instead of biosimilar medicines (56). Physicians sometimes have limited knowledge about the approval procedure for biosimilar medicines, similarity to the originator, and the cost benefits. This leads to the suboptimal confidence of physicians in the efficacy and safety of biosimilar medicines, and hence, results in a reluctance to prescribe these biosimilar medicines. The same can be said for pharmacists in Belgium (56; 55). Furthermore, physicians have no prescription quota for or other (financial) incentives to use biosimilar medicines.

5.2 France

5.2.1 Pricing and reimbursement of medicines in France

In France, the Ministry of Health and Social Affairs makes the decision whether a medicine should be included in the so-called “positive list” (11). Inclusion in the positive list yields reimbursement coverage of the medicine within the social insurance system. To decide whether a medicine should be included, the ministry uses the advice of the HAS and the Economic Committee for Health Products (*Comité Économique des Produits de Santé*; CEPS).

In order to apply for inclusion in the positive list, the medicine manufacturer should request a health technology assessment from the HAS and is obliged to provide documentation to support this health technology assessment (11). The health assessment is performed prior to market entry and directly determines the coverage rate within the social insurance system and indirectly influences the reimbursement price. The received documents are critically reviewed by two reviewers and subsequently discussed by the Transparency Commission (*Commission de la Transparence*) of the HAS (11; 52). The health technology assessment follows a two-step procedure:

- 1 Determination of the medical benefit of the medicine. This assessment involves analysis of the clinical efficacy, side-effects, the severity of the treated disease and public health relevance (quality of life and epidemiological aspects). The medical benefit of the medicine is subsequently expressed in a *Service Médical Rendu* (SMR) score. The SMR score determines the coverage rate of the medicine within the social insurance system (11). This approach applies to branded and also generic medicines.
- 2 Determination of the incremental benefit of the medicine compared to available comparators. This assessment involves analysis of the improvement in the relative medical benefit of a medicine (*Amélioration de Service Médical Rendu*; ASMR). The ASMR-score is expressed on a scale from 1 (major improvement compared to available comparators) to 5 (no improvement compared to available comparators). This ASMR-score will automatically be a 5 for generic medicines and biosimilars will score a 4 or 5. The ASMR-score influences the reimbursed price of the medicine (11).

A third step may be added to the procedure and involves an economic evaluation of the medicine (11; 15). This third step was added to the reimbursement and pricing procedure in 2014, with the aim to provide a new means of cost-containment. Economic evaluation is mandatory for all medicines with an ASMR score 1 to 3 and with significant impact on SHI expenditures (over € 20 million of annual sales forecasted in the first two years) (11). As generic and biosimilar medicines have an ASMR score of 5, economic evaluation is not applicable to generic and biosimilar medicines.

The Commission for Economic Evaluation and Public Health (*Commission d'Évaluation Économique et de Santé Publique*; CEESP) of the HAS is responsible for performing the economic evaluation (52). The CEESP assesses the cost-effectiveness of medicines in parallel to the health technology assessment by the Transparency Commission in order to prevent delays in market entry. Manufacturers have to provide data regarding the cost-effectiveness of the medicine to the CEESP, who then forms an opinion on the cost-

effectiveness of the drug relative to comparative medicines. Similar to the ASMR-score, the opinion of the CEESP influences the reimbursed price of the medicine (11). It is worthwhile to note that unlike other European countries, CEESP does not employ a predetermined threshold for cost-effectiveness.

The next step in the pricing and reimbursement process for medicines in France is determining the reimbursement price. The reimbursement price is set through a bargaining process between the manufacturers and the CEPS (11). CEPS is composed of representatives of the central government, SHIs and complementary insurance organisations. To set the reimbursement price, CEPS takes the following information into account: the ASMR-score, the advice of the CEESP, the price of other comparator medicines and the estimated financial impact. Manufacturers of medicines classified with ASMR-score 1 to 4 may opt for price setting via an external price referencing system instead of via bargaining. The external price referencing system in France references prices to four other European Union countries: Germany, Italy, Spain and the UK (52).

The set price is usually revised periodically, depending on the duration of the agreements. However, prices can also be revised ad hoc when new evidence is available, when a generic medicine enters the market or when the expenditures of the medicine threaten the national expenditure ceiling of the SHIs (ONDAM) (52; 11).

Medicines who have successfully completed the health technology assessment and for which a reimbursement price has been set can be placed on the positive list by the Ministry of Health and Social Affairs. In principle, the reimbursement decision of the medicine is revised every five years (52). If research shows new insights or the Ministry of Health requests so, a review also can be initiated ad hoc.

For novel medicines with no alternatives on the market, the reimbursement and pricing process is different. In contrast to other types of medicines, market entry can be allowed prior to marketing authorization using the *Autorisation Temporaire d'Utilisation* scheme (52). Prices are set freely by manufacturers in this scheme. However, as soon as the medicine has obtained its marketing authorization, a price will be bargained using the procedure as described above. If the bargained price is lower than the price which was set in the temporary authorisation scheme, the manufacturer has to pack back the difference (52).

There has been a significant focus on containment of the expenditures on medicines in France. This is shown in a decrease in the share of medicine expenditures as part of the total health expenditure, from 18% in 2005 to 15% in 2015 (15). Multiple policies have been implemented for cost-containment of medicines:

- Introduction of economic evaluation by the CEESP, as previously mentioned in this chapter.
- Higher co-payments for medicines with low effectiveness (low SMR-scores) (14).
- Delisting of medicines with low effectiveness from the positive list (11).
- Lower reimbursement prices for medicines upon revision of the agreed prices (11).
- The introduction of reimbursement restrictions, which can be applied to specific products or to certain patient or prescriber groups. Reimbursement restrictions are present in approximately 20% of the medicines in France (52). A recent example of

a patient group specific restriction is the budget cap for hepatitis C treatments, which was enforced after market-entry of high-cost medicines against hepatitis C.

— Stimulation of the use of generic medicines, as discussed later in this chapter.

5.2.2 Procurement landscape of medicines for hospitals in France

Public hospitals in France are required to procure medicines through public tenders (57). For-profit private hospitals and not-for-profit private hospitals are not required to do so. As previously noted, the CEPS determines the manufacturers selling prices through bargaining with the manufacturers. However, hospital-only medicines are excluded from assessment by CEPS and manufacturers are free to set prices (60). Hospitals, therefore, rely on the tendering process to obtain competitive prices. The award criteria of tenders are often a mix of price and supply-related criteria such as delivery time, security to supply, criteria related with the characteristics of the product and potential services associated to the product (57). Tenders can be commissioned by individual hospitals or hospital buying groups (61). Depending on the setting of the tender, tenders can be carried out by the hospital pharmacists or by a committee composed of physicians, hospital managers and hospital pharmacists. The French government promotes efficient buying by hospitals and issues guidelines which specify how tenders should be issued (61).

For most medicines, the hospitals receive (indirect) reimbursement via the GHS-system (11). This incentivizes the hospital to procure medicines at low prices in order to positively impact the bottom-line financial result. Some expensive medicines are not covered by the GHS-system and additional funding is available through the '*liste en sus*'. For all the medicines that fall under the '*liste en sus*', hospitals receive additional activity-based funding which usually matches with the procurement price. Therefore, hospitals are mainly incentivized to employ such expensive medicines when necessary, as there is no economic benefit or risk for the hospital to use these expensive medicines.

Generic medicines:

Generic medicines in the hospital market are usually tendered by groups of hospitals or hospitals via central purchasing bodies for the private sector (54). Tender contracts are awarded by active substance and the average contract duration is two to three years, with prices not subject to change until the next tendering round. Generally, there is no commitment from the hospitals on the minimum or maximum volume estimates in the tenders. The main criterion for tenders of generic medicines is price, however, also other factors can be taken into account such as customer service, quality, the ability to supply and characteristics associated to the product (54). The maximum price of generic medicines is regulated in France and is set at 40% of the price of the originator medicine (54). However, the actual net prices are usually considerably lower in the hospital market.

Biosimilar medicines:

Similar to generic medicines, biosimilar medicines are usually tendered by groups of hospitals or hospitals via central purchasing bodies for the private sector (55). The contract duration of the tenders varies per issuing hospital. Since the adoption of the

2017 budget law, tenders for new patients and patients already undergoing treatment with a biological medicine will be in one lot (55). The tender usually results in one winner, however, exceptions to this rule may be made. At hospital level, the following principle applies to biosimilar medicines: « prices of hospital drugs should be equivalent in order to respect fair competition ». *Concretely, the initial discount is 30% at commercialization of the first biosimilar. The discount is the same for the reference biological and the biosimilar. However, this discount only fixes a maximum price which will be the same for all biologicals. During the tendering process, the players can fix a lower price which will be determined through competition. Biosimilars and the reference product are competing on equal terms. In practice, the biosimilar often has the lowest price.*

The market access procedure for biosimilar medicines is mostly similar to the procedure for innovative medicines. There are a few differences, such as the fact the SMR is usually automatically set to the same level as the originator and the ASMR level is generally automatically set at the lowest level (level 5) (62). In addition, biosimilar medicines may be subject to a shortened version of the Transparency Commission review procedure.

In October 2018, a new pilot scheme was launched that aims to increase the levels of biosimilar drugs prescribed in participating hospitals by 15% in the next three years (63). The pilot aims to enrol 40 hospitals and targets biosimilar medicines that:

- Have recently been approved for reimbursement;
- Are (mainly) dispensed in community pharmacies;
- Have relatively low market penetration.

In practice, the pilot will likely target two groups of biosimilars: anti-TNF alpha medicines in the 'etanercept group' and insulin glargine's. The pilot incentivizes hospitals prescribe more biosimilar medicines by providing 2 possible mechanisms:

- Remuneration of 20% of the price difference between the reference medicine and corresponding biosimilar medicine for the hospitals that signed the *Contrat d'Amélioration de la Qualité et de l'Effizienz des Soins – CAQES* or
- A more direct remuneration of hospital services for certain selected hospitals: remuneration of 30% of the difference between the reimbursed price of the reference medicine and the corresponding biosimilar medicines).

5.2.3 Enablers for generic and biosimilar medicines in the hospital setting in France

An important enabler for uptake of generic medicines in the hospital setting in France are the CAQES contracts between hospitals, SHIs and ARSs that aim to enhance the quality and efficiency of hospital care. These CAQES contracts have set a target of 46% for generic prescriptions at hospital level (64).

Another enabler for generic medicines is that prescription via INN is obligatory since March 2015. However, this obligation has not been fully put into practice yet (14). To further stimulate uptake of generic medicines the National Action Plan For the Promotion of Generics was composed in 2017. This plan aims to increase the market share of generic medicines by five percentage points by the end of 2018 (14). In addition, the Ministry of Health and Social Affairs launched a campaign in 2016 to increase awareness

of, and confidence in, generic medicines among medical specialists and the public (15). Finally, the French Competition Regulating Authority (*l'Autorité de la concurrence*) is actively involved in the prevention of tactics by pharmaceutical companies that try to delay market entry of generic medicines. An example of this involvement is the € 25 million fine that Johnson & Johnson has received in December 2017 for delaying the market entry of generic alternatives to Durogesic (15).

An important enabler for biosimilar medicines in France is that the system incentivizes the procurement of medicines at low prices. For biosimilars covered by the GHS-system, such as Epo and Filgrastim, acquiring medicines at lower prices result in lower costs for the hospitals, while the revenue for the hospital (the tariff for the GHS) remains the same. For biosimilars not covered by the GHS-system, such as Infliximab, there are benefit sharing incentives for the hospital, as the hospital and the SHI split the savings that originate from the difference in the price actually paid and the reimbursement tariff. Another incentive for hospitals to employ biosimilar medicines are the recent CAQES contracts between hospitals, SHIs and ARSs, which have set a target of 70% for biosimilar prescriptions at hospital level (64).

Next to these financial enablers for biosimilar medicines, the ANSM provides another enabler for biosimilar medicine uptake in France, as it allows switching²⁵ from the originator to biosimilars medicines for patients already undergoing treatment with an originator (62). However, this is only allowed under certain conditions. Another non-financial enabler for uptake of biosimilar medicines are handbooks and leaflets targeted to patients (55). These handbooks and leaflets aim to inform patients about biosimilar medicines and are distributed (and developed) by hospitals.

5.2.4 Barriers for generic and biosimilar medicines in the hospital setting in France

One of the main barriers for generic medicines in the hospital setting in France are major penalties related to supply disruptions. Pharmaceutical companies feel that there the penalties lead to an unbalance between risk and reward and are disproportionate as:

- Time between winning tender procedures and first delivery is often short, making the lead time to the first supply deadline challenging;
- Penalties are based on list price instead of net price;

Such penalties can create distortions in the marketplace and could lead undersupply of certain segments of hospitals (e.g. private hospitals).

In addition, deadlines for tender calls are perceived by pharmaceutical companies as too tight, leading to suboptimal competition in the tender procedure as companies might not be able to timely address the tender call.

For biosimilar medicines, one of the main barriers for increased market uptake is the lack of prescription guidelines for physicians regarding biosimilar medicines (55). In addition, prescribing using solely INN is not allowed for biosimilar medicines as prescriptions must contain both brand name and INN. Another barrier for (rapid) market uptake of biosimilar

²⁵ Switching is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent. Based upon "Biosimilars in the EU", report by EMA and EC, 2017. Available [here](#).

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medicines is the fact that tender contracts do not have to be re-opened automatically once a biosimilar medicine enters the market (55).

5.3 Germany

5.3.1 Pricing and reimbursement of medicines in Germany

Regulation of the pharmaceutical market is organised on a national level in Germany, with BfArM being the responsible authority for the safety of medicines and granting marketing authorisation (17). Marketing authorisation can also be granted by the European Medicines Agency. Germany enables fast access to newly authorized medicines, with an average time to market of 2 months, which ranks among the lowest in the EU (52).

When marketing authorisation is granted, the G-BA commissions IQWiG or a third party to perform a scientific evaluation of the added therapeutic benefit of a medicine (52). Unlike many other EU countries, Germany does not have a positive list of reimbursable medicines. In other words, all medicines in Germany are in principle reimbursed, with exception of certain medicines that have failed the benefit assessment issued by the G-BA or medicines that have been excluded by law (e.g. lifestyle medicines) and certain over-the-counter medicines (17). Benefit assessments can be revised at the earliest one year after the G-BA decision and can be initiated by the appearance of new evidence, by request of the manufacturer or because of the expiration of the previous reimbursement decision (52).

As the German healthcare system reimburses in principle all medicines, Germany relies mainly on price mechanisms to regulate pharmaceutical spending (18). Therefore, an array of price regulations are present in Germany: mandatory discounts, rebate contracts, reference pricing (for medicines without a proven additional therapeutic benefit) and price negotiations (for medicines with proven additional therapeutic benefits) (65; 17; 52). However, these price regulations focus exclusively on the retail pharmacy market, which is by far the largest pharmaceutical market in Germany, with approximately 84% of market share in value (2011 data) (17). In contrast, hospital pharmacies have 8% market share in value terms. For the hospital pharmacy market, price regulations are absent and prices are a direct result of negotiations between the hospitals and medicine manufacturers.

5.3.2 Procurement landscape of medicines for hospitals in Germany

Hospital pharmacies can choose to procure medicines individually, or through groups of hospitals (66). Consolidation in hospital procurement by the formation of hospital purchasing groups is an ongoing trend. Generally speaking, hospitals do procure medicines via non-public tenders or via direct negotiations with manufacturers (57). Price is often the most important award-criterion in these non-public tenders and negotiations. Public tenders are not often used, mainly because of cost-aspects and the exposure to litigation (66).

For most medicines, hospitals receive (indirect) reimbursement via the G-DRG system (65). Medicines for inpatients are not billed separately to the sickness funds, but are included in the DRGs which are the basis for reimbursement of hospitals. This clearly incentivizes hospitals to procure medicines at low prices in order to positively impact the bottom-line financial result of a DRG. Some expensive medicines, such as biologicals,

are not (entirely) covered by the G-DRGs. For these medicines, hospitals may receive additional surcharges (*Zusatzengelt*) determined by InEK. InEK bases these additional surcharges on empirical cost data which have been supplied by reference hospitals (65). Another route to cover costs of expensive drugs for hospitals is the procedure for new methods for treatment and screening (NUB). If a new method for treatment and screening is deemed innovative by InEK and has not been already included in a DRG, InEK may grant NUB payments to cover such innovative treatment and screening procedures.

For outpatients which are served by hospital pharmacies, hospitals do receive direct reimbursement via the sickness funds as defined in the so-called 129a SGB-V contracts (67). The most frequently employed reimbursement model by sickness funds for reimbursement of medicines for outpatients in hospitals is to cover list price minus a standard discount percentage. In this case, the incentive for a hospital is to maximize the difference between reimbursed and net price. This could lead to situations where hospitals are incentivized to procure medicines with higher net prices, due to a more optimal spread between reimbursed and net prices.

Generic medicines:

Generic medicines for use in hospitals are generally procured by (groups of) hospitals via non-public tenders in Germany (54). Tender contracts are often based on active substance or therapeutic indication and have an average duration of approximately 12 months. Prices are subject to change during the contract duration (54). Depending on the tender, the issuing party does or does not make commitments with respect to the minimum or maximum volume that is associated with the tender. The main award-criterion often is price, however a proven track record of the ability to supply sometimes is also taken into account in determining the winner of the tender (54).

Biosimilar medicines:

In Germany, biosimilar medicines for use in hospitals are generally procured by (groups of) hospitals via direct negotiation with the manufacturers.

5.3.3 Enablers for generic and biosimilar medicines in the hospital setting in Germany

Instantaneous market access after authorisation by BfArM or the European Medicines Agency, due to absence of additional pricing and reimbursement procedures for the hospital market in Germany, enables fast market penetration of generic and biosimilar medicines in the German hospital market (68).

An important enabler for uptake of generic medicines in the German hospital market is the way hospitals are reimbursed for using medicines. Generic medicines and their originators are mainly financed via G-DGRs, yielding a clear incentive for hospitals to procure medicines with the lowest net price. Another enabler for market access of generic medicines in hospitals is the relative high market share of generic medicines in the ambulatory sector, which stimulates acceptance of generic medicines in the hospital sector.

For Germany, the biggest enabler for biosimilars are 'quotas'. As a barrier – there are regional differences in the quotas and some are highly managed/ enforced and others not.

A key enabler for uptake of biosimilar medicines in the German hospital market is the attitude of hospital physicians and hospital pharmacists towards biosimilar medicines, which has become generally positive, with efficacy, quality and safety of biosimilar medicines no longer frequently being questioned (67). Hospital physicians and hospital pharmacists are the chief stakeholders in the decision whether to prescribe originator or biosimilar medicines in hospitals. However, for novel biosimilar medicines, there is still some reservation with respect to efficacy, quality and safety (67).

Another important enabler for uptake of biosimilar medicines in the German hospital market is the way hospitals are reimbursed for using biological medicines for inpatients. Biological medicines are usually high-cost drugs and therefore financed via additional surcharges (*Zusatzentgelt*). Such surcharges are based on active substance and hospitals, therefore, receive the same reimbursement for the originator or biosimilar medicine within the same active substance group. This leads to a clear incentive for hospitals to procure the biological medicine with the lowest price within the same active substance group, which often yields an advantage for biosimilar medicines (67).

