HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The healthcare economy in Belgium involves both public and private actors working under a unified regulatory framework. Reimbursed healthcare services are offered by public institutions, private institutions, and individual healthcare providers, all of whom generally adhere to the same rules, enjoy therapeutic freedom and provide comparable services. The organisation of the healthcare system is primarily shared between the federal government and federated governments (in the three regions of Flanders, Wallonia and Brussels).

The federal authorities oversee matters of national interest, such as the compulsory national health insurance system, the regulation of healthcare products and activities, and the oversight of healthcare professionals and patients' rights. This is managed through the Federal Public Service (FPS) for Health, Food Chain Safety and Environment, specifically its Health Directorate, which ensures the overall organisation and functioning of the healthcare system. The federated authorities focus on regional aspects of healthcare, including the organisation of primary care, elderly care, mental health services, rehabilitation, health promotion and disease prevention.

Private health insurance in Belgium plays a supplementary role in the healthcare economy. It covers services not fully reimbursed by the public system, such as additional inpatient costs or enhanced accommodations during hospitalisation. These policies are offered by both mutual insurance funds and private for-profit insurance companies, providing complementary and supplementary coverage options. Mutual insurance funds, as non-profit private entities, operate the reimbursement system for healthcare services covered by compulsory health insurance and provide replacement income in cases of long-term illness. Additionally, the Auxiliary Fund for Sickness and Disability Insurance, a public entity, offers compulsory health insurance to individuals who are not affiliated with any recognised mutual insurance funds. Unlike the others, the auxiliary fund provides only compulsory health insurance and does not offer supplementary coverage.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

Belgium's legal framework for healthcare financing and reimbursement is complex and multi-layered, with the Coordinated Law of 14 July 1994 on Compulsory Insurance for Medical Care and Benefits serving as its cornerstone. This foundational law establishes the main principles of universal access to healthcare, reimbursement mechanisms, and the roles and

responsibilities of key stakeholders within the system. This framework is further elaborated through specific royal (and/or ministerial) decrees.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

In Belgium, health policy and the regulation of the healthcare system are divided between the federal state and federated governments. At the federal level, the Federal Parliament acts as the legislative body, while the Minister of Social Affairs and Public Health carries the executive functions. Several other bodies play crucial roles in healthcare financing and regulation. The FPS for Health, Food Chain Safety and Environment oversees healthcare professionals and hospitals, managing licensing, recognition and quality standards for facilities and practitioners. The FPS for Social Security coordinates federal social security policy by conducting research, analysing data, developing regulations and recognising benefits for disabled individuals. It works alongside the National Social Security Office (NSSO) and National Institute for Social Security of the Self-employed, which collect social security contributions and redistribute the budget across sectors. The National Institute for Health and Disability Insurance (NIHDI) manages compulsory health insurance, organising and controlling the reimbursement of healthcare services and products, ensuring financing for healthcare providers and sickness funds, and monitoring healthcare expenditure. Mutual insurance funds, which are private non-profit organisations with a public interest mission, administer compulsory health and disability insurance under the supervision of the Authority for Sickness Funds and National Associations of Sickness Funds.

Other important federal entities include the Federal Agency for Medicines and Health Products (FAMHP); the Federal Agency for the Safety of the Food Chain (FASFC); Sciensano (a federal research institute); the Belgian Health Care Knowledge Centre (KCE), which provides advice on scientific and technical healthcare matters; and the Superior Health Council, which serves as the link between government policy and the scientific community in public health.

Healthcare organisation and policy are also heavily influenced by a variety of non-governmental stakeholders. These include professional and deontological associations of healthcare professionals, healthcare institutions, associations representing the pharmaceutical industry, trade unions, employer organisations and other interest groups.

At the federated level, each region – Flanders, Wallonia and Brussels – has its own parliament, government and budget. Executive power lies with regional ministers and deputy ministers responsible for healthcare, overseeing areas such as primary care, mental health services, disease prevention and health promotion.