The new framework contract between sickness funds and hospitals regarding discharge management is likely another enabler for uptake of biosimilar medicines in the German hospital market (67). The framework contract stimulates that hospital-based physicians take into account the economic prescription guidelines of the ambulatory physicians, in order to prevent treatment switching from originator to biosimilar medicine due to discharge. Effectively, the economic prescribing guidelines in the retail pharmacy sector, which generally favour biosimilar medicines, might thus create a 'reverse' spill-over effect into the hospital sector.

5.3.4 Barriers for generic and biosimilar medicines in the hospital setting in Germany

A barrier for generic and biosimilar medicines in the inpatient hospital setting in Germany is the way hospitals are financed. In the previous section regarding enablers, we have shown that the hospital financing system for inpatient medicines is a clear enabler for market uptake of generic and biosimilar medicines, by incentivizing hospitals to procure medicines for low net prices. Hence, it may seem strange to also include the hospital financing system in the category of barriers. The rationale for doing so is that the incentive to procure at low net prices yields a constant pressure on price, which on the long run might decrease competition and therefore also sustainability of these low (net) prices, due to a limited number of suppliers (67).

In addition to the pressure on price, based on our interview with members of the German hospital working group of Medicine for Europe, pharmaceutical companies feel that the penalties for failure to supply pose too much risk, as they are based on list price. Taken together with the ongoing pressure on prices, the balance between risk and reward might be suboptimal, which could lead to a reduced appetite for manufacturers of generic medicines and biosimilar medicines.

For outpatients, the most frequently employed 129a SGB-V contract model, which covers list price minus a standard discount percentage, is a barrier for uptake of biosimilar

medicines (67). As the list price of a biosimilar medicine is usually lower than the list price of its respective originator, the reimbursed amount is generally lower as well, thus decreasing the incentive for hospitals to procure biosimilar medicines.

5.4 Italy

5.4.1 Pricing and reimbursement of medicines in Italy

Regulation of the pharmaceutical market is organised on a national level in Italy, with AIFA being the responsible authority. When marketing authorisation is granted by the European Medicines Agency or AIFA, the pricing and reimbursement process can be initiated. Within AIFA, the Technical Scientific Committee is responsible for the assessment of the scientific evidence in the marketing authorisation procedure (52).

AIFA is responsible for determination of the reimbursement level and reimbursement price (52). In 2017, the Italian Council of State confirmed that AIFA has the ultimate authority over medicine pricing, which limits the authority of regions to negotiate their own deals with manufacturers of medicines (27). Within AIFA, the Pricing and Reimbursement Committee (*Comitato Prezzi e Rimborso*, CPR) simultaneously negotiates price and reimbursement levels with the manufacturers (52). Pricing decisions only apply to medicines which are listed in class A and class H (26). Class A contains medicines that are deemed essential and can be distributed by either hospitals or community pharmacies. Medicines in class A are reimbursed by the SSN and usually involve a modest co-payment, which may vary regionally. Class H includes medicines that can only be distributed by hospitals and are fully reimbursed. To set the reimbursement price of class A and class H medicines, criteria such as for instance cost-effectiveness and risk-benefit ratios, financial impact on the SSN and pricing in other European Union countries are taken into account. Class C medicines are not-reimbursed in the SSN and are not subject to price setting by AIFA (26). Reimbursement decisions are usually revised after 2 years, however, they may also be revised *ad hoc* due to a change of indication (52). Pricing decisions are also subject to revision, which can be performed periodically or *ad hoc* (52). It is worthwhile to note that Italy has an average time to market of 13 months, which ranks amongst the longest times to market in the EU (52).

A study among fifteen European countries shows that Italy has the most managed entry agreements (MEAs) (52). MEAs aim to enable access to high-cost medicines for which there is uncertainty regarding cost-effectiveness and / or budget impact for the SSN. MEAs are negotiated between payers and pharmaceutical companies and usually focus on determining the impact on the SSN budget by making price-volume agreements, or are focussed on outcomes. In Italy, over 50% of MEAs are outcome-based. Analysis of MEAs in oncology by KPMG Italy shows that for the 60 MEAs in oncology, 53% are outcome-based, 26% are based on financial discounts and 21% are based on appropriateness of use. AIFA publishes quarterly the economic impact of the MEAs on the budget of the SSN.

AIFA publishes also a monthly transparency list, which gives an overview of off-patent drugs that are on the Italian market. SSN reimburses the lowest price of an off-patent medicine within a group of medicines belonging to the same reference price group (26).

5.4.2 Procurement landscape of medicines for hospitals in Italy

The SSN is the major provider of pharmaceutical care in Italy (26). Medicines are dispensed by two channels in Italy: community pharmacies and hospital pharmacies. Hospital pharmacies are responsible for procurement and dispensing drugs to hospital patients. In addition, hospital pharmacies may deliver certain type of drugs (e.g. anti-retroviral drugs) to out-patients (26). Procurement of medicines for hospitals is usually tendered at either a regional level or by (groups of) individual hospitals. As hospitals are mainly funded via global budgets or DRG's, there is a clear incentive for hospitals to procure medicines at low (net) prices. Price is therefore usually the chief award-winning criterion in tenders (57). In general, hospital pharmacies in Italy have at least a 50% discount on the nominal price of medicines.

The former government in Italy has set a ceiling for hospital pharmacy expenditures, with spending capped at 6.89% of the total healthcare expenditures (27). A payback mechanism is in place, which stipulates that when regions exceed the hospital pharmacy expenditure ceiling, 50% of the excess is charged to the regional government and 50% is charged to the pharmaceutical industry. In the first half of 2017, 20 regions were above the hospital pharmaceutical spending limit (27).

Generic medicines:

Generic and other off-patent medicines for use in hospitals are tendered on a regional level by the LHAs or locally by (groups) of hospitals (54). On average the contract duration is 24 months and this period can be extended with an additional 24 months. Prices are not subject to change during the contract duration. There are no commitments from the issuing party with respect to the minimum or maximum volume that is associated with a generic medicine tender (54). Tenders are awarded by active substance. The main award-criterion in tenders of generic medicines is price, however, the reliability to supply may also be taken into account in determining the winner of the tender. Generic medicine prices are regulated with a maximum of 80% of the originator price (54).

Biosimilar medicines:

In Italy, biosimilar medicines for use in hospitals are tendered either on a regional level or locally by (groups) of hospitals (55; 62). The tender is for a duration of 24 months with a possibility for elongation of an additional 24 months. Since December 2016, the procurement of biosimilar medicines for patients that already are undergoing treatment and patients that still have to start treatment (naïve patients) is similar (55). AIFA requests a minimum reduction of 20% in price compared to the originator medicine (62), however, the actual reduction in practice is typically around 30% according to KPMG Italy, which analysed the launches of biosimilar medicines in Italy in the period 2015-2017.

5.4.3 Enablers for generic and biosimilar medicines in the hospital setting in Italy

Efforts to increase market uptake of generic medicines include information campaigns targeting physicians and patients, in order to inform them regarding the quality, safety and economic value of generic medicines (54). In addition, the regionality of tenders for generic medicines offers pharmaceutical companies multiple commercial opportunities.

An important enabler for the uptake of biosimilar medicines in Italy is the 2017 procurement law for biosimilar medicines. The new procurement law stipulates that:

- Multi-winner tenders are enablers and good for sustainability
- The originator and biosimilar medicines will directly compete in the same tender based on therapeutic equivalence;
- Tenders have to be re-opened within 60 days after market entry of a biosimilar medicine;
- Physicians are obliged to prescribe the winning medicine(s) from the tender for new patients. However, physicians are allowed to keep prescribing medicines which have lost the tender to patients already undergoing therapy, in order to be able to provide therapeutic continuity. However, LHAs can ask for medical justification, as this exception is only aimed at patients who are too unstable to switch medicines.

Another enabler for the uptake of biosimilar medicines are the regional biosimilar medicine quotas which are present in the Campania region and serve as prescription guidelines (62; 55). Furthermore, experiments with benefit sharing in the region of Campania incentivized hospitals to increase the uptake of biosimilar medicines, leading to more than € 2 million in savings, of which approximately 50% was re-allocated to the hospitals (62). In addition, the regionality of tenders offers biosimilar pharmaceutical companies multiple commercial opportunities.

5.4.4 Barriers for generic and biosimilar medicines in the hospital setting in Italy

Market penetration of generic medicines in Italy is relatively low compared to other European countries and large differences in market penetration exists between Italian regions (25). Generally speaking, market penetration in the Southern regions of Italy is lower than in the more Northern regions (26). These differences are likely not caused by differences in policies between regions, but are rather due to cultural differences and the monitoring systems of the different LHAs (25). Another reason might be the lack of awareness regarding (the benefits of) generic medicines among the public. Previous studies showed that in the northern regions approximately 65% of citizens reported to be aware of generic medicines while in the more southern regions this was 44% (26). At the hospital level, differences in market penetration of generic and biosimilar medicines are less evident.

An important barrier for market penetration of generic medicines in the hospital setting is the tendering process (69; 70). Pharmaceutical companies have the opinion that the current tendering system is too time-consuming and bureaucratic, is lacking a minimum order quantity and yields too much uncertainty with respect to the different phases within the tendering procedure, such as start date of the tender and the first order dispatch date (69). In addition, the chief (and often sole) award criteria in the tenders for generic

medicines is price, which incentivizes pharmaceutical companies to offer the lowest price and could lead to price erosion. Hence, the appetite of the pharmaceutical companies to compete in the current tender procedures might be suboptimal. A study on the generic medicines tender market in Italy by Nomisma showed that the participation rate of pharmaceutical companies in tenders has steadily decreased from 2.9 bids per published lot to 2.5 bids per published lot during the period 2011-2015 (70). This trend indicates that competition in the generic medicines market has been decreasing, which could potentially lead to unfavourable market characteristics such as medicine shortages or price hikes.

Furthermore, the Nomisma study shows that the number of unawarded lots has increased from 22% to 27% in the period 2011-2015 (70). A possible explanation for this increase are the maximum bidding prices which are put in place in the tenders by the issuing parties. If these maximum bidding prices are too low, they might form a barrier for manufacturers of (generic) medicines to participate in the tender procedure, potentially leading to a lack of participants and hence unawarded lots.

An important barrier for market penetration of generic medicines in the hospital setting with respect to tenders is the risk of financial penalties due to the payback mechanism (70). The mechanism of payback, which was originally intended for the outpatient sector (retail pharmacies), was extended to the hospital sector (including off patent medicines) in 2012. The mechanism obliges companies to cover 50% of the cost of any overrun in the annual budget, which is predefined by AIFA. The method used to calculate the annual budget allocated to companies has been shrouded in mystery. As hospital medicines are purchased via tenders, which oblige manufacturers to provide any quantities requested by the hospital at the winning price, overruns on the statutory ceiling for hospital spending are outside of the circle of influence of manufacturers. The Nomisma study shows that the impact of the payback mechanism on the revenues of manufacturers can be quite significant: up to a 45% decrease of revenues (70).

The payback mechanism forms a barrier for market penetration of generic medicines due to the fact that it decreases competition, as budgets for manufacturers are predetermined, which prevents manufacturers of generic medicines to further penetrate the market by gaining market share. Next to being a barrier for further uptake of generic medicines in the hospital setting, the payback mechanism might also lead to higher prices, as companies might factor potential paybacks into their future tender bids.

The average market share of biosimilar medicines in Italy was 19% at the end of 2017 and the market share is characterized by high variance (55; 62). This variance applies to differences within the country and also to the differences between biosimilar medicines. For instance, Filgrastim had 88% uptake in 2015, whereas Infliximab only had 11% uptake. There are multiple barriers with respect to uptake of biosimilar medicines in Italy that could explain the observed market shares. First, the present quotas for biosimilar medicines are only present in one region in Italy and are not enforced (62). As a consequence, prescriptions do not fully adhere to the imposed quotas in this region. In addition, there are no recommendations from AIFA for switching patients currently on originator medicines to biosimilar medicines (62). However, the latest position paper of AIFA on biosimilar medicines (March 2018) does suggest that AIFA now sees originator and biosimilar medicines as interchangeable, both for naïve patients and patients already undergoing treatment (71).

Next, the mandatory discount on the list price level of biosimilar medicines limits opportunities for pharmaceutical companies in price negotiations, and this is perceived by the pharmaceutical companies as a potential barrier for sustainable uptake of biosimilar medicines (62). Finally, similar to tenders for generic medicines, the tenders for biosimilar medicines are perceived by the pharmaceutical companies as (too) time-consuming and complex, potentially leading to a reduced appetite of these companies in the Italian biosimilar medicine market (62).

5.5 Poland

5.5.1 Pricing and reimbursement of medicines in Poland

Regulation of the pharmaceutical market is organised on a national level in Poland, with URPL-WMiDP responsible for the safety of medicines and granting marketing authorisation (29; 52). When marketing authorisation is granted by URPL-WMiDP, or by the European Medicines Agency, manufacturers can apply for a mandatory health technology assessment by AOTMiT. AOTMiT analyses clinical effectiveness, cost-effectiveness and budget impact of new medicines and provides the Ministry of Health with a recommendation regarding (maximum) price and reimbursement rate (29; 52). The final decision regarding the (maximum) price and reimbursement rate is made by the Ministry of Health. The Ministry of Health employs both internal as well as external reference pricing mechanisms to do so (52). The reimbursement and pricing decisions by the Ministry of Health are often issued for two, three or five years, depending on the effectiveness of the medicine. Decisions regarding price can be revised ad-hoc, for instance when a new medicine with the same active substance enters the market (52).

The Ministry of Health regularly employs reimbursement restrictions, especially for high-cost medicines in the hospital sector (52). Such high-cost medicines usually are reimbursed through so-called drug programmes (through the NFZ), which cover a limited number of patients and which set certain (medical) criteria that determine eligibility (29). These programmes cover the price of the medicines but do not cover the price of the treatments (e.g. time of medical specialist, costs of the used facilities etc.). Therefore, hospitals have a financial incentive not to participate in such drug programmes, as the cost of treatments has to be borne by the hospitals. However, hospitals are pushed by the government, media and patients to participate in these drug programmes.

The Ministry of Health introduced a reimbursement act in 2012 in order to decrease spending on medicines. The act set fixed prices and margins for reimbursed drugs and increased co-payment levels. Both measures concerned ambulatory care and are therefore not applicable to the hospital setting. In addition, the act set a ceiling on the spending on reimbursed medicines (17% of the total public healthcare budget) and created financial penalties (pay-back) for pharmaceutical companies that cause overspending (29; 31). In addition to these policies, the Ministry of Health has increased the value-added tax on medicines (31). These reforms were deemed successful, as sales of reimbursement medicines have fallen since. Further legislation was announced to introduce more flexibility in the reimbursement system in 2016. For instance, orphan medicines are not required to provide full cost-effectiveness evidence anymore.

5.5.2 Procurement landscape of medicines for hospitals in Poland

Medicines in the hospital sector are tendered publicly in Poland and are delivered free of charge to inpatients (29; 52). The main criterion in public procurement is price, however, hospitals can also use other criteria such as for instance the speed of delivery (72; 57). Polish law stipulates that price constitutes at least 50% of the weighted value of the award criteria in tenders. The “lowest bid” award procedure is employed in approximately 85% of hospital tenders (57).

Hospitals are reimbursed for the costs of medicines through various channels, such as the JGP-system, chemotherapy schemes and the drug programmes (29). These channels create a financial incentive for hospitals to procure medicines at low (net) prices (72).

Generic medicines:

Generic medicines in the hospital market are usually tendered by individual hospitals or hospitals in groups (54). However, for medicines within the scope of the drug programmes, tenders can also be performed on a regional or national level. Tender contracts are awarded by active substance and the average contract duration is two to three years, with prices not subject to change until the next tendering round. There are no commitments from the tendering hospitals with respect to the minimum or maximum volume that is associated with the tenders. The main criterion for tenders of generic medicines is price, however, also other factors can be taken into account (54).

Maximum prices of generic medicines are regulated in Poland. Generally speaking, there is a mandatory discount of 25% with respect to the list price of the originator medicine (54). However, external reference pricing is also applied, with a target of at least a 30% price reduction compared to the average generic medicine price in the referenced countries.

Biosimilar medicines:

For biosimilar medicines, tenders for the hospital market are performed on hospital or national level with price being the main criterion (55; 62). On average these tenders have a duration of 6 to 12 months, depending on the product and the therapeutic programme. Both naïve patients and patients already undergoing treatment with biological medicines can be placed within the same tender.

Prices of biosimilar medicines are regulated similarly to generic medicines in Poland, with a 25% minimum mandatory discount with respect to the list price of the originator medicine and additional external reference pricing (55; 62).

5.5.3 Enablers for generic and biosimilar medicines in the hospital setting in Poland

Generic medicines have a single process for pricing and reimbursement which takes approximately two months for products which have reimbursed substitutes, enabling relative fast market penetration of generic medicines in Poland (54). For physicians, the prescription of generic medicines is encouraged by recommending INN prescribing, however, INN prescribing is not mandatory (54). In addition, information campaigns have targeted physicians to promote prescription rates of generic medicines and have targeted patients in order to inform them about the value of generic medicines (54).

Biosimilar medicines are treated similarly to generic medicines with respect to pricing and market access procedures, enabling relative fast market penetration of biosimilar medicines in Poland (55). For physicians, the prescription of biosimilar medicines is encouraged by target agreements (quotas) and by allowing INN prescribing for biological medicines (55). In addition, the Ministry of Health enables the market penetration of a

particular biosimilar medicine (Infliximab) by stipulating that switching to Infliximab is allowed at any level of therapy.

Hospitals are incentivized to procure the cheapest medicines within the reference price group as the reimbursement price of the hospital is set at the predetermined price of the reference price group. As biosimilar medicines generally have a lower price compared to the originator, this encourages procurement of biosimilar medicines (62). There is no shared-savings system in the Polish hospital setting, however by saving money due to procurement of biosimilar medicines, the hospitals can treat more patients within the existing budget of the respective drug programme (62). Next to these measures, patients in Poland are informed about the benefits of biosimilar medicines via websites, leaflets and seminars. Looking from a biosimilar medicine manufacturers' perspective, the multiple tenders for the hospital setting creates multiple opportunities for market access (62).

5.5.4 Barriers for generic and biosimilar medicines in the hospital setting in Poland

A potential barrier for sustainable use of generic and biosimilar medicines in the Polish hospital setting are the mandatory price cuts on list price levels and the high discounts on net price level for generic and biosimilar medicines, which potentially reduces the appetite of pharmaceutical producers to enter or stay in the Polish hospital generic and biosimilar medicine market (62). Furthermore, pharmaceutical companies deem the current hospital tendering system as too time-consuming and complex (62). In addition, competition between pharmaceutical companies seems limited in the Polish biosimilar medicines market, with only a few companies that actively supply the market (62).

An additional barrier for market uptake for biosimilar medicines in the hospital setting is the fact that guidelines that enable treatment switching to a biosimilar medicine lack for most active substance groups, with Infliximab being the exception (62). Another barrier for biosimilar medicines is reluctance among physicians in Poland to prescribe biosimilar medicines due to interchangeability concerns related mainly to safety and efficacy. In addition, there is usually only one product available per active substance group within a hospital formulary, limiting the options for switching towards biosimilar medicines.

5.6 Portugal

5.6.1 Pricing and reimbursement of medicines in Portugal

Regulation of the pharmaceutical market is a responsibility of the national government in Portugal. When marketing authorisation is granted by the European Medicines Agency or INFARMED, the pricing and reimbursement process can be initiated. For inpatient care, INFARMED decides whether new medicines are to be reimbursed and bases its decision on an economic evaluation of the new medicine. In addition, INFARMED determines the maximum price of new medicines by administrative procedure of International Reference Prices calculation.

Decisions with respect to reimbursement of medicines for inpatients are revised every two years (52). Prices are generally revised annually in Portugal, and in addition, prices also can be revised ad hoc (52). It is worthwhile to note that Portugal has an average time to market of over approximately 12 months, which ranks amongst the longest times to market in the EU (52).

In March 2016, the government and the pharmaceutical industry signed a covenant that aims to curb public spending on ambulatory and hospital medicine for the period 2016-2018 (35). This covenant stipulates that the pharmaceutical industry issues refunds to the SNS if its annual spending on medicines exceeds 2 billion euros.

Additionally, the government established extraordinary taxes to be applied to all the medicines excluded from the covenant (Protocol). These taxes are unequal on the concern of generic and biosimilar medicines at the hospital level which have the highest level of tax. This taxation is penalizing the generic and biosimilar segment of the market, which bring competition to the market.

5.6.2 Procurement landscape of medicines for hospitals in Portugal

As hospitals in the SNS are mainly financed via global budgets, there is a clear incentive for public hospitals to procure medicines at low (net) prices. Procurement of medicines for the public hospital market is usually performed via public tenders and / or via direct negotiations, which can be performed by groups of hospitals or individual hospitals (73; 35). Public tenders which can be centralized or decentralized are usually managed by the *Serviços Partilhados do Ministério da Saúde* (SPMS) and are often awarded by therapeutic group, with price often being the only award-criterion (73). Hospitals are allowed to bargain for further discounts subsequent to public tenders. Discounts are fairly prevalent but often not transparent for the public. SPMS may also issue tenders at a national level. An example of such national tendering procedure is the procurement of contraception medicines.

Generic medicines:

Tender contracts for generic medicines in the hospital setting are awarded by active substance in Portugal. Depending on the scope of the tender, the average duration of the tender contract is 1 to 2 years for national tenders and approximately 3 months for tenders by hospitals (54). Prices may be subject to change during the contract period.

The list price of generic medicines is regulated at the national level in Portugal, and for inpatient care, the list price of generic medicines has to be at least 30% lower than the list price of the originator product. There are binding commitments from the issuing party with respect to the volume that is associated with tenders for generic medicines in the hospital setting (54). In general, the sole award criterion for tenders of generic medicines in the hospital setting is price.

Biosimilar medicines:

Similar to generic medicines, tenders for biosimilar medicines can be performed on a national level or on a per hospital level (55). The average contract duration of tenders is 12 months. Usually, there are separate tenders for naïve patients and patients already undergoing treatment. Per type of tender, one winner is usually selected (55). The list price of biosimilar medicines is regulated at the national level in Portugal and has to be at least 20% lower than the list price of the originator product or 30% lower if the biosimilar medicines reached 5% of market share.

5.6.3 Enablers for generic and biosimilar medicines in the hospital setting in Portugal

A chief enabler for generic and biosimilar medicines in the Portuguese hospital setting is the financing system of the hospitals, which incentivizes hospitals to procure medicines at low (net) prices. If a generic or biosimilar medicine offers the lowest net price, a clear incentive is present to procure this generic or biosimilar medicine.

Another important enabler for market access to generic medicines is the ongoing effort of the Portuguese government to promote the use of generic medicines (36). For instance, INN prescribing is mandatory in most circumstances (69). However, most policies to increase market access to generic medicines seem to be aimed at the retail pharmaceutical market, instead of the hospital market. Examples of such retail focused policies are reducing the financial incentives for pharmacists to sell higher priced products and allowing substitution by pharmacists (35).

5.6.4 Barriers for generic and biosimilar medicines in the hospital setting in Portugal

There are four current barriers that might reduce the appetite of manufacturers to compete in the Portuguese generic and biosimilar market, and therefore might contribute to a reduced market uptake of generic and biosimilar medicines in the medium to long-term due to lack of competition (69):

- **Price revisions:** maximum list prices of generic and biosimilar medicines are directly dependent on the list price of the originator medicine. If the list price of the originator is reduced, the maximum list price of the corresponding generic or biosimilar medicines is automatically also reduced. This methodology basically allows originator manufacturers to determine the maximum list price of generic and biosimilar medicines.
- **Two-stage procurement procedure, with both stages focusing on price:** manufacturers often first have to compete in a national tender, which usually awards the bids with the lowest price. Subsequently, the procuring hospital typically bargains

for even lower prices, or issues a hospital tender in which the winners of the national tender are invited to compete. Again, price is usually the sole award criterion. This effectively creates two pressure points with respect to price, which might lead to price erosion and subsequently a reduced appetite for manufacturers to compete in the Portuguese generic and biosimilar medicine market.

- **Price erosion:** The initial price that works as ceiling price is calculated considering the average price of last 1-2 years, not taking into account exceptional price reductions that were set by a provider that prefers to drop the price to levels below the cost aiming to destroy the stock with additional expenses. This particular situation creates an extreme price erosion and induce medicine shortages/absence of suppliers).
- **Covenant between the Ministry of Health and the pharmaceutical industry:** the 2016 covenant between the Ministry of Health and the pharmaceutical industry stipulates that the pharmaceutical industry issues refunds to the SNS if its spending on medicines exceeds 2 billion euros each year. Generic medicines and biosimilar medicines are included in this arrangement, even though they generally already contribute to limiting the spending of the SNS on medicines by offering reduced prices compared to the originator medicines.

Other barriers for biosimilar medicines in Portugal are the lack of national guidelines with respect to treatment switching and lack of implementation of benefit sharing methods.

5.7 Spain

5.7.1 Pricing and reimbursement of medicines in Spain

Regulation of the pharmaceutical market is a responsibility of the national government in Spain. When marketing authorisation is granted by the European Medicines Agency or the AEMPS, the pricing and reimbursement process can be initiated. The DGCF determines whether a new medicine should be reimbursed throughout the SNS (52). To do so, it takes decision criteria such as the severity of the disease and the therapeutic value and efficacy of the medicine into account. The Intra-Ministerial Commission on Drug Prices determines the reimbursement prices of medicines using guidelines set by the DGCF (40). For reimbursed medicines that have a generic equivalent, prices are set at the price of the generic equivalent (41). If there is no generic equivalent available, prices are set through negotiation with the manufacturer and the DGCF will base its position in the negotiations on cost-efficiency and external reference pricing analyses (41; 52). If the reimbursement decision by the DGCF is negative, the manufacturer is free to set its price, but the medicine will not be reimbursed in Spain.

Reimbursement decisions are usually reviewed annually within a maximum of three years after the initial decision (52). Prices are revised every two years and can also be revised ad hoc, for instance when a medicine with the same active substance enters the market (52).

A study among fifteen European countries shows that Spain has a relatively high level of managed entry agreements (MEAs) (52). MEAs aim to enable access to high-cost medicines for which there is uncertainty regarding cost-effectiveness and / or budget impact for the SNS. MEAs are negotiated between the payers and pharmaceutical companies and usually focus on determining the impact on the SNS budget by making price-volume arrangements or by linking price to clinical outcomes. MEAs are widespread in Spain and therefore appear to contest the regular pricing and reimbursement process (52). As MEAs frequently have a confidential nature, insights in the overall impact of MEAs are generally limited.

Like many countries, Spain has focussed on decreasing expenditures on medicines. This is shown in a decrease of the share of medicine expenditure as part of total health expenditures, from 21% in 2005 to 18% in 2015, which is still well above the OECD average of 16% (41). Multiple policies have been implemented over the past decade in order to curb the rising costs of medicines:

- Introduction of new co-payment thresholds for medicines in 2012, as previously described in section 3.7.2.
- A revision of the reference pricing system for innovative medicines in 2014 (42).
- Issuing a 7.5% rebate imposed on innovative drugs with less than 10 Years in the market. Generic medicines do not have this rebate due to being included in the Reference Price System; biosimilars do not have this rebate neither once Reference Price System is implemented for the molecule. (74).
- Decreasing the price of generics by at least 40% (74).
- Stimulation of the use of generic medicines, as discussed later in this chapter.

Recently, the MHSSE and the National Trade Association of the Spanish Pharmaceutical Industry (Farmaindustria) signed an extension of the 2016 voluntary pharmaceutical covenant (42). The goal of this covenant is to align spending of medicines with economic growth, in order to increase the sustainability of the SNS. Another goal of the covenant is to ensure the access to innovative medicines for patients across all CAs. According to the covenant, Farmaindustria is required to compensate the SNS if the increase in spending on medicines exceeds the GDP growth rate. Two incentives have been introduced to stimulate CAs to adhere to the covenant (42). First, CAs that adhere to covenant have access to attractive credit options from the *Fondo de Liquidez Autonómica* (near 0% interest and a 10 year payback time). Secondly, CAs that do not adhere to the covenant lose their ability to add additional regional benefits to the reimbursed benefits package. However, these incentives have been heavily criticized, as they are deemed to invade the autonomy of the CAs (42).

5.7.2 Procurement landscape of medicines for hospitals in Spain

Approximately 30% of all revenue of medicine sales in Spain in 2017 concerned the hospital market (42). As public hospitals and regional health services are funded via global budgets, there is a clear incentive for public hospitals and regional health services to procure medicines at low (net) prices. Procurement of medicines for the public hospital market is usually performed by (groups of) public hospitals or by the regional health services (57). When there are more than two suppliers present for a certain medicine, procurement is usually publicly tendered. The award criteria are mainly focused on price. Suppliers are allowed to offer discounts in the tender procedure, leading to net prices lower than the list prices. However, suppliers are not allowed to offer rebates to individual doctors or pharmacists in Spain, a prohibition that safeguards the independence of these medical professionals (57). In some cases more centralised purchasing practices are present. For instance, the 20 medicines with the highest in-hospital consumption (including paracetamol, lamivudine, omeprazole and gemcitabine) are procured centrally by 11 CAs (42). Besides tendering, direct negotiations at hospital level also occur in Spain.

Generic medicines:

Tender contracts for generic medicines in the hospital setting are awarded by active substance or groups of active substances (54). The average contract duration for generic medicines is one to two years and prices are not subject to change during this contract period (54). There are no commitments from the issuing party with respect to the minimum or maximum volume that is associated with the tenders for generic medicines. The list price of generic medicines is regulated at national level in Spain and has to be at least 40% lower than the original list price of the originator medicine (54). The reference price for all medicines within a reference group (including originator and generic medicines) is set equal to the price of the lowest priced medicine. In general, the sole award criterion for tenders of generic medicines in the hospital market is (net) price.

Biosimilar medicines:

Biosimilar medicines in the hospital market are tendered at hospital level, but also at regional level and national level (55). Tenders have to be re-opened once a biosimilar medicine enters the market. For naïve patients, procurement of biosimilar medicines is usually performed in a mixed tender, including both originator and the biosimilar medicines (62). The list price of biosimilar medicines is regulated at national level in Spain and has to be at least 20-30% lower than the list price of the originator medicine (62). Similar to generic medicines, creation of reference pricing groups for biosimilar medicines leads to a reference price which applies for all medicines within the reference price group (including originator medicine) and is set at the price level of the lowest priced medicine (62). Usually, the award criterion in tenders for biosimilar medicines is the lowest (net) price.

5.7.3 Enablers for generic and biosimilar medicines in the hospital setting in Spain

A chief enabler for generic and biosimilar medicines in Spain is the financing system of the hospitals, which frequently results in budget caps per patient (62). This leads to an incentive to procure medicines at low prices. If a generic or biosimilar medicine offers the lowest net price within the reference group, a clear incentive is present to procure this generic or biosimilar medicine.

Another enabler for generic medicine uptake is the obligation to prescribe using the INN methodology for acute treatments and for treatments of new patients with chronic conditions (54). In addition to these enablers, informational campaigns have been organized that aim to inform patients and physicians about the quality and value of generic medicines.

For biosimilar medicines, an important enabler is the prescription guidelines issued by the regional health services which aim to increase the prescription rates of less expensive alternative medicines, however the guidelines often do not differentiate between biosimilar and reference medicines (62). In addition, informational campaigns have been organized by the authorities and by the biosimilar medicines industry (55), with the aim to inform patients about the quality and value of biosimilars. In some regions, there are also indicators to prescribe biosimilar medicines.

5.7.4 Barriers for generic and biosimilar medicines in the hospital setting in Spain

A barrier for uptake of generic medicines in the hospital setting is that there is effectively no list price differentiation between the originator and generic medicines, as both are mandatorily listed at the price level of the lowest priced medicine within the reference group (69). If the originator medicine remains in the market at this new list price level after patent expiry, it has the advantage of already being in the market and can benefit from the fact that it will not be undercut in list price by generic medicines. This might lead to a lack of incentives for payers and hospitals to switch from the originator medicine to a generic variant, although clearly, net price is the main driver for such incentives.

This lack of list price advantage with respect to the originator medicine applies not only to generic medicines, but also to biosimilar medicines (62). As biosimilar medicines are generally more complex to develop than generic medicines, an automatic price reduction

might reduce the appetite of pharmaceutical companies to enter the biosimilar market in Spain (55).

In addition, biological medicines are not allowed to be prescribed by INN and for biological medicines the hospital pharmacists need to dispense the commercial brand as prescribed by the physician (55; 62). Furthermore, pharmaceutical companies deem the current hospital tendering system for biosimilar medicines too time-consuming and complex (62). On the other hand, however, the decentral tendering system does offer multiple opportunities to compete for market share.

5.8 The United Kingdom

5.8.1 Pricing and reimbursement of medicines in the UK

Regulation of the pharmaceutical market is organised on the UK level, with the MHRA being the responsible authority (45) and the European Medicines Agency & European Regulatory network. The MHRA authorizes clinical trials, monitors the safety and the quality of medicines and grants a marketing authorization.

NICE plays an important role in determining the uptake or adoption status of new medicines which have obtained marketing authorization (52). It provides CCGs guidelines based on health-economic analyses concerning which medicines are cost-effective and should, therefore, be prescribed and reimbursed at the price proposed or agreed in the NICE appraisal (45; 75). NICE tends not to recommend new medicines as cost-effective if they exceed £20,000–30,000 per Quality Adjusted Life Year (QALY) (13). CCGs have the final authority on use decisions and take account of NICE recommendations. However, NICE guidance is not offered for all available medicines. In addition, NICE guidance indicates how a new medicine should be used in the treatment pathway for the patients. For example, whether the medicine should be used as first line treatment or only after other treatments have been tried. CCGs also have to make their own judgements based on effectiveness (75). Reimbursement decisions are usually revised periodically (every one to three years) (52). In Scotland, the procedures are different from the rest of the UK (52). The Scottish Medicines Consortium is responsible for similar recommendations in Scotland.

Unlike many other EU countries, the UK does not directly regulate prices of medicines. The costs of prescription branded medicines are contained by the Pharmaceutical Price Regulation Scheme (PPRS) (13). The latest scheme, which was introduced in 2014 and lasts five years, is expected to be replaced by a different scheme by 2019. This will no longer regulate the profits that pharmaceutical companies can make selling medicines to the NHS. It will instead place a cap on total expenditure on prescription branded medicines to be achieved by rebates on manufacturers' revenues. It is a voluntary scheme, negotiated between the Department of Health and the Association of British Pharmaceutical Industry (45). It will give pharmaceutical companies freedom to set prices of new branded medicines and exempt them for rebate for a specific period.

The pricing of non-branded generic medicines is not controlled by PPRS. A different voluntary scheme exists for unbranded generic medicines. It will be replaced in early 2019 by new statutory provisions which mirror the voluntary scheme. This will provide for freedom of pricing for unbranded generic medicines with the ability for the government to intervene if competition is not effective in controlling prices.

5.8.2 Procurement landscape of medicines for hospitals in the UK

Hospital pharmacies are encouraged to procure medicines centrally via the NHS Commercial Medicines Unit (75). They may procure individually or as part of smaller buying groups with neighbouring NHS trusts. If the value of the procured medicines is above the European publicity threshold, procurement has to be performed via public tenders (57). There has been a dominating tendency to position price as the most

important award-criterion in tenders (57). For contracts below the threshold, the general principles of transparency and equal treatment still apply.

The question as to who ultimately pays for medicines prescribed in a hospital will depend on the patients' treatment pathway. It will be the NHS Trust or CCG. This creates a financial incentive for hospitals to procure medicines for prices as low as possible. (76). Individual hospitals in the UK generally purchase medicines in relatively low-volume batches and from multiple wholesalers, resulting in a potential loss of economies of scale which the CMU tendering system is designed to reinstate, through their framework agreements.

Generic medicines:

Generic medicines are usually tendered on a national or regional level (regions: South West & Central, London North & North West and London South & North East). The Commercial Medicines Unit (CMU) of NHS England supports this tendering process (77). When the patent of an originator pharmaceutical expires, the CMU will move the product to being tendered under a generic tender, sometimes following a short transition tender when a product first becomes off-patent. The CMU conducts separate tenders for injectables, oral medicines and commodity generic medicines. The main decision criterion is lowest price and for injectable medicines, the system has been changed to avoid a national single winner and tenders may result in a single winner for the different regions (54; 57). In the situation that the prices are equal, the medicines with multiple distribution channels are favoured (54). The prices agreed on in the tender are the actual procurement prices for hospitals, and there should be no further bargaining by hospitals after the CMU-tender, but some hospitals do purchase medicines outside of the framework agreement. The average tender contract duration that is received by the winner is 18-24 months, with prices not due to change during the contract period (54). Tenders do not offer a guarantee for minimum or maximum volume.

Biosimilar medicines:

Biosimilar medicines are usually procured via a CMU tender process, historically on a regional level, with four tender regions: South, London, Midlands and East, North (55; 77). On average these tenders have had a duration 24 months and have one winner. However, other medicines in the same reference group may be procured for the same price as determined for the winning medicine in the tender.

NHS England has begun to view each biosimilar launch in its own right and has been moving towards a specific approach for each molecule depending on its individual circumstances. This is to ensure maximum fast use of biosimilar medicines and to ensure that are multiple manufacturers in the market in the long-term rather than one manufacturer taking the whole market. The price of biosimilar medicines are set by the tender, however, they are included within the PPRS agreement and its successor and are subject to rebates in this scheme (62).

5.8.3 Enablers for generic and biosimilar medicines in the hospital setting in the UK

Immediate pricing and reimbursement of generic medicines in the United Kingdom enable fast market penetration (68). Policies in the UK aim to drive generic medicine use by encouraging generic medicine prescription and dispensing (52; 54). The starting point is in medical school where prescribers are educated to always use INN prescribing. Therefore 87% of all UK prescriptions are written generically. Due to limited budgets of CCGs, doctors are financially incentivised to lower pharmaceutical expenditure in order to be able to spend the savings on all types of care. In addition, NHS England offers financial incentives to stimulate higher uptake of generic (and biosimilar) medicines, with the aim to contain healthcare expenditures at national level.

The prescription of biosimilar medicines instead of the originator medicines is driven by NHS England national guidance, prescription guidelines by NICE, by educational campaigns supporting physicians and patients, and by creating financial incentives (55; 62). The financial incentives include benefit sharing methods where the hospitals and CCGs both benefit from increased cost-efficiency (55; 62). This is seen as a promising incentive to increase biosimilar use, however, benefit sharing agreements are commonly implemented, but there is still complexity in determining the shared savings. In general, the United Kingdom is seen as a country that helps to increase the biosimilar use in a sustainable way, though recent falls in prices risk threatening the sustainability of the industry in the UK (62)

The NHS has issued the 'Commissioning framework for biological medicines (including biosimilar medicines)' in 2017, which provides an outline of how biological medicines are to be commissioned across the NHS (78). The framework is based on the founding principle that switching to the 'best value' biological medicine should be clinical practice. Therefore, this framework might enable higher penetration of biosimilar medicines in the hospital market in the near future. The framework sets thresholds for biosimilar use which, if met, provide a financial reward (CQUIN).

5.8.4 Barriers for generic and biosimilar medicines in the hospital setting in the UK

Based on our interview we gathered that pharmaceutical companies feel that there is an unbalance between risk and reward in the tender system for the generic medicines market of the UK, more specifically:

- **Reward:** The main (and often sole) award criterion in tenders is price.
 - This incentivizes competition between pharmaceutical companies to offer the lowest price.
- **Risk:** The tender system yields two financial risks for pharmaceutical companies:
 - If a company wins a tender and subsequently (partly) fails to supply, the organization which issued the tender will procure the medicines from other companies. This is often done at list price, which is usually significantly higher than the price agreed in the tender. The tender-winning company which has failed to supply is obliged to cover the difference in price between the tender and the actual procurement price. This also applies to the situation where the actual

procured volumes are higher than indicated in the tender. This is a major cause of some manufacturers not participating in tenders and/or withdrawing the market.

- The tenders do not guarantee a minimum volume, leading to the risk of unused stocks and low economies of scale.

This potential unbalance between risk and reward in the generic market may lead to strategic countermeasures of pharmaceutical companies that may not be beneficial to patients.

For biosimilar medicines, a barrier for (rapid) market access is the fact that tender contracts are not re-opened when a biosimilar medicine hits the market (55). Other barriers for biosimilar medicines are the lack of standardised benefit sharing methods and the suboptimal implementation of the 2017 NHS England 'Commissioning framework for biological medicines (including biosimilar medicines)' into clinical practice.

In addition to these barriers for generic and biosimilar medicines, pharmaceutical companies deem the regional tendering processes as too time-consuming and complex, leading to a potentially reduced appetite for pharmaceutical companies to enter or stay within the UK's generic and biosimilar medicines market (62). On the other hand, the regional tendering systems do offer multiple commercial opportunities for pharmaceutical companies.

6 Urge to improve the hospital environment to increase the utilization of generic and biosimilar medicines

Before we start this chapter it is important to state that – in general – higher utilization of generic and biosimilar medicines is associated with cost-efficiency and a similar level of quality of care²⁶. Therefore heightening the use of generic and biosimilar medicines is a route to enhance the efficiency (outcome per euro spent) of hospital care. In addition, generic and biosimilar medicines enhance the efficiency of hospital care by increasing competition for branded medicines.

Nonetheless, it is important to state that on a molecule level it can well be that the price level of a branded or originator drug can be at the same (or lower) price level than the generic or biosimilar version due to discounts. To what extent branded or originators drugs are at the same (or lower) cost levels compared to generic or biosimilar medicines in a particular country at a specific time is often impossible to indicate given the confidentiality of discounts.

The main objective of this chapter is to underline the urge improve the hospital environment to increase utilization of generic and biosimilar medicines by showcasing:

- 1 Differences between countries in the utilization of generic and biosimilar medicines in hospitals, due to diverse hospital environments such as the enablers and barriers for generic and biosimilar medicines as mentioned in the previous chapter.
- 2 A decrease in market competitiveness due to manufacturers abandoning the market as a result of the barriers as discussed in the previous chapter.
- 3 The average lag between the first use of a generic medicine after loss of exclusivity (LOE) of the respective originator and the corresponding hospital opportunity loss.

²⁶ See for instance “QuintilesIMS Report. Delivering on the potential of biosimilar medicines. 2016.” In this report Quintiles IMS state that the introduction of biosimilars saved EUR 1.5B in the EU-5 countries alone up until 2016 and that the future potential is way (up to EUR 47 B in the 2016-2020 period) higher. Regarding generic medicines, according to “IMS Health, The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective. 2015”, generic medicines provide an opportunity for European governments to achieve efficiency gains which can be invested in other components of healthcare systems. Without competition from generic medicines, payers in Europe would have had to pay €100BN more in 2014.

6.1 Differences between countries in the utilization of generic and biosimilar medicines in hospitals

6.1.1 Generic medicines

Figure 15 describes the differences in market shares (value and volume) of generics in the European hospital setting. Comparing value and volume market shares, it is evident that there is an unbalance. Originators and off-patent brands have typically a combined volume market share of <30%, whereas the budgetary impact of originators and off-patent brands typically exceeds 60%.²⁷

According to the data presented in Figure 15, France and Germany have hospital environments which enable the highest utilization of generic medicines compared to the other countries in scope of this study. On the other side of the spectrum, Belgium shows the most potential to further optimize the hospital environment in order to stimulate higher uptake of generic medicines. Compared to countries such as Lithuania and Austria however, all countries in scope of this study show potential for (further) improving value and volume market shares of generic medicines in the hospital setting.

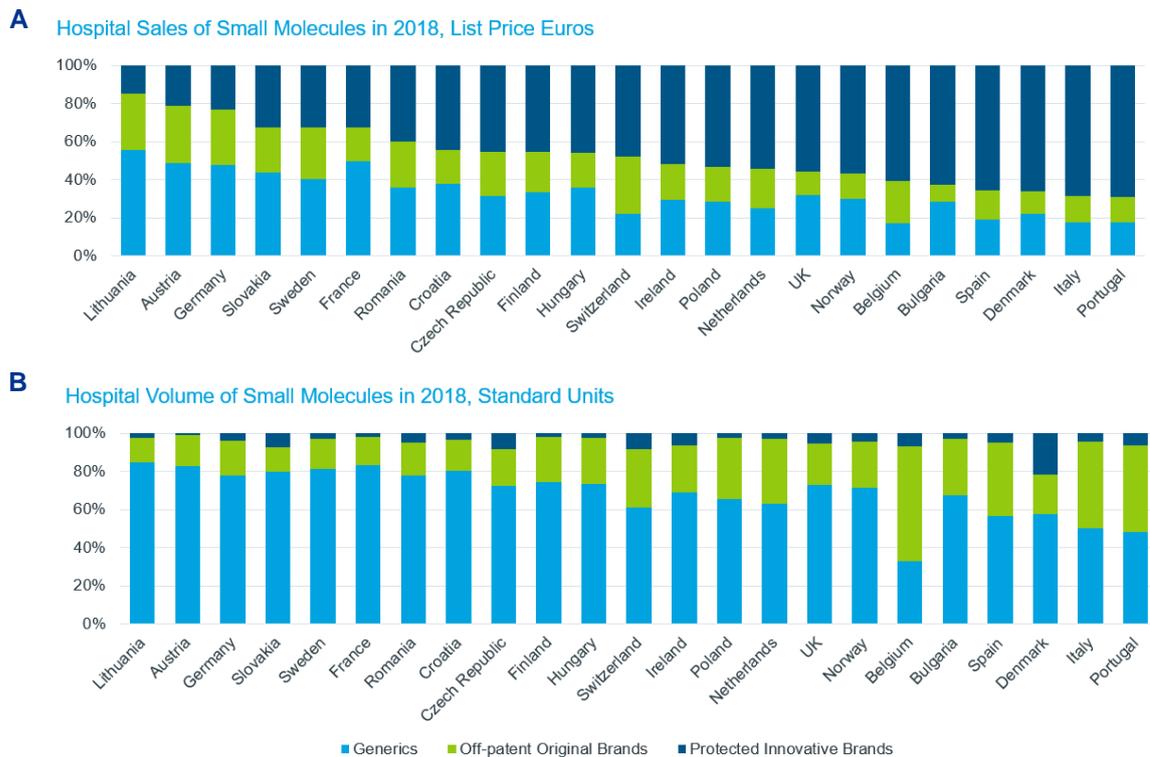


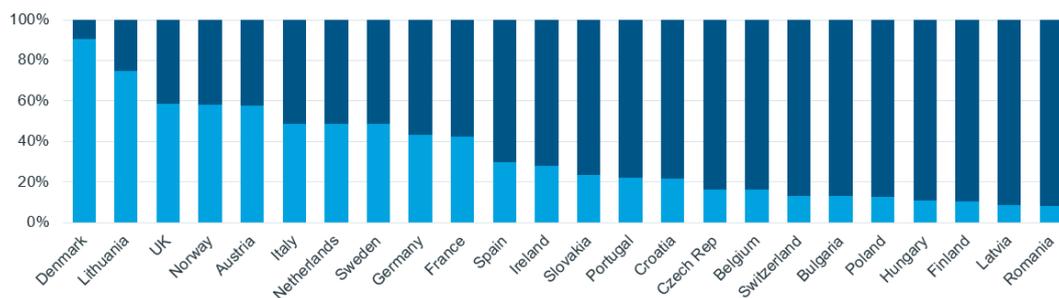
Figure 15: Hospital sales (A) and volume (B) of small molecules in 2018, expressed in Euros (list price) and standard units, respectively. Note: Generics include unbranded and branded generics. Source: IQVIA European Thought Leadership, IQVIA MIDAS FY2018, Innovation Insights, excluding hospital solutions, imaging and other.

²⁷ Please note that these analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.

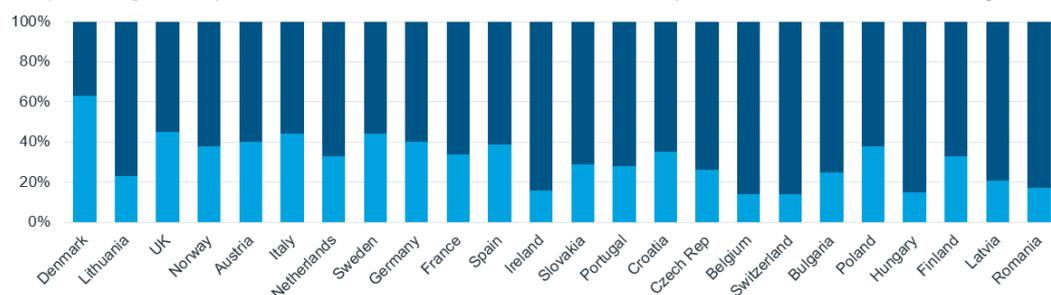
6.1.2 Biosimilar medicines

The differences in market shares (value and volume) of biosimilars in the European hospital setting are shown in Figure 16.^{28,29}

A Hospital Sales of Biosimilars in March 2019, List Price Euros



B Simple Average of Hospital Biosimilar Volume in March 2019, Treatment Days



C

		Hospital Biosimilars Volume, Treatment Days, March 2019															
		Simple Average*	Adalimumab	Enoxaparin Sodium	Epoetin	Etanercept	Filgrastim	Foliotropin Alfa	Infliximab	Insulin Glargine	Insulin Lispro	Pegfilgrastim	Rituximab	Rituximab IV only	Somatropin	Trastuzumab	Trastuzumab IV only
EU Weighting		6%	48%	9%	3%	0.5%	0.3%	12%	12%	2%	0.5%	2%	2%	2%	2%	2%	2%
Denmark	63%	96%	0%	53%	89%	93%	26%	97%	8%	0%	100%	78%	93%	78%	98%	99%	
UK	45%	39%	53%	6%	81%	96%	52%	93%	16%	0%	12%	79%	90%	22%	32%	81%	
Italy	44%	25%	35%	84%	48%	97%	26%	84%	16%	21%	1%	70%	88%	25%	42%	66%	
Sweden	44%	55%	0%	81%	65%	99%	16%	81%	33%	50%	21%	22%	58%	2%	43%	90%	
Germany	40%	81%	3%	80%	96%	94%	0%	24%	23%	0%	3%	71%	77%	2%	47%	58%	
Austria	40%	9%	12%	80%	52%	99%	0%	91%	0%	0%	22%	83%	95%	0%	67%	89%	
Spain	39%	12%	41%	77%	39%	94%	85%	59%	24%	0%	2%	43%	59%	20%	17%	40%	
Poland	38%	1%	0%	100%	40%	86%	0%	97%	21%	35%	8%	0%	0%	100%	11%	50%	
Norway	38%	0%	0%	100%	100%	86%	0%	98%	4%	0%	15%	80%	94%	0%	7%	76%	
Croatia	35%	8%	0%	100%	24%	100%	64%	67%	10%	0%	28%	30%	62%	25%	5%	12%	
France	34%	28%	0%	42%	49%	99%	0%	61%	47%	0%	13%	62%	76%	0%	36%	80%	
Netherlands	33%	25%	0%	19%	22%	39%	0%	82%	30%	0%	15%	95%	97%	15%	80%	99%	
Finland	33%	10%	0%	100%	14%	91%	0%	11%	29%	10%	0%	43%	54%	100%	19%	89%	
Slovakia	29%	0%	0%	100%	0%	100%	0%	33%	25%	0%	67%	29%	40%	0%	26%	80%	
Portugal	28%	4%	0%	96%	29%	93%	0%	61%	0%	0%	3%	51%	78%	12%	13%	35%	
Czech Rep.	26%	8%	0%	85%	22%	100%	4%	60%	8%	0%	27%	21%	31%	7%	1%	7%	
Bulgaria	25%	0%	0%	100%	0%	100%	0%	100%	0%	0%	0%	19%	21%	0%	0%	1%	
Lithuania	23%	0%	0%	100%	0%	100%	92%	0%	2%	0%	0%	0%	0%	0%	100%	100%	
Latvia	21%	0%	0%	0%	0%	100%	74%	0%	0%	100%	0%	0%	0%	0%	0%	0%	
Romania	17%	0%	0%	100%	0%	100%	0%	0%	17%	0%	2%	7%	7%	0%	0%	0%	
Ireland	16%	0%	0%	100%	0%	41%	0%	47%	0%	0%	0%	23%	23%	0%	2%	3%	
Hungary	15%	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%	73%	97%	0%	27%	78%	
Belgium	14%	0%	0%	14%	0%	32%	47%	33%	6%	0%	0%	2%	4%	40%	2%	5%	
Switzerland	14%	0%	0%	21%	23%	83%	0%	24%	1%	0%	0%	14%	15%	11%	0%	0%	

Figure 16: Hospital sales (A) and volume (B-C) of biosimilars and biologics in 2018, expressed in Euros (list price) and treatment days, respectively. Note: All biosimilars launched in Europe by March 2019 are in scope. * Simple average calculated including subcutaneous formulation for Rituximab and Trastuzumab. Source: IQVIA European Thought Leadership, IQVIA MIDAS MTH March 2019

²⁸ Please note that these analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.

²⁹ See appendix C for weighted use of biosimilars in EU and German hospital setting, respectively

Denmark shows the highest volume market shares of all countries, whereas Central Eastern European countries score typically low, as well as Belgium and Switzerland. The relatively low volume market shares in these countries points towards a lack of access to biosimilar medicines in the hospital setting, and as such limited potential of competition for the originator biologic medicines.

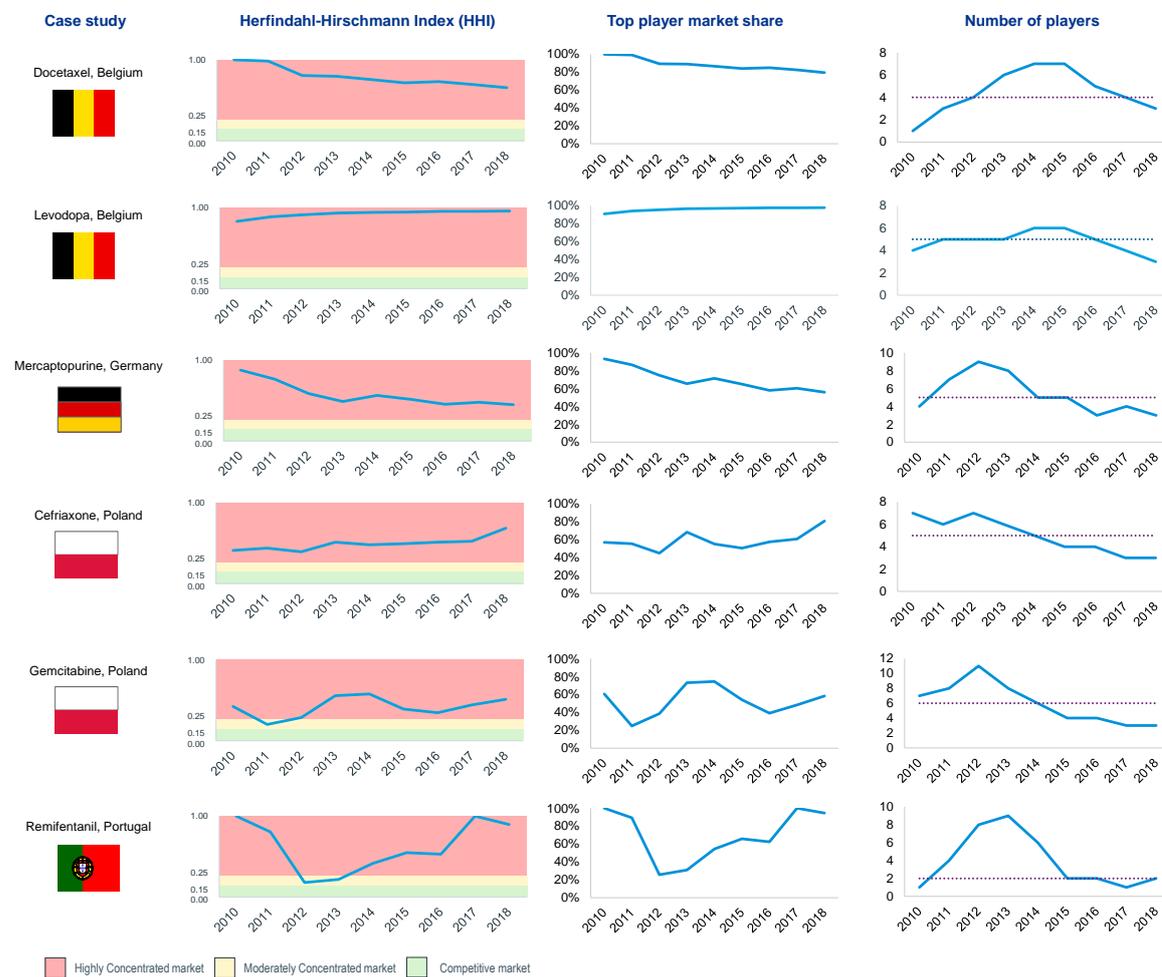
Of the countries within scope of this study, it is the UK which comes closest to the Danish biosimilar volume market shares and it is Belgium that shows most room for improvement in this respect. As none of the countries in scope match Denmark with respect to utilization of biosimilar medicines in the hospital sector, there is still room to further optimize the hospital environment for each of the country within scope of this study.

6.2 Decrease in market competitiveness due to manufacturers abandoning the market

Figure 17 displays six case studies into the market competitiveness of small molecules. These case studies show that the market is increasingly getting more concentrated, as manufacturers are abandoning the market.

A good example of this trend are the case studies concerning Ceftriaxone in Poland and Remifentanil in Portugal. Both case studies show a steady decline in the number of players in the market from a situation with more than 6 players in 2012 to a situation with only 2 players in 2018. In addition, in both case studies the top market player has a market share that surpasses 80%, showing that competition in these markets is rather limited. In such cases with a small number of players and a top player which has the vast majority of the market, market effectiveness is rather low (as expressed by a high Herfindahl-Hirschman Index score). This subsequently might lead to de-novo monopolies and unsustainable market characteristics.

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Herfindahl-Hirschman Index (HHI)

HHI is a common measure of market concentration, and is used to determine market competitiveness. It is calculated by summing the squares of the market shares. Numbers closer to 1.0 are deemed non-competitive (smaller number of players and/or concentrated market share, numbers closer to 0.0 indicate healthier competition (share spread evenly across many players).

	Company A	Company B	Company C		HHI	
Share	98%	1%	1%	$0.98^2 + 0.01^2 + 0.01^2$	0.96	Strong Monopoly
Share	80%	10%	10%	$0.8^2 + 0.1^2 + 0.1^2$	0.66	Weaker Monopoly
Share	33%	33%	33%	$0.33^2 + 0.33^2 + 0.33^2$	0.33	Even share, 3 players
Share	50%	50%		$0.5^2 + 0.5^2$	0.50	Even share, 2 players

Figure 17: Six case studies into market concentration of selected generic medicines in the hospital sector of selected countries. Source: IQVIA European Thought Leadership

6.3 Average lag between the first use of a generic medicine after loss of exclusivity of the respective originator and the corresponding hospital opportunity loss

Figure 18 shows the lag between the first use of a generic medicine after loss of exclusivity (LOE) of the respective originator and the corresponding hospital opportunity loss. From the 8 countries studied, Italy, Belgium and Poland have the longest delay in to access to the first generic medicine post LOE (6, 8 and 10 months, respectively). However, each country studied shows a delay of at least two months, and therefore an opportunity is present for each country to accelerate the utilization of generic medicines in the hospital setting after LOE. This opportunity has amounted up to €266Mn in the last three years.³⁰ To be able to seize this opportunity, it is crucial that purchasing procedures (e.g. tenders) as well as pricing and reimbursement procedures are streamlined.

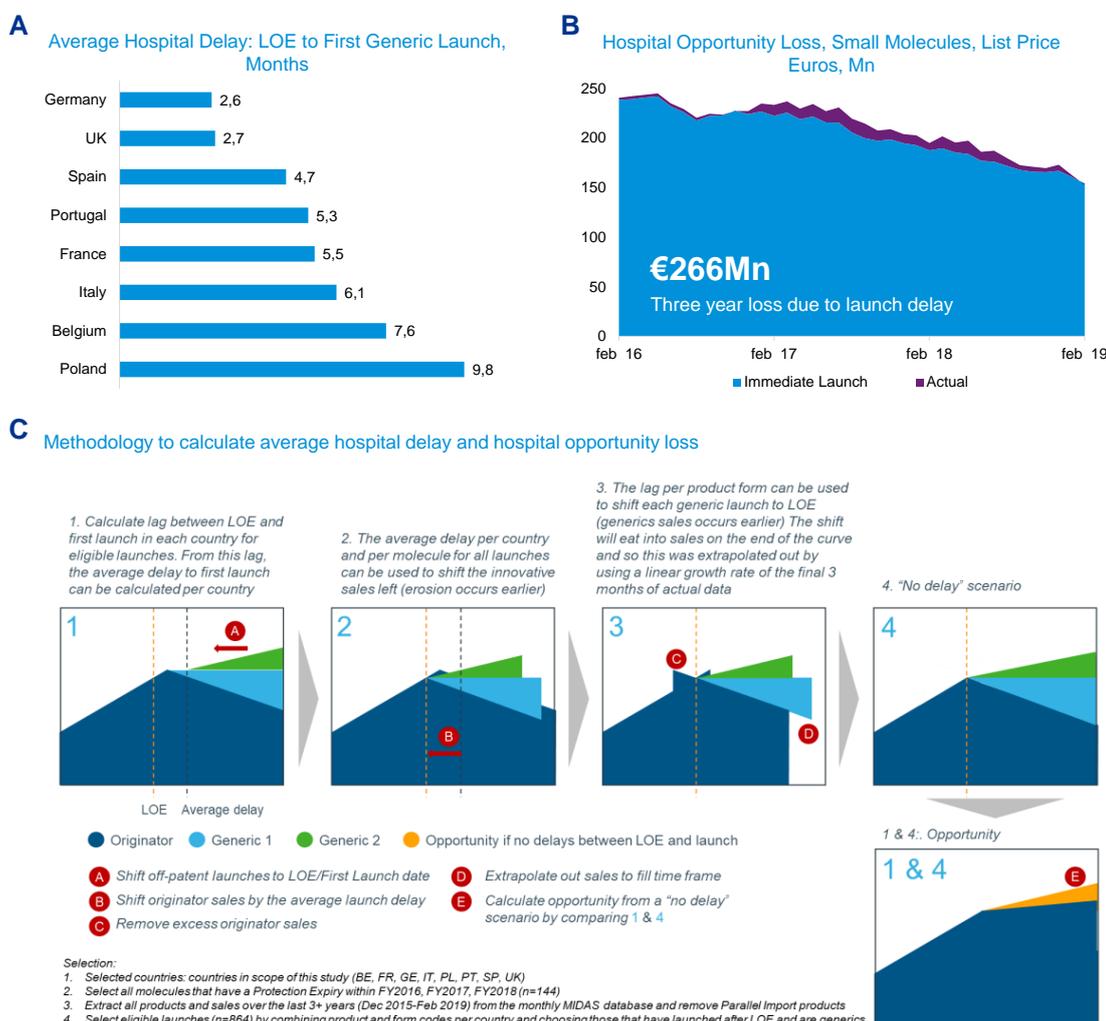


Figure 18: Average hospital delay (A) and hospital opportunity loss (B) for small molecules after loss of exclusivity and used methodology (C) to calculate average hospital delay and hospital opportunity loss. Notes: Small Molecules only; Calculations are based on list prices. Source: IQVIA European Thought Leadership, IQVIA MIDAS MTH Jan 2019

³⁰ Please note that these analyses are based on list prices and therefore do not take into account the (often confidential) discounts that manufacturers give to hospitals and other buying entities.

7 Recommendations to improve access to generic, biosimilar and value added medicines in the hospital setting

This final chapter describes a set of overarching recommendations to increase hospital system value by stimulating long-term competition and timely access to generic and biosimilar medicines in the hospital setting. Our recommendations are a synthesis of the previous chapters and are furthermore based on interviews with hospital experts from KPMG and national associations.

With the recommendations as described in this chapter, a step can be taken in the realization of the potential impact of increased utilization of generic and biosimilar medicines in the hospital market in the eight studied countries. This can have a positive impact on the hospital care system value: costs of hospital care can be lowered or investments can be made to improve the quality of delivered care in the hospital systems. Based on the findings of this study, as presented in the previous chapters, there is potential as well as urgency for each of the studied countries to improve utilization of generic and biosimilar medicines in the hospital setting in order to increase hospital care system value.

7.1 Overarching recommendations for improved access to generic and biosimilar medicines in the hospital setting

This section describes nine key ingredients for a hospital pharmaceutical environment that optimally fosters utilization of generic and biosimilar medicines. Please note that some of the studied countries may already have one or multiple of the key ingredients listed below present in their hospital pharmaceutical market. In addition, some countries require additional country-specific ingredients to optimally foster utilization of generic and biosimilar medicines. Country-specific recommendations for increased utilization of generic and biosimilar medicines in the hospital setting can be found in Appendix B.

Figure 19 shows these **nine key ingredients prioritized** according to ease of implementation and impact on the system.

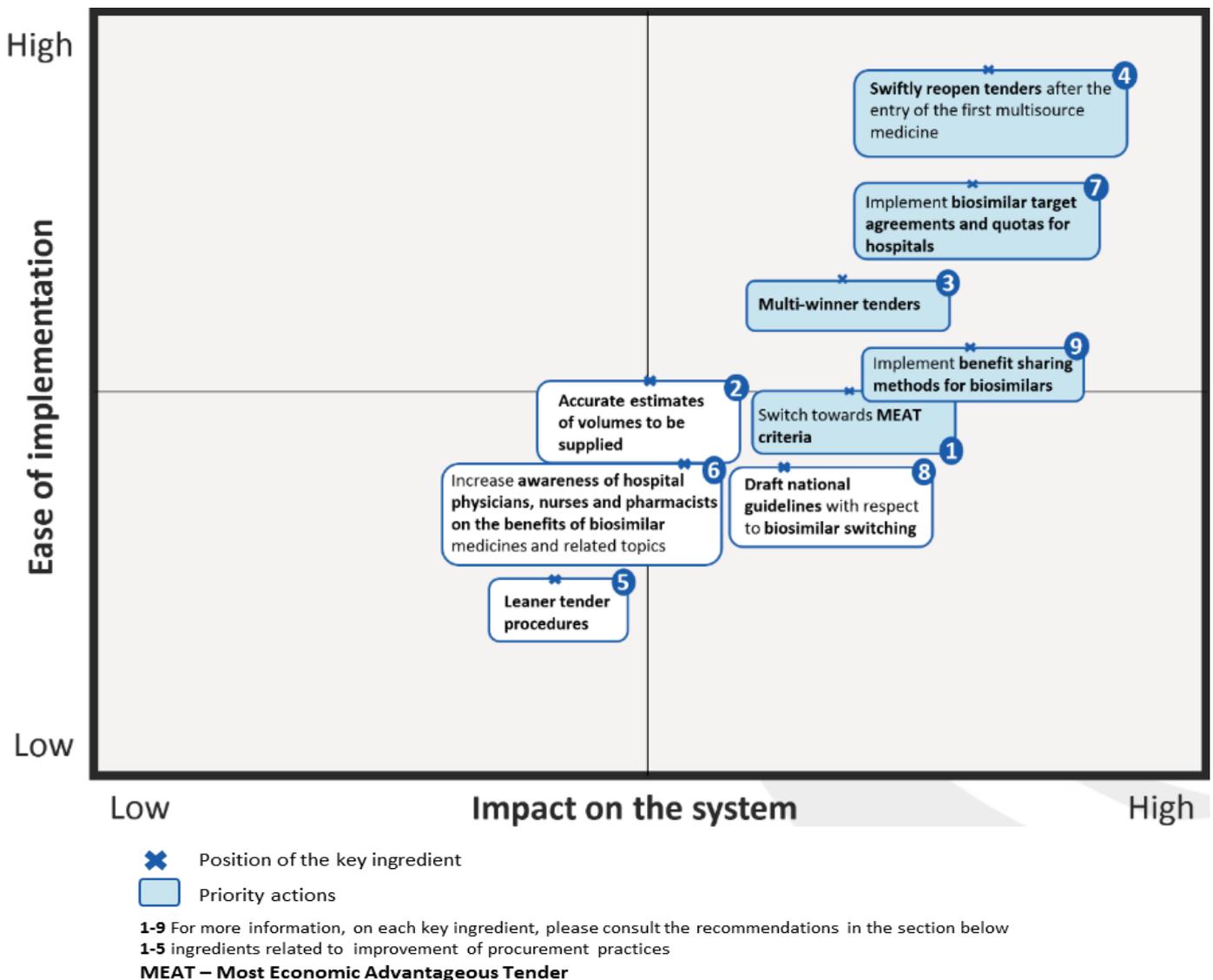


Figure 19: 9 key ingredients for increased utilization of generic and biosimilar medicines in the hospital setting and prioritisation of these ingredients according to ease of implementation and impact on the hospital system.

7.1.1 **Nine key ingredients for increased utilization of generic and biosimilar medicines in the hospital setting³¹**

A key ingredient for increased utilization of generic and biosimilar medicines in the hospital setting is a **procurement/purchasing system that stimulates competition**. Competition forms a cornerstone for sustainable market dynamics and creates an opportunity for hospitals to achieve efficiency gains which can be invested in other aspects of hospital care. Many hospital systems choose to conduct procurement/purchasing mechanisms using tendering systems, which can be an efficient mechanism when conducted appropriately. Stimulation of long-term competition can be sustainably achieved by finding the fair spot between risk and reward in the procurement/purchasing system.

In order to stimulate a long-term sustainable competition, we recommend:

- 1 Switch from the frequently employed lowest bid procedure towards a most economically advantageous procedure**, which takes other qualitative elements into account that add value to bids, such as a proven track record of supply reliability on company level. A shift to more 'economically advantageous' procedures may stimulate competition as it creates more opportunities and interest from manufacturers to compete sustainably on more parameters than just price. Actions that ensure the active participation of the manufacturers in the hospital market will stimulate competition and consequently originate efficiency gains that can be invested and benefit the hospital system as a whole. It is important to closely monitor the effects of such additional award-criteria, to ensure that this is well balanced and does not prevent competition, such as in Belgium, where additional award-criteria seem to favour the originator manufacturers (see chapter 4.1.4).
- 2 Set accurate volume estimates to guarantee a continuous supply**. This ingredient raises the interest of manufacturers to compete, as it enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids. The settlement of accurate volumes to be supplied, helps manufacturers to better forecast demand creating predictability and attractiveness to bid which not only stimulates competition and benefits the healthcare system but also reduces the chance of medicine shortages.
- 3 Award tenders to multiple winners³²**. Single-winner tenders lead to a risk of reduced competition, as only one manufacturer is active in the market and other manufacturers might choose to discontinue their production. This might lead to a reduced number of manufacturers participating in the next round of tenders, reducing competition. In addition, single-winner tenders might contribute to medicine shortages. In the case of a supply issue of the sole tender winner, other manufacturers might not be able to cope with the sudden demand as they might have significantly reduced or even entirely discontinued their production. Hence, multi-winner tenders with predictability of volumes for each winner not only increase supply reliability that is essential to prevent medicine shortages but also sustain healthier levels of competition in the tendering system, which both benefit the healthcare

³¹ Please see appendix B for country-specific recommendations for improved access to generic and biosimilar medicines in the hospital setting.

³² Except situations/countries where the quantity of medicines tendered is too low and consequently the market volume is too small to create a mature and balanced market.

system as a whole (please see positive examples in Italy and UK chapters, respectively).

- 4 Swiftly reopen tender procedures after the entry of the first multisource medicine.** Reopening tender procedures directly after the entry of the first multisource medicine fosters competition. This enables timely patient access to cost-effective treatments i.e. generics and biosimilars. Timely enhanced competition in tender procedures promotes a better allocation of economic resources which benefits the healthcare system as a whole³³.
- 5 Make the tendering procedure leaner.** The tendering systems in most studied countries are administrative, disharmonious and labour intensive, which may discourage medicine manufacturers from participating in tenders. A concerted effort to make tendering operational procedures harmonious and simpler by requiring submission of essential information for the tender and by fully digitizing the procedure reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in hospital tenders. A leaner tendering incentivizes the participation of multiple manufacturers in the tenders, which stimulates competition in the procedure and benefits the healthcare system as a whole.

Next to the key ingredients 1-5, which biosimilar medicines share with generic medicines, we have identified **four biosimilar-specific key ingredients** for increased utilization in the hospital setting. These four biosimilar-specific key ingredients focus on improving market access of biosimilar medicines by increasing awareness of hospital physicians, nurses and pharmacists, implementing biosimilar target agreements and quotas and by drafting guidelines on treatment switching. In order to increase access of biosimilar medicines in the hospital market and to stimulate competition, we recommend:

- 6 Create guidelines and/or information campaigns to increase awareness of patients and healthcare professionals (including hospital physicians, nurses and pharmacists) regarding the efficacy, quality and safety of biosimilar medicines as well as other important topics such as biosimilar medicines introduction in the clinical practice and physician-led switching.** A general lack of awareness/education on biosimilar medicines still contributes to some resistance among healthcare professionals including hospital physicians, nurses and pharmacists. In order to improve the clinical use of biosimilar medicines by healthcare professionals, and therefore to increase patient access to biologic medicines, it is important for hospitals and other trusted stakeholders to create information campaigns and educational settings to disseminate information on the benefits of biosimilar medicines and relevant biosimilar-related topics such as physician-led switching. In addition, it might be useful to disseminate information about the importance of biosimilar medicines in cost-efficient quality care improvement in the hospital setting not only to healthcare professionals but also to controllers and managers which issue the tenders and often have an incentive to limit pharmaceutical spending (e.g. hospitals, regional health agencies or central procurement agencies). For instance in UK, the update of NICE guidelines after biosimilar filgrastim launch in

³³ Important to take into consideration a balanced re-opening of tenders for biosimilar medicines. Frequent re-opens associated with short duration would be challenging given the extended manufacturing lead time and consequent less predictability.

2008³⁴ reflected the improved cost-effectiveness of biosimilar filgrastim vs. alternative treatments. As a result, G-CSF prescribing restrictions were relaxed and usage also recommended for primary prophylaxis of neutropenia versus secondary prophylaxis only. Consequently, this guideline update stimulated an increased use of biosimilar filgrastim and enabled a greater number of patients to access these treatments at an earlier stage of the therapeutic cycle.

- 7 Create incentives for biosimilar use that take into consideration the long-term sustainability of the sector such as the implementation of target agreements and quotas for biosimilar medicine use.** Setting concrete milestones for the use of biosimilar medicines with target agreements for physicians and quotas for hospitals, is acknowledged to stimulate competition, to increase patient access to biologics and to supply physicians with more treatment options. Targets must be accompanied by robust tracking to ensure accurate awareness of progress towards milestones. Regarding target agreements for physicians, there is a concrete example in Germany in the region of Westfalen-Lippe where these target agreements are applied and the physician association plays a major supporting role to physicians by organising information campaigns and by providing reporting to physicians about the progress of the management of the switch.
- 8 Draft national and or local hospital guidelines with respect to treatment changes & medicines exchange.** By drafting national/hospital guidelines on treatment switching, hospital stakeholders are informed on the safe and positive experience of physician-led switching and on the process of exchanging therapeutic alternative medicines (switching from a group of patients already undergoing treatment with an originator biological medicine to a biosimilar). Ample evidence supports the safety of switching to biosimilar medicines and can be incorporated in hospital guidelines and communication to physicians and patients^{35,36}.
- 9 Implement benefit sharing methods.** Benefit sharing models and schemes should be encouraged so that cost-effectiveness gains resulting from the increased use of biosimilar medicines are re-invested into healthcare for the benefit of patients and all the relevant hospital stakeholders. For instance, in the University Hospital Southampton NHS Foundation Trust in the UK , there is an example of a benefit sharing model, where a managed physician-led switching program of biosimilar infliximab for all inflammatory bowel disease patients is available. This switching to biosimilar medicines allowed more patients to be treated and created the opportunity for re-investment in improvements of patients' care, e.g. hiring more nurses to provide targeted support/better care to the patients.

To conclude this report, we take a brief look at a third category of medicines relevant in the context of hospital care delivery efficiency and outcomes: value added medicines. The next chapter describes value added medicines and their benefits, the current access barriers in the hospital setting and our recommendations for improved access to value added medicines in the hospital setting.

³⁴ Simon-Kucher & Partners, IMS Health, MIDAS, IMS Consulting Group, Nov 2015

³⁵ Kurki P, van Aerts L, Wolff-Holz E, Giezen T, Skibeli V, Weise M.

Interchangeability of Biosimilars: A European Perspective. *BioDrugs*. 2017 Apr; 31(2):83-91.

³⁶ Ebbers HC, Muenzberg M, Schellekens H. The safety of switching between therapeutic proteins. *Expert Opin Biol Ther*. 2012 Nov;12(11):1473-85.

7.2 Value added medicines in the hospital setting and recommendations to improve access to value added medicines

This study shows that optimized utilization of generic and biosimilar medicines in the hospital market can increase quality and efficiency of hospital care. To conclude this report, we took a brief look at a third category of medicines relevant in the context of hospital care delivery efficiency and outcomes: **value added medicines**.

Value added medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers (1)³⁷. Examples of relevant improvements that value added medicines can achieve are:

- Expand therapeutic use to different indications or populations.
- Optimize administration of medicines and their ease of use;
- Increase of efficacy, safety and/or tolerability of medicines;

Such improvements have the potential to enhance health care delivery and efficiency and can be realized in three different ways (1):

- Reformulation of medicines, such as changing the pharmaceutical formulation, the pharmacokinetic profile, the drug delivery system or route of administration;
 - *E.g. self-injected subcutaneous formulation of a product already available on the market as intravenous formulation administered only at hospital under medical monitoring in a severe inflammatory disease*
- Combination of medicine/medicine or combination of a medicine/medical device.
 - *E.g. New inhaled device to administer genericized products in Chronic Obstructive Pulmonary Disease (COPD) indication with evidence of reducing inhaler errors versus current device used with these active substances*
 - *E.g. Therapeutic drug monitoring device developed in association with a known cancer therapy exhibiting a narrow therapeutic window to potentialise drug efficacy while minimizing toxicity*
 - *E.g. Fixed-dose combination of 2 products already available on the market and used as free dose combination in arterial hypertension to reduce pill burden, improve compliance and avoid intake errors in a highly medicated patient population*
- Repositioning the medicine in order to expand therapeutic use of the medicine;
 - *E.g. repositioning of a well-known product in a rare pediatric indication as an alternative to reference treatments not specifically approved in this indication*

Value added medicines present an opportunity to address the needs of hospital delivery and efficiency. The table on the next page briefly illustrates potential exemplary benefits value added medicines could provide.

³⁷ Please note that our recommendation only applies to value added medicines, which means that these medicines were improved after patent expiration (and/or developed by a different manufacturer than the originator).

Examples of value added medicines that meet hospital inefficiencies

Examples	Optimization of medical quality and processes	Increase of cost-productivity	Improvement of the commitment treatment-patient and/or treatment-healthcare professional
An extended-release formulation of a product already available on the market for a neurocognitive disease indication, reducing administration regimen from once-weekly injection to 3-monthly injection	Improving the rational use of medicines and hospital resources	Reduce the costs associated with a reduced number of hospitalisations/healthcare professional visits	Improving adherence/convenience to already available therapies
Pre-filled syringes with automatic dosing of an already known product (click-based procedure; 1 click=1 dose)	New and appropriate medicine packaging and/or vial conditioning contributes to limited medicine wastage	Reduced costs associated with medicine wastage and reduced additional steps from healthcare professionals to reconstruct a medicine	Safer-use of medicines for patients and/or healthcare professionals
Electronic-based inhalers in asthma can inform on patient clinical status including alerts when degradation of respiratory function and inform on medication adherence to tailor treatment plans to each patient	Optimise timely treatment monitoring	Combination of a clinical status alert system with a treatment	Improvement of patient adherence to the treatment and improvement of the healthcare professional management of the patient condition

Despite of the benefits that value added medicines present in the hospital setting, during the hospital expert meetings, common barriers to patient access to these medicines were identified in the European hospital landscape:

- Limited involvement of patients and/or relevant hospital functional areas in the decision-making processes in the hospital setting
- Only a few countries present the opportunity for early dialogue between manufacturers and hospital stakeholders (e.g. FR and BE)
- The current purchasing processes are mainly focused on price and do not take into consideration the additional benefits of value added medicines

Recommendations to unlock the potential of value added medicines in the hospital setting

In order to unlock the potential of value added medicines for hospital care delivery and efficiency, **the following could be recommended:**

- 1 Integration of patients and/or other relevant expert areas in identification of key purchasing criteria
 - There is a need for patients and/or relevant hospital actors (healthcare professionals, hospital administrators and purchasing units) to work together to break the silos between clinical/organizational/budgetary aspects in the hospital setting
- 2 Opportunity for an early dialogue between manufacturers and hospital stakeholders
 - Importance for all stakeholders to have the opportunity to discuss the needs being addressed through specific value added medicines in the hospital sector
- 3 Adjustment of purchasing processes that take into consideration additional value dimensions that reward the additional value created.
 - Examples of these dimensions are:
 - *Benefits for patients*, for instance improved quality of life, patient ease-of-use/handling & functionality, reduced treatment duration or more convenient route of administration.
 - *Benefits for healthcare providers*, for instance improved safe-use while handling the medicine, support in monitoring the patient and reduced number of required healthcare activities for the healthcare professionals.
 - *Benefits for caregivers*, for instance reduced travel times and reduced burden for caregivers.
 - *Benefits for the healthcare system as a whole*, for instance reduced long-term costs of treatment and reduced hospitalization rates.
 - *Benefits for the economy as a whole*, for instance fewer missed days at work.

The additional value dimensions would be considered a ‘bonus’ on top of the price and would likely have different weights according to the different purchasing entities/countries. Enhanced competition stimulates innovation to address the needs in hospital care delivery and efficiency. Therefore purchasing systems have to stimulate innovation and allow its recognition and reward, but cannot be mandatory or descriptive in the benefits accepted and cannot undermine competition.

8 References

1. **Toumi M, Rémuzat C.** *Value Added Medicines: Rethink, Reinvent & Optimize Medicines, Improving Patient Health & Access.* s.l. : AIX Marseille Université and Creativ-Ceutical, 2016.
2. **OECD.** *Health at a Glance 2017, OECD Indicators.* Paris : OECD Publishing, 2017.
3. —. OECD Stat - Health expenditure and financing. [Online] [Cited: 22th June 2018.] <http://stats.oecd.org/Index.aspx?DataSetCode=SHA>.
4. **Gerken S, Merkur, S.** Belgium, Health System Review. *Health Systems in Transition.* 2010, Vol. 12, 5.
5. **OECD / European Observatory on Health Systems and Policies .** *Belgium: Country Health Profile 2017, State of Health in the EU.* Brussels : OECD Publishing, Paris / European Observatory on Health Systems and Policies, 2017.
6. **The Economist Intelligence Unit.** *Industry Report Healthcare Belgium.* London : The Economist Intelligence Unit, 2017.
7. **Pharmaceutical Health Information System.** *PHIS Hospital Pharma Report, Belgium.* 2009.
8. **Statista.** Total expenditure on health as a percentage of gross domestic product (GDP) in Belgium from 1980 to 2016. [Online] [Cited: 9th May 2018.] <https://www.statista.com/statistics/429242/healthcare-expenditure-as-a-share-of-gdp-in-belgium/>.
9. **Christelijke Mutualiteit.** *Info-fiche: De organisatie en financiering van de ziekenhuizen.* s.l. : Christelijke Mutualiteit, 2013.
10. **European Commission and Economic Policy Committee.** The 2015 Ageing Report - Economic and budgetary projections for the 28 EU Member States (2013-2016). *European Economy.* 2015, 3.
11. **Chevreur K, Berg Brigham K, Durand-Zaleski I, Henández-Quevedo C.** France: Health system review. *Health Systems in Transition.* 2015, Vol. 17, 3.
12. **Britnell, Mark.** *In Search of the Perfect Health System.* London : Palgrave, 2015.
13. **Mossialos E, Djodjevic A, Osborn R, Sarnak D.** *International profiles of health care systems.* s.l. : The Commonwealth Fund, 2017.
14. **OECD/European Observatory on Health Systems and Policies.** *France: Country Health Profile 2017, State of Health in the EU.* Paris / Brussels : OECD/European Observatory on Health Systems and Policies, 2017.
15. **The Economist Intelligence Unit.** *Industry Report Healthcare France.* London : The Economist Intelligence Unit, 2018.
16. **IRDES.** *Historique de la politique du médicament en France.* s.l. : IRDES, 2017.
17. **Busse R, Blümel M.** *Germany: health system review. Health systems in Transition.* 2014.
18. **OECD / European Observatory on Health Systems and Policies.** *Germany: Country Health Profile 2017, State of Health in the EU.* s.l. : OECD Publishing / European Observatory on Health Systems and Policies, 2017.
19. **The Economist Intelligence Unit.** *Industry Report Healthcare Germany.* s.l. : The Economist Intelligence Unit, 2018.
20. **GKV-Spitzenverband.** GKV-Spitzenverband. [Online] [Cited: 9 April 2018.] https://www.gkv-spitzenverband.de/krankenversicherung/kv_grundprinzipien/alle_gesetzlichen_kranken_kassen/alle_gesetzlichen_krankenkassen.jsp.
21. **KPMG Germany.** *KPMG Gesundheitsbarometer.* s.l. : KPMG Germany, 2017.

22. **European Observatory on Health Systems and Policies.** The Health Systems and Policy Monitor - Germany. [Online] [Cited: 12th June 2018.] <http://www.hspm.org/countries/germany28082014/countrypage.aspx>.
23. **Röttger, J. et al.** Forgone care among chronically ill patients in Germany - Results from a cross-sectional survey with 15 565 individuals. *Health Policy*. 2016, Vol. 120, 2.
24. **Porter, M. and Guth, C.** *Redefining German healthcare: Moving to a value-based system*. Heidelberg : Springer, 2012.
25. **OECD and the European Observatory on Health Systems and Policies.** *Italy: Country Health Profile 2017, State of Health in the EU*. s.l. : OECD Publishing, Paris and European Observatory on Health Systems and Policies, Brussels, 2017.
26. **Ferré F, Giulio de Belvis A, Valerio L, Longhi S, Lazzari A, Fattore G, Ricciardi W, Maresso A.** Italy: Health System Review. *Health Systems in Transition*. 2014, Vol. 16, 4.
27. **The Economist Intelligence Unit.** *Industry Report Healthcare Italy*. London : The Economist Intelligence Unit, 2017.
28. **Osservatoria Sulla Aziende e Sul Sistema Sanitario Italiano.** *Rapporto OASI 2016*. s.l. : Osservatoria Sulla Aziende e Sul Sistema Sanitario Italiano, 2016.
29. **Sagan A, et al.** Poland: Health system review. *Health Systems in Transition*. 2011, Vol. 13, 8.
30. **OECD/European Observatory on Health Systems and Policies.** *Poland: Country Health Profile 2017, State of Health in the EU*. Brussels : OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels, 2017.
31. **The Economist Intelligence Unit.** *Industry Report Healthcare Poland*. London : The Economist Intelligence Unit, 2017.
32. **Statista.** Number of hospitals in Poland from 2000 to 2015. [Online] [Cited: 23th April 2018.] <https://www.statista.com/statistics/557052/hospitals-in-poland/>.
33. **Polska Federacja Szpitali.** Healthcare system in Poland in 2017. [Online] [Cited: 23th April 2018.] <http://www.pfsz.org/english/>.
34. **European Observatory on Health Systems and Policies.** The Health Systems and Policy Monitor. *Poland*. [Online] 25th January 2018. [Cited: 23th April 2018.] <http://www.hspm.org/countries/poland27012013/countrypage.aspx>.
35. **Simões J, Augusto GF, Fronteira I, Hernández-Quevedo C.** Portugal: Health system review. *Health Systems in Transition*. 2017, Vol. 19, 2.
36. **The Economist Intelligence Unit.** *Industry Report Healthcare Portugal*. London : The Economist Intelligence Unit, 2017.
37. **OECD / European Observatory on Health Systems and Policies.** *Portugal: Country Health Profile 2017, State of Health in the EU*. s.l. : OECD Publishing, Paris / European Observatory on Health Systems and Policies, Brussels, 2017.
38. **SNS.** *Os hospitais e a Reforma do Serviço Nacional de Saúde*. 2016.
39. **OECD / European Observatory on Health Systems and Policies.** *Spain: Country Health Profile 2017, State of Health in the EU*. Paris / Brussels : OECD Publishing / European Observatory on Health Systems and Policies, 2017.
40. **García-Armesto S, Abadía-Taira MB, Durán A, Hernández-Quevedo C, Bernal-Delgado E.** Spain: Health system review. *Health Systems in Transition*. 2010, Vol. 12, 4.
41. **The Economist Intelligence Unit.** *Industry Report Healthcare Spain*. s.l. : The Economist Intelligence Unit, 2017.
42. **The Health Systems and Policy Monitor.** Health Systems in Transition (HiT) profile of Spain. *European Observatory on Health Systems and Policies*. [Online]

[Cited: 6th May 2018.]

<http://www.hspm.org/countries/spain25062012/countrypage.aspx>.

43. **Ministry of Health, Social Services and Equality.** *Sistema de información sobre listas de espera en el sistema nacional de salud.* s.l. : Ministry of Health, Social Services and Equality, 2016.
44. **OECD/European Observatory on Health Systems and Policies.** *United Kingdom: Country Health Profile.* s.l. : OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels, 2017.
45. **Cylus J, Richardson E, Findley L, Longley M, O'Neill C, Steel D.** *United Kingdom: Health system review. Health systems in Transition.* 2015.
46. **The Economist Intelligence Unit.** *Industry Report Healthcare - United Kingdom.* London : The Economist Intelligence Unit, 2018.
47. **The Guardian.** How much choice do NHS patients really have? . [Online] 25th February 2016. [Cited: 18th April 2018.] <https://www.theguardian.com/healthcare-network/2016/feb/25/how-much-choice-do-nhs-patients-really-have>.
48. **GHK Consulting Ltd. and Office of Fair Trading.** *Programme of Research Exploring Issues of Private Healthcare Among General Practitioners and Medical Consultants: Population Overview Report for the Office of Fair Trading.* s.l. : GHK Consulting Ltd. and Office of Fair Trading, 2011.
49. **Nuffield Trust.** *Public Payment and Private Provision: The Changing Landscape of Health Care in the 2000s.* s.l. : Nuffield Trust, 2013.
50. **S., Gainsbury.** *Feeling the Crunch: NHS Finances to 2020.* s.l. : Nuffield Trust, 2016.
51. **Health Consumer Powerhouse.** Euro Health Consumer Index 2017. [Online] 1st January 2018. [Cited: 22nd June 2018.] <https://healthpowerhouse.com/publications/#200118>.
52. **European Observatory on Health Systems and Policies.** Pharmaceutical regulation in 15 European Countries. *Health Systems in Transition.* 2016, Vol. 18, 5.
53. **Hogan Lovells.** *EU Pricing & Reimbursement.* 2014.
54. **Medicines for Europe.** *Market Review - European Generic Medicines Markets - Policy Overview.* 2016.
55. —. *Market Review - Biosimilar Medicines Markets - Policy Overview.* 2017.
56. **KCE.** *Barriers and opportunities for the uptake of biosimilar medicines in Belgium - Synthesis.* 2013.
57. **Bird&Bird.** *Public procurement of medicinal products.* 2014.
58. **RIVIZ-INAMI.** Het referentietrugbetalingssysteem . [Online] 24th February 2017. [Cited: 17th April 2018.] <http://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/geneesmiddel-gezondheidsproduct/terugbetalen/specialiteiten/Paginas/referentietrugbetaalsysteem-03032016.aspx#.WtXMY8JIIaV>.
59. **RIZIV-INAMI.** Convenant “Doorstart voor biosimilaire geneesmiddelen in België”. [Online] 16th December 2016. [Cited: 9th September 2018.] <https://www.riziv.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/geneesmiddel-gezondheidsproduct/geneesmiddel-voorschrijven/Paginas/biosimilaire-geneesmiddelen.aspx>.
60. **Global Health PR.** Reimbursography France. [Online] [Cited: 3th May 2018.] <http://www.globalhealthpr.com/services/france/>.
61. **Blachier C, Kanavos, P.** *Country Profile France, Pharmaceutical Pricing and Reimbursement.*

62. **Simon Kucher & Partners.** *Payers' price & market access policies supporting a sustainable biosimilar medicines market.* s.l. : Medicines for Europe, 2016.
63. **Dechert LLP.** A new incentive to encourage the prescription of biosimilars. [Online] 26th April 2018. [Cited: 27th August 2018.]
<https://www.lexology.com/library/detail.aspx?g=1eafc443-10e2-4472-9e8d-f1a1d4fb1ac3>.
64. **Smart Pharma Consulting.** *The French Generics Market (Including Biosimilars).* Paris : Smart Pharma Consulting, 2018.
65. **IGES.** *Reimbursement of Pharmaceuticals in Germany.* 2017.
66. **Danisch Ministry of Health and Prevention.** *Analysis of Hospital Pharmaceuticals - Country Report - Germany.* s.l. : COWI, 2009.
67. **Simon Kucher & Partners.** *Biosimilars in the German hospital market.* s.l. : Simon Kucher & Partners, 2017.
68. **Carone G, Schwierz C, Xavier A.** Cost-containment policies in public pharmaceutical spending in the EU. *European Economy Economic Papers.* 2012, Vol. 461.
69. **Medicines for Europe.** *Country Specific Market Access Policies.* Brussels : Medicines for Europe, 2017.
70. **Nomisma - Società Di Studi Economici S.p.A.** *The Generic Medicines System in Italy: Hospital spending, effects of tenders and sustainability.* s.l. : Nomisma, 2016.
71. **Agenzia Italiana del Farmaco (AIFA).** Presentato Secondo Position Paper AIFA sui Farmaci Biosimilari. [Online] 27 March 2018. [Cited: 1 May 2018.]
<http://www.agenziafarmaco.gov.it/content/presentato-secondo-position-paper-aifa-sui-farmaci-biosimilari>.
72. **PHIS.** *PHIS Hospital Pharma Report Poland.* 2009.
73. **Pharmaceutical Health Information System.** *PHIS Hospital Pharma Report 2010 Portugal.* s.l. : Pharmaceutical Health Information System, 2010.
74. **Belloni A, Morgan D, Paris V.** Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges. *OECD Health working Papers.* 2016, 87.
75. **PHIS.** *PHIS Pharma Profile United Kingdom.* 2010.
76. —. *PHIS Hospital Pharma Report United Kingdom.* 2009.
77. **Specialist Pharmacy Service, NHS.** An overview of NHS Procurement of Medicines and Pharmaceutical Products and Services for acute care in the United Kingdom. [Online] 19th December 2017. [Cited: 19th April 2018.]
<https://www.sps.nhs.uk/articles/an-overview-of-nhs-procurement-of-medicines-and-pharmaceutical-products-and-services-for-acute-care-in-the-united-kingdom/>.
78. **NHS England.** Commissioning framework for biological medicines (including biosimilar medicines). [Online] 12th September 2017. [Cited: 29th August 2018.]
<https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf>.
79. **Pharmaphorum.** The PPRS – new UK medicines pricing system reviewed. [Online] 13th May 2014. [Cited: 19th April 2018.] <https://pharmaphorum.com/views-and-analysis/the-pprs-new-uk-medicines-pricing-system-reviewed/>.
80. **Tillett C, Arnold A.** Pharmaphorum. [Online] 7 June 2017. [Cited: 4 April 2018.]
<https://pharmaphorum.com/views-and-analysis/uk-drug-pricing-legislation/>.
81. **Sweetman, A.** The Pharmaceutical Journal. [Online] 19 October 2017. [Cited: 4 April 2018.] <https://www.pharmaceutical-journal.com/opinion/comment/the-medical-costs-act-what-it-means-for-pharma-and-pharmacy/20203330.article>.

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82. **OECD.** OECD.Stat. *Health expenditure and financing* . [Online] [Cited: 6th June 2018.] <https://stats.oecd.org/Index.aspx?DataSetCode=SHA#>.

83. **Morgan S, Vogler S, Wagner A.** Payers' experiences with confidential pharmaceutical prices discounts: A survey of public and statutory health systems in North America, Europe and Australasia. *Health Policy*. 2017, Vol. 121.

A **Appendix A: Selection of indicators of quality of care**

In this appendix the selection of the indicators for the analysis of quality of hospital care as performed in Chapter 4 is presented. These indicators are based on available EHCI and OECD data and were included in this study if they meet both of the following two inclusion criteria:

- 1 Does the indicator refer to hospital care?
- 2 Does the indicator refer to quality of care? Please note that both outcome of care as well as accessibility to care are viewed as measures of quality.

The table below shows all indicators and shows for each indicator whether the indicator has been included in this study.

Source	Description of indicator	Subgroup	Hospital care?	Outcome or accessibility?	Selected for this research
EHCI	Patient organisations involved in decision making	Patient Rights & Information	Yes	No	No
EHCI	Right to second opinion (Without paying extra)	Patient Rights & Information	Yes	No	No
EHCI	Access to own medical record (Can patients read their own medical records?)	Patient Rights & Information	Yes	No	No
EHCI	Registry of bona fide doctors (Public awareness of ready access the info: "Is doctor X a bona fide specialist?")	Patient Rights & Information	Yes	No	No
EHCI	Web or 24/7 telephone HC info with interactivity (Information which can help a patient take decisions of the nature: "After consulting the service, I will take a paracetamol and wait and see" or "I will hurry to the A&E department of the nearest hospital")	Patient Rights & Information	No	No	No
EHCI	Cross-border care seeking financed from home (Reimbursement of cross-border care 2015 > 10 Euro € per capita during 2015)	Patient Rights & Information	No	No	No
EHCI	Provider catalogue with quality ranking ("NHS Choices" in the U.K. a typical qualification for a Green score)	Patient Rights & Information	Yes	No	No
EHCI	Patient records e-accessible (By doctor to whom patient has been referred)	Patient Rights & Information	Yes	No	No
EHCI	Patients' access to on-line booking of appointments? (Can patients book doctor appointments on-line?)	Patient Rights & Information	Yes	No	No

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EHCI	e-prescriptions	Patient Rights & Information	Yes	No	No
EHCI	Family doctor same day access (Can I count on seeing a primary care doctor today?)	Accessibility	No	No	No
EHCI	Direct access to specialist (Without referral from family doctor (GP))	Accessibility	Yes	No	No
EHCI	Major elective surgery <90 days (Coronary bypass/PTCA and hip/knee joint)	Accessibility	Yes	Yes	Yes
EHCI	Cancer therapy < 21 days (Time to get radiation/ chemotherapy after decision)	Accessibility	Yes	Yes	Yes
EHCI	CT scan < 7days (Wait for advanced diagnostic (non-acute))	Accessibility	Yes	Yes	Yes
EHCI	A&E waiting times ("Waiting time": the period between arrival at the hospital door and when a doctor starts treating/attending the problem)	Accessibility	Yes	Yes	Yes
EHCI	30-day Case Fatality for AMI (30-day case fatality for hospitalised heart infarct. For countries not in OECD: Inclination of ischaemic heart disease death trend line (log values))	Outcomes	Yes	Yes	No (OECD indicator)
EHCI	30-day Case Fatality for stroke (30-day case fatality for hospitalised. stroke. For countries not in OECD: Inclination of stroke death trend line (log values))	Outcomes	Yes	Yes	No (OECD indicator)
EHCI	Infant deaths (per 1000 live births)	Outcomes	Yes	Yes	Yes
EHCI	Cancer survival (1 minus ratio of mortality/incidence 2012 ("survival rate"))	Outcomes	Yes	Yes	Yes
EHCI	Potential Years of Life Lost (All causes, Years lost, /100000 population, age standardised)	Outcomes	No	Yes	No
EHCI	MRSA infections (Susceptibility results for S. aureus isolates, % of hospital infections being resistant)	Outcomes	Yes	Yes	Yes
EHCI	Abortion rates (# per 1000 live births)	Outcomes	No	Yes	No
EHCI	Depression (Average score on 5 mental health questions)	Outcomes	No	Yes	No
EHCI	% of diabetes patients with HbA1c < 7 (Diabetes type 1 and diabetes type 2 (latest available period))	Outcomes	No	Yes	No

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EHCI	Equity of healthcare systems (Public HC spend as % of total HC spend)	Range and reach of services provided	No	No	No
EHCI	Cataract operations per 100 000 age 65+ (Total number of procedures divided by 100 000's of pop. ≥ 65 years)	Range and reach of services provided	Yes	No	No
EHCI	Kidney transplants per million pop. (Living and deceased donors)	Range and reach of services provided	Yes	No	No
EHCI	Is dental care included in the public healthcare offering? (% of average income earners stating unmet need for a dental examination (affordability))	Range and reach of services provided	No	No	No
EHCI	Informal payments to doctors (Mean response to question: "Would patients be expected to make unofficial payments?")	Range and reach of services provided	No	No	No
EHCI	Long-term care for the elderly (# of nursing home and elderly care beds per 100 000 population 65+)	Range and reach of services provided	No	No	No
EHCI	% of dialysis done outside of clinic (% of all Dialysis patients on PD or HD in the home)	Range and reach of services provided	No	No	No
EHCI	Caesarean sections (# per 1000 live births; low = Good pre-natal care)	Range and reach of services provided	Yes	Yes	Yes
EHCI	Infant 8-disease vaccination (Tetanus, pertussis, poliomyelitis, haemophilus influenza B, hepatitis B, measles, mumps, rubella arithmetic mean)	Prevention	No	No	No
EHCI	Blood pressure (% of people 18+ with a blood pressure)	Prevention	No	No	No
EHCI	Smoking Prevention (Cigarette sales per capita age 15+ (2015) with illicit cigarettes)	Prevention	No	No	No
EHCI	Alcohol ("Binge drinking adjusted" alcohol intake p.p. 15+)	Prevention	No	No	No
EHCI	Physical activity (Hours of physical education in compulsory school)	Prevention	No	No	No
EHCI	HPV vaccination (National programme for teenage girls)	Prevention	No	No	No
EHCI	Traffic deaths (SDR/ 100 000 population)	Prevention	No	No	No

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EHCI	Rx subsidy (Proportion of total sales of pharmaceuticals paid for by public subsidy)	Pharmaceuticals	No	No	No
EHCI	Novel cancer drugs deployment rate (ATC code L01XC (monoclonal antibodies) Use per capita, MUSD p.m.p.)	Pharmaceuticals	No	No	No
EHCI	Access to new drugs (time to subsidy) (Between registration and inclusion in subsidy system)	Pharmaceuticals	No	No	No
EHCI	Arthritis drugs (TNF- α inhibitors, Standard Units per capita, prevalence adjusted)	Pharmaceuticals	No	No	No
EHCI	Statin use (Statin deployment (ATC code C10A))	Pharmaceuticals	No	No	No
EHCI	Antibiotics/capita (ATC code J01, DDD/1000 citizens per day)	Pharmaceuticals	No	No	No
OECD	Life expectancy at birth	Health status	Yes	Yes	Yes
OECD	Life expectancy by sex and education level	Health status	Yes	Yes	No
OECD	Main causes of mortality	Health status	No	No	No
OECD	Mortality from circulatory diseases	Health status	Yes	Yes	No (taken into account with life expectancy)
OECD	Mortality from cancer	Health status	Yes	Yes	No (taken into account with life expectancy)
OECD	Infant health	Health status	No	Yes	No
OECD	Mental health	Health status	No	No	No
OECD	Perceived health status	Health status	No	Yes	No
OECD	Cancer incidence	Health status	Yes	No	No
OECD	Diabetes prevalence	Health status	No	No	No
OECD	Smoking among adults	Risk factors for health	No	No	No
OECD	Alcohol consumption among adults	Risk factors for health	No	No	No
OECD	Smoking and alcohol consumption among children	Risk factors for health	No	No	No

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OECD	Healthy lifestyles among adults	Risk factors for health	No	No	No
OECD	Healthy lifestyles among children	Risk factors for health	No	No	No
OECD	Overweight and obesity among adults	Risk factors for health	No	No	No
OECD	Overweight and obesity among children	Risk factors for health	No	No	No
OECD	Air pollution	Risk factors for health	No	No	No
OECD	Population coverage for healthcare	Access to care	No	No	No
OECD	Unmet needs for healthcare due to cost	Access to care	No	No	No
OECD	Out-of-pocket medical expenditure	Access to care	No	No	No
OECD	Geographic distribution of doctors	Access to care	No	No	No
OECD	Waiting times for elective surgery	Access to care	Yes	Yes	Yes
OECD	Patient experience with ambulatory care	Quality and outcomes of care	Yes	Yes	Yes
OECD	Prescribing in primary care	Quality and outcomes of care	No	No	No
OECD	Avoidable hospital admissions	Quality and outcomes of care	Yes	Yes	Yes
OECD	Diabetes care	Quality and outcomes of care	No	No	No
OECD	Mortality following ischaemic stroke	Quality and outcomes of care	Yes	Yes	Yes
OECD	Mortality following acute myocardial infarction (AMI)	Quality and outcomes of care	Yes	Yes	Yes
OECD	Hospital mortality rates	Quality and outcomes of care	Yes	Yes	No, same score as mortality following AMI
OECD	Waiting times for hip fracture surgery	Quality and outcomes of care	Yes	Yes	Yes
OECD	Surgical complications	Quality and outcomes of care	Yes	Yes	Yes
OECD	Obstetric trauma	Quality and outcomes of care	Yes	Yes	Yes

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OECD	Care for people with mental health disorders	Quality and outcomes of care	No	Yes	No
OECD	Screening, survival and mortality for breast cancer	Quality and outcomes of care	Yes	Yes	Yes
OECD	Survival and mortality for colorectal cancer	Quality and outcomes of care	Yes	Yes	Yes
OECD	Survival and mortality for leukaemia in children	Quality and outcomes of care	Yes	Yes	Yes
OECD	Vaccinations	Quality and outcomes of care	No	No	No
OECD	Health expenditure per capita	Health expenditure	No	No	No
OECD	Health expenditure in relation to GDP	Health expenditure	No	No	No
OECD	Financing of healthcare	Health expenditure	No	No	No
OECD	Sources of healthcare financing	Health expenditure	No	No	No
OECD	Health expenditure by type of service	Health expenditure	No	No	No
OECD	Health expenditure by provider	Health expenditure	No	No	No
OECD	Capital expenditure in the health sector	Health expenditure	No	No	No
OECD	Health and social care workforce	Health workforce	No	No	No
OECD	Doctors (overall number)	Health workforce	Yes	No	No
OECD	Doctors by age, sex and category	Health workforce	Yes	No	No
OECD	Medical graduates	Health workforce	No	No	No
OECD	Remuneration of doctors (general practitioners and specialists)	Health workforce	No	No	No
OECD	Nurses	Health workforce	Yes	No	No
OECD	Nursing graduates	Health workforce	Yes	No	No
OECD	Remuneration of nurses	Health workforce	Yes	No	No
OECD	Foreign-trained doctors and nurses	Health workforce	Yes	No	No
OECD	Consultations with doctors	Healthcare activities	Yes	No	No
OECD	Medical technologies	Healthcare activities	Yes	No	No
OECD	Hospital beds	Healthcare activities	Yes	No	No

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OECD	Hospital discharges	Healthcare activities	Yes	No	No
OECD	Average length of stay in hospitals	Healthcare activities	Yes	No	No
OECD	Hip and knee replacement	Healthcare activities	Yes	No	No
OECD	Caesarean sections	Healthcare activities	Yes	No	No
OECD	Ambulatory surgery	Healthcare activities	Yes	No	No
OECD	Pharmaceutical expenditure	Pharmaceutical sector	No	No	No
OECD	Pharmacists and pharmacies	Pharmaceutical sector	No	No	No
OECD	Pharmaceutical consumption	Pharmaceutical sector	No	No	No
OECD	Generics and biosimilars	Pharmaceutical sector	No	No	No
OECD	Research and development in the pharmaceutical sector	Pharmaceutical sector	No	No	No
OECD	Demographic trends	Ageing and long-term care	No	No	No
OECD	Life expectancy and healthy life expectancy at age 65	Ageing and long-term care	Yes	Yes	Yes
OECD	Self-reported health and disability at age 65	Ageing and long-term care	No	Yes	No
OECD	Dementia prevalence	Ageing and long-term care	No	No	No
OECD	Recipients of long-term care	Ageing and long-term care	No	No	No
OECD	Informal carers	Ageing and long-term care	No	No	No
OECD	Long-term care workers	Ageing and long-term care	No	No	No
OECD	Long-term care beds in institutions and hospitals	Ageing and long-term care	No	No	No
OECD	Long-term care expenditure	Ageing and long-term care	No	No	No

B ***Appendix B: Country-specific recommendations for improved access to generic and biosimilar medicines in the hospital setting***

This appendix provides for each of the studied countries the most significant recommendations to improve access to generic and biosimilar medicines in the hospital setting. The eight studied countries are ordered alphabetically in this appendix, starting with Belgium and ending with the United Kingdom.

B.1 Belgium

For Belgium, the most important recommendation to improve access to generic medicines in the hospital market concerns the optimization of the award-criteria in tenders, which currently seem to favor originator medicines. To balance the award-criteria in order to create a level playing field for all types of pharmaceutical companies (e.g. multinationals and small-medium enterprises; originator companies and companies focusing on generic and biosimilar medicines), we recommend:

- **To incentivize physicians to implement tender award-criteria that stimulate most economic advantageous bids, instead of criteria which favor originator medicines.** Currently, physicians seem to have an incentive to add award-criteria to tenders that favor originator medicines. Incentives for most economic advantageous bids are mainly only present for hospital management, which can save the budget by reducing spending on medicines. Physicians yield considerable influence in the determination of the award-criteria. However, physicians are often self-employed and therefore an incentive to opt for award-criteria that stimulate economic advantageous bids is lacking. We, therefore, recommend implementing a benefit sharing system, where the physicians co-benefit from tenders which select the most economic advantageous bid.
- **To regulate the allowed award-criteria used in tenders.** Hospitals frequently employ award-criteria that are a proxy for quality, such as for instance distance to the manufacturing plant. In order to create a tender that stimulates the most economic advantageous bids, it is important that the tender-criteria are focused on value. Value consists of price and quality. However, the currently used proxies for quality are quite distant from actual quality, and furthermore are particularly suitable to game the tendering system in order to steer the outcome of the tender towards certain manufacturers. For instance, distance to the manufacturing plant is at best a secondary proxy for quality, as the speed of delivery is the actual proxy that distance to the manufacturing plant emulates. Thus, if the speed of delivery is important for a certain class of medicines, the speed of delivery should be the award criterion to serve as a proxy for quality, instead of distance to manufacturing plant. It is, therefore, our recommendation that a set of award criteria which serve as a proxy for quality is determined on a national basis, in order to reduce the possibility to game the tendering system. In addition, certain proxies for quality such as for instance dissolution speed of biological medicines, might require an independent assessor to fairly determine the scores across the medicines competing in a tender.

Next to optimization of the award-criteria of tenders, our recommendation is to focus on making the tendering procedure more efficient. We therefore recommend:

- **To make the tendering procedure leaner.** This reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in hospital tenders. A leaner tendering procedure stimulates competition in the procedure, which benefits the health system as a whole.
- **To define a minimum quantity per lot.** This enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids. In addition, minimum quantities per lot help manufacturers to better forecast demand, which reduces the chance of medicine shortages. The minimum quantities ideally are set at an ambitious level, in order to create an optimal balance between the required effort to participate in tenders and the potential gains of winning the tender. In order to realize ambitious minimum quantities per tender lot, tendering by groups of hospitals, instead of individual hospitals, should be encouraged.
- **To swiftly reopen tender procedures after the entry of the first multisource medicine.** Reopening tender procedures directly after entry of the first multisource medicine ensures that competition is fostered in a timely fashion. Accelerating the impact of enhanced competition in tender procedures benefits the health system as whole.

In addition, in order to stimulate market access of biosimilar medicines in the Belgian hospital setting, we recommend investing **in the education of physicians and pharmacists regarding the similarity, safety, effectiveness and cost-benefits of biosimilar medicines.** Currently, Belgian physicians and pharmacists generally have limited trust in biosimilar medicines, which is due to inadequate knowledge regarding the approval procedure for biosimilar medicines and the cost-benefits. In order to stimulate prescriptions of biosimilar medicines in hospitals, it is important that biosimilar medicines gain more trust from physicians and pharmacists.

Finally, Belgian policies such as medicine quotas focus on stimulating market shares of 'low cost' medicines. Low-cost medicines include generic and biosimilar medicines, but also originator medicines which have reduced their price. **In order to truly stimulate market access of generic and biosimilar medicines, it is important that policies such as medicine quotas start focussing specifically on generic and biosimilar medicines, instead of 'low cost' medicines.**

B.2 France

For France, the most important recommendations to improve access to generic medicines in the hospital market are related to the terms of the tenders. In order to optimize the tender procedures to stimulate access to generic medicines by fostering sustainable competition, we recommend:

- **To avoid disproportionate penalties.** Most procurement contracts stipulate penalties in case the manufacturer is unable to supply the awarded medicine. Such penalties have two chief goals:
 - To incentivize the winning manufacturer to ensure a steady supply of the awarded medicine;
 - To compensate the buying party in case of supply issues, as the buying party might have to acquire the tendered medicine from other manufacturers - at a higher price.

The height of the penalties should be sufficient to ensure that both goals are realized. However, in current practice the height of penalties seems to overshoot, which has an important negative consequence: manufacturers might decide not to participate in a tender due to disproportionality of these penalties. This consequently leads to reduced competition in the tender procedures.

In order to combat this unwarranted side-effect from such supply penalties, it might be worthwhile to explore avenues such as capping penalties and opening a dialogue with pharmaceutical companies in order to find solutions that on the one hand sustain the incentive for the manufacturer to ensure a steady supply and on the other hand don't reduce the level of competition in the tender procedures.

- **To make the tendering procedure leaner.** This reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in hospital tenders. A leaner tendering procedure stimulates competition in the procedure, which benefits the health system as a whole.

In order to further stimulate market access to biosimilar medicines in the French hospital market, we recommend:

- **To increase awareness of hospital physicians regarding the efficacy, quality and safety of biosimilar medicines.** There is still cultural reluctance among physicians in France to prescribe biosimilar medicines. In order to improve the attitude of hospital physicians towards biosimilar medicines, it is important to disseminate information regarding efficacy, quality and safety to hospital physicians, who are key procurement stakeholders in the hospital market. Especially independent scientific associations and specialized media are useful for this purpose, as they are generally accepted as trustworthy and objective.

B.3 Germany

For Germany, the most important recommendations to improve access to generic medicines in the hospital market are related to the terms of the (non-public) tenders. In order to optimize the tender procedures to stimulate access to generic medicines by fostering sustainable competition, we recommend:

- **To define a minimum and a maximum volume estimates.** This enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids and to more accurately weigh the impact of potential penalties in case of medicine shortages. In addition, minimum and maximum quantities per lot help manufacturers to better forecast demand, which reduces the chance of medicine shortages.
- **To avoid disproportionate penalties.** Most procurement contracts stipulate penalties in case the manufacturer is unable to supply the awarded medicine. Such penalties have two chief goals:
 - To incentivize the winning manufacturer to ensure a steady supply of the awarded medicine;
 - To compensate the buying party in case of supply issues, as the buying party might have to acquire the tendered medicine from other manufacturers - at a higher price.

The height of the penalties should be sufficient to ensure that both goals are realized. However, in current practice the height of penalties seems to overshoot, which has an important negative consequence: manufacturers might decide not to participate in a tender due to disproportionality of these penalties. This consequently leads to reduced competition in the tender procedures.

In order to stimulate market access to biosimilar medicines in the hospital market in Germany, we recommend:

- **To intensify informational campaigns for novel biosimilar medicines.** In order to improve the attitude of hospital physicians and hospital pharmacists towards novel biosimilar medicines, it is important to disseminate information regarding efficacy, quality and safety to the key procurement stakeholders in the hospital market: hospital physicians and hospital pharmacists. Especially independent scientific associations and specialized media are useful for this purpose, as they are generally accepted as trustworthy and objective (67). In addition, it might be useful to disseminate information about cost-efficiency to hospital controllers and hospital managers, who have an incentive to limit pharmaceutical spending in hospitals (67).
- **To stimulate innovative models for 129a SGB-V outpatient contracts that reward the most economical medicines.** The most frequently employed 129a SGB-V contract model covers list price minus a standard discount percentage, which generally results in higher reimbursement prices for originator biologicals than for biosimilar medicines. In order to create savings for the sickness funds, and thus for the German healthcare system as a whole, more innovative models of 129a SGB-V contracts that focus on cost-savings should be stimulated. Examples for such contract models are a standard reimbursement amount per INN, or differentiated discount rates between originator and biosimilar medicines (67).

- **To further implement and enforce quotas for biosimilar medicine use.** Quotas for biosimilar medicines in the hospital market are another way to increase hospital market access to biosimilar medicines. Compared to the financial incentive of procurement of the biological medicine with the lowest net price, quotas have the advantage that they give physicians more therapeutic freedom, which might increase acceptance among clinical decision makers. In addition, quotas do not create a constant price pressure, which might lead to more sustainable market dynamics in the longer run (67). Currently there are regional differences in Germany with respect to quotas: some are highly managed/ enforced and others not.

B.4 Italy

For Italy, the main recommendation to improve market access to generic and biosimilar medicines in the hospital setting is to sustainably foster competition in the tender procedure for generic medicines by balancing risk and reward.

- To increase the potential reward, we recommend to **deviate from the currently employed lowest bid procedure towards a most economic advantageous procedure**, which takes other qualitative elements into account that add value to bids, such as for instance availability of different medicinal strengths, availability of required devices for administration of the medicine and reliability of suppliers. A shift to a most economic advantageous procedure likely stimulates competition, as manufacturers can compete on more parameters than just price. However, it is important to closely monitor the effects of such additional award-criteria, as they should not a priori favor certain manufacturers, such as for instance in Belgium, where additional award-criteria seem to favor the originator manufacturers (see chapter 4.1.4).
- To decrease the potential risks, we propose the following recommendations:
 - **Define a minimum and maximum volume estimates.** This enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids and to accurately weigh the impact of potential budget overruns and subsequent penalties due to the payback system in their bids. In addition, minimum and maximum quantities per lot help manufacturers to better forecast demand, which reduces the chance of medicine shortages. In order to enable medicine manufacturers to weigh economies of scale in their bids, price/volume adjustment mechanisms in tenders should be defined (e.g. different prices for different ranges of order quantities).
 - **Eliminate the payback mechanism.** As described in chapter 5.4.4, the payback mechanism creates significant revenue risks for manufacturers, decreases competition and might lead to higher costs for the healthcare system in the medium to long term. We therefore recommend to replace the payback mechanism with more apt policies to limit pharmaceutical spending in the hospital sector, by not only focusing on pharmaceutical companies, but rather focusing on the entire ecosystem, including prescribers and providers.
 - **Make the tendering procedure leaner.** This reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in tenders. A leaner tendering procedure stimulates competition in the procedure, which benefits the health system as a whole.
 - **Optimize the value of the starting bid prices.** Starting bid prices should be optimized in order to prevent discouragement of medicine manufacturers to participate in the tender. This stimulates competition and also likely reduces the number of unawarded lots, with benefits to the healthcare system as a whole.

In addition to fostering sustainable competition in the tender procedure by balancing risk and reward, competition can be stimulated by **swift reopening of tender procedures upon market entry of a generic (or biosimilar) medicine**. In current practice, procurement authorities usually turn to the originator manufacturer upon

market entry of a generic or biosimilar medicine, demanding a lower price from the originator manufacturer. Swift reopening of the tender procedure, instead of asking for a discount from the originator company, increases the level of competition, and therefore will benefit the healthcare system as a whole.

B.5 Poland

For Poland, the most important recommendations to improve access to generic medicines in the hospital setting are related to the public tender procedures. In order to optimize these procedures to stimulate access to generic medicines by sustainably fostering competition, we recommend:

- **To define accurate volume estimates.** This enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids. In addition, minimum and maximum quantities per lot help manufacturers to better forecast demand, which reduces the chance of medicine shortages.
- **Make the tendering procedure leaner.** This reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in tenders. A leaner tendering procedure stimulates competition in the procedure, which benefits the health system as a whole. This recommendation also applies to tenders for biosimilar medicines.

In order to stimulate market access to biosimilar medicines in the hospital setting in Poland, we recommend:

- **To increase awareness of hospital physicians and pharmacists regarding the efficacy, quality and safety of biosimilars.** There is still reluctance among physicians in Poland to prescribe biosimilar medicines due to interchangeability concerns related mainly to safety and efficacy. In order to improve the attitude of hospital physicians towards biosimilar medicines, it is important to disseminate information regarding efficacy, quality and safety to hospital physicians. Especially independent scientific associations and specialized media are useful for this purpose, as they are generally accepted as trustworthy and objective. In addition, it might be useful to disseminate information about cost-efficiency to hospital controllers and hospital managers, who have an incentive to limit pharmaceutical spending in hospitals.
- **To expand guidelines regarding treatment switching.** Currently, only for Infliximab a guideline regarding treatment switching is available. This guideline allows switching to biosimilar variants of Infliximab at any level of therapy. Expanding this guideline to other originator biologicals would allow NFZ and hospitals to put more focus on increasing access to biosimilar medicines for the group of patients already undergoing treatment with an originator biological medicine.

B.6 Portugal

For Portugal, the most important recommendations to improve access to generic and biosimilar medicines in the hospital market are related to procurement and pricing. In order to optimize the procurement and pricing systems to stimulate access to generic and biosimilar medicines, we recommend:

Revise the current model of central hospital tenders and abolish further hospital auctions

The current model of central hospital tenders - CPAs (*Contrato Público de Aprovisionamento*)* - leads to a decrease of 91% on the average price of medicines. Additionally to this price decrease, generic and biosimilar manufacturers can still be subject to hospital tenders leading to a further price decrease. This extreme price erosion undermines the sustainability of manufacturers and may force generic and biosimilar manufacturers out of the market leading to decreased competition and a higher risk of medicines shortages. To guarantee long-term sustainability and competition, we recommend:

- **To balance the pressure on price of generic and biosimilar medicines to guarantee the long-term sustainability** of the generic and biosimilar manufacturers. The resultant prices of the central hospital tenders must be adjusted to the average price of sales in the last two years, to increase the number of suppliers/competition and decrease the risk of medicine shortages
- To establish mandatory **lead times of 120 days to guarantee predictability**
- To **eliminate the practice of raffling the tender winners** when there is equality of prices. The criterion to win the tender should be a repartition between the manufacturers with the same price or respect the hospital procedures previously foreseen

Award tenders to multiple winners. Single-winner tenders lead to a risk of reduced competition, as only one manufacturer is active in the market and other manufacturers might choose to discontinue their production consequently. This might lead to a reduced number of manufacturers participating in the next round of tenders. In addition, single-winner tenders might contribute to medicine shortages. In the case of a supply issue of the sole tender winner, other manufacturers might not be able to cope with the sudden demand as they might have significantly reduced or even entirely discontinued their production. Hence, multi-winner tenders increase competition in the tendering system and might help to prevent medicine shortages, which both benefit the health system as a whole.

Abolish the 'payback rates' for the generic and biosimilar medicines industry

A 'payback rate' of 14.3% for medicines applied to the prescription of medicines in hospitals/clinics puts in place a barrier for the introduction of generic and biosimilar medicines in the hospital sector threatening the sustainability and efficiency of the healthcare system. As generic and biosimilar medicines are driving healthcare efficiency rather than healthcare costs, these 'payback rates' must urgently be reconsidered and not applied to this sector.

Increase the minimum target agreements of 20% to use biosimilar medicines

Hospitals should be rewarded if pre-established target agreements of certain biosimilar medicines are attained respectively during the first, second and third year of marketing of that biosimilar medicine. Currently, there is a minimum target agreement of 20% that should be increased to guarantee that more patients are treated with biosimilar medicines.

To draft national guidelines with respect to treatment switching. A guideline with respect to treatment switching would allow hospitals and governing bodies such as health authorities and government agencies to put more focus on increasing access to biosimilar medicines for the group of patients already undergoing treatment with an originator biological medicine.

Reinforce the benefit sharing methods. In order to create cost-efficiency and incentivize hospitals, HCP and authorities to increase the use of biosimilar medicines in the group of patients already undergoing treatment, benefit sharing methods should be encouraged. Share financial savings will result to more employment of biosimilar medicines, between the hospitals and the governing bodies that finance the hospitals in the national health systems. Furthermore, if the benefit sharing methods are also applied to physicians and other healthcare professionals, an additional incentive to prescribe and use of biosimilar medicines will be reached.

B.7 Spain

For Spain, the most important recommendations to improve access to generic medicines in the hospital setting are related to the tender procedures. In order to optimize the tender procedures to stimulate access to generic medicines by sustainably fostering competition, we recommend:

- **To define accurate volume estimates.** This enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids. In addition, minimum and maximum quantities per lot help manufacturers to better forecast demand, which reduces the chance of medicine shortages. The minimum quantities ideally are set at an ambitious level, in order to create an optimal balance between the required effort to participate in tenders and the potential gains of winning the tender.
- **To switch from the frequently employed lowest bid procedure towards a most economic advantageous procedure,** which takes other qualitative elements into account that add value to bids, such as for instance availability of different medicinal strengths, availability of required devices for administration of the medicine and reliability of suppliers. A shift to more economic advantageous procedures likely stimulates competition, as manufacturers can compete on more parameters than just price. However, it is important to closely monitor the effects of such additional award-criteria, as they should not a priori favor certain manufacturers, such as for instance in Belgium, where additional award-criteria seem to favor the originator manufacturers (see chapter 4.1.4).
- **Make the tendering procedure leaner.** This reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in tenders. A leaner tendering procedure stimulates competition in the procedure, which benefits the health system as a whole. This recommendation also applies to tenders for biosimilar medicines.

In order to stimulate market access of biosimilar medicines in the hospital setting in Spain, we recommend:

- **To implement hospital quotas for biosimilar medicine use.** Quotas for biosimilar medicines in the hospital market are an alternative way to increase hospital market access of biosimilar medicines. Compared to the financial incentive of procurement of the biological medicine with the lowest net price, quotas have the advantage that they give physicians more therapeutic freedom, which might increase acceptance among clinical decision makers. In addition, quotas do not create a constant price pressure, with might lead to more sustainable market dynamics in the longer run. In some regions in Spain quotas are already implemented, however there is still much potential for further implementing hospital quotas for biosimilar medicine use across Spain.
- **To differentiate between generic medicines and biosimilar medicines in pricing and reimbursement regulations.** Similar to generic medicines, biosimilar medicines face automatic price reductions upon market entry. However, compared to generic medicines, biosimilar medicines generally require more R&D-investments, mainly owing to the requirement of extensive clinical comparability studies. As biosimilar medicines do require a significant investment prior to market entry, automatic price reductions might reduce the appetite of manufacturers to invest in the development

of biosimilar medicines for the Spanish market. Abolishment (or decrease) of the automatic price reductions likely increases competition within the biosimilar medicine market, which benefits the health system as a whole.

- **To draft a national guideline with respect to treatment switching.** A guideline with respect to treatment switching would allow regional health authorities to put more focus on increasing access to biosimilar medicines for the group of patients already undergoing treatment with an originator biological medicine.

B.8 The United Kingdom

For the UK, the most important recommendations to improve access of generic medicines in the hospital setting are related to the tender procedures. In order to optimize the tender procedures to stimulate access of generic medicines by sustainably fostering competition, we recommend:

- **To define a minimum and a maximum quantity per lot.** This enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids and to more accurately weigh the impact of potential penalties in case of medicine shortages. In addition, minimum and maximum quantities per lot help manufacturers to better forecast demand, which reduces the chance of medicine shortages. The minimum quantities ideally are set at an ambitious level, in order to create an optimal balance between the required effort to participate in tenders and the potential gains of winning the tender. In order to realize ambitious minimum quantities per tender lot, tender sizes batches should be optimized: large enough to encourage participation, but not so big that a single manufacturer dominates a market, as the latter might lead to an increased risk of medicine shortages in case of supply issues at the dominating manufacturer.
- **To switch from the frequently employed lowest bid procedure towards a most economic advantageous procedure,** which takes other qualitative elements into account that add value to bids, such as for instance availability of different medicinal strengths, availability of required devices for administration of the medicine and reliability of suppliers. A shift to more most economic advantageous procedures likely stimulates competition, as manufacturers can compete on more parameters than just price. However, it is important to closely monitor the effects of such additional award-criteria, as they should not a priori favor certain manufacturers, such as for instance in Belgium, where additional award-criteria seem to favor the originator manufacturers (see chapter 4.1.4).
- **To avoid disproportionate penalties.** Most procurement contracts stipulate penalties in case the manufacturer is unable to supply the awarded medicine. Such penalties have two chief goals:
 - To incentivize the winning manufacturer to ensure a steady supply of the awarded medicine;
 - To compensate the buying party in case of supply issues, as the buying party might have to acquire the tendered medicine from other manufacturers - at a higher price.

The height of the penalties should be sufficient to ensure that both goals are realized. However, in current practice the height of penalties seems to overshoot, which has an important negative consequence: manufacturers might decide not to participate in a tender due to disproportionality of these penalties. This consequently leads to reduced competition in the tender procedures.

In order to stimulate market access of biosimilar medicines in the hospital setting in the UK, we recommend:

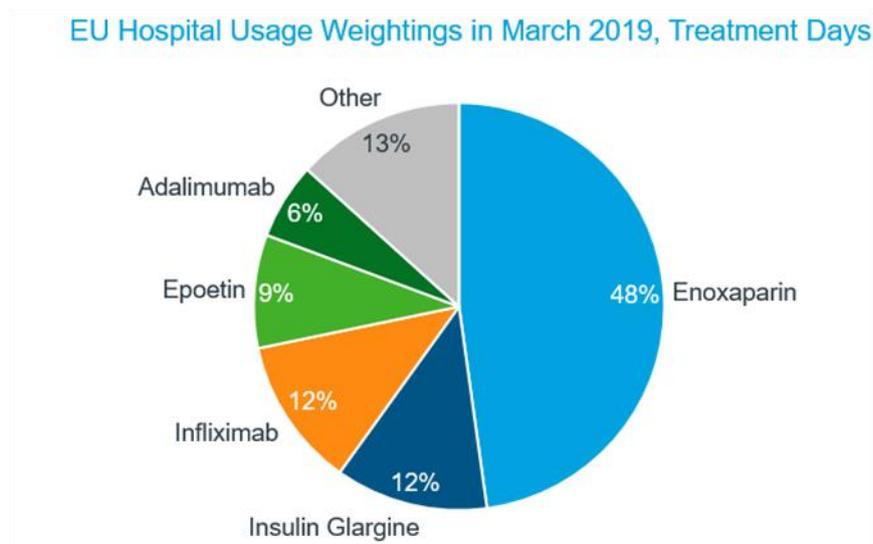
- **To standardize the use of benefit sharing methods for all biosimilar medicines**
In order to incentivize hospitals to increase market share of biosimilar medicines in

the group of patients already undergoing treatment, common benefit sharing methods should be encouraged that share financial savings, owing to more employment of biosimilar medicines, between the hospitals and CCGs.

- **To replicate the principles of the 2017 ‘Commissioning framework for biological medicines (including biosimilar medicines)’ by NHS England into clinical practice.** In order to do so, commissioners should ensure that providers have policies in place to encourage clinically and cost effective prescribing of biological medicines. In addition, commissioners and providers should have a communication and implementation plan in place to alert prescribers and to engage patients with respect to better value biosimilar medicines that become available.

C **Appendix C: Usage of biosimilar medicines in the hospital setting**

A



B

Germany Hospital Usage Weightings in March 2019, Treatment Days

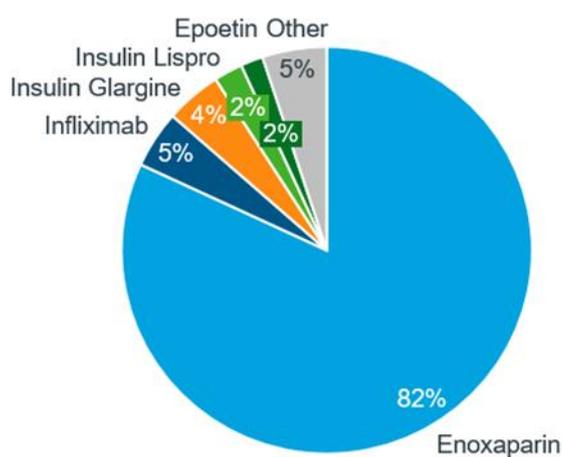


Figure 20: Weighted use of biosimilar in EU hospital setting (A) and Germany (B). All biosimilar launched in Europe by March 2019 are included. Source: IQVIA Thought Leadership, IQVIA Midas MTH March 2019.