4. Has there been a change to healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The Covid-19 pandemic had a significant operational and financial impact on the Belgian healthcare system. Temporary measures were implemented, such as increased hospital funding, rapid procurement of medical supplies, and support for vaccination campaigns and mental health services. Substantial emergency funds were allocated at both the federal and regional levels to address immediate challenges. However, these actions did not lead to any significant permanent changes to the healthcare financing and reimbursement system, except

for introducing the possibility to request the reimbursement of telemedicine consultations (under specific conditions, see the answer to question 7), which was not recognised prior to the pandemic.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

The Belgian healthcare system is based on compulsory health insurance, which ensures solidarity among all citizens without selection based on health risks. To access this system, individuals must meet two conditions: registration with a recognised mutual insurance fund and the payment of social contributions. Approximately 99 per cent of the population is covered under this system, which includes two main schemes: the general scheme for most citizens and a specific scheme for the self-employed. Both economically active and inactive individuals, as well as their dependents, are included. The small percentage of the population not covered, primarily due to unmet administrative or financial requirements, is not entirely excluded from necessary medical care. Support is available through the Public Centre for Social Assistance (Openbaar Centrum voor Maatschappelijk Welzijn or OCMW/Centre public d'action sociale or CPAS). Vulnerable groups, such as undocumented migrants, asylum seekers, and refugees, can access care through the Urgent Medical Aid scheme, their reception centre or local public welfare services. Additionally, some individuals are eligible for a higher reimbursement rate, which reduces their personal financial contributions for specific services.

Healthcare providers in Belgium operate as independent professionals and are not directly contracted by mutual insurance funds. The services eligible for partial or full coverage under compulsory health insurance are listed in the national fee schedule, as further described in the answer to question 7. The same applies to suppliers of medical goods. For more information on the reimbursement regimes and reimbursement conditions, please refer to the answer to question 12.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

The financing of the Belgian social security system, including compulsory health insurance, is based on the principle of pooling funds. It combines resources from various sources into a single fund, which then allocates money across the seven branches of social security based on their financial needs. These branches include old-age and survivor's pensions, unemployment, insurance for accidents at work, insurance for occupational diseases, family benefits, annual vacations and compulsory health insurance, the latter being managed by the NIHDI.

Public funding for compulsory health insurance is only partially derived from 'own receipts'. The main revenue sources are social security contributions, supplemented by alternative financing, government subsidies, specific allocated receipts and other sources. Social contributions (premiums) are proportional to income and completely independent of health risk.

Under the general scheme, both employees and employers contribute to the system, with

payments made to the NSSO as a proportion of gross income. The contribution rates vary depending on the worker's status. Self-employed individuals pay their contributions to the Social Insurance Funds with which they are affiliated, and these funds forward the contributions to the Social Security Office for the Self-Employed.

The budget for compulsory health insurance is distributed by the NIHDI to the mutual insurance funds, which reimburse and make payments to their members. In addition to this public financial funding, members of private mutual insurance funds also pay a mandatory annual membership fee, which varies between funds, but is quite limited and typically ranges from €97.20 to €114 per year. This fee finances the funds' supplementary services, such as childbirth benefits or affordable youth vacations.

For supplementary private insurance, financial contributions (annual or monthly premiums) are determined by the offering entities, whether they are non-profit mutual insurance funds or private insurers. While these entities have the autonomy to set premiums, their rates and policies are subject to regulatory oversight to ensure fairness and transparency.

7. How is the coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

The coverage of medical services by health insurance carriers in Belgium is regulated through a nationally established fee schedule, known as the 'nomenclature'. This document specifies the official fees and cost-sharing mechanisms for reimbursed services. The fees and conditions are determined through conventions and agreements negotiated on a recurrent basis between representatives of mutual insurance funds and healthcare providers. These agreements may also include specific conditions related to the content, quality or quantity of care provided. All agreements must remain within the allocated budget and are submitted to the Budget Control Committee within the NIHDI for approval.

Services not included in the nomenclature are not eligible for reimbursement. Sickness funds are legally obligated to reimburse claims from their registered members based on the official reimbursement rates established in the fee schedule. Reimbursement decisions fall under the jurisdiction of various commissions within the NIHDI, which prioritise evidence-based practices with high therapeutic value. Aesthetic services, such as plastic surgery or orthodontics, are only reimbursed under specific conditions.

Since the Covid-19 pandemic, telemedicine consultations have been eligible for reimbursement under specific conditions (and thus included in the nomenclature). A new telemedicine reimbursement system was adopted on 1 August 2022. It covers both telephone and video consultations, and both services provided by general practitioners and specialists. Reimbursed telemedicine consultations include consultations with a physician who has an established treatment relationship with the patient, referrals to specialists by a primary care physician and consultations as part of organised on-call general practitioner services. Telemedicine appointments must be requested by the patient, agreed upon by the physician, and conducted with access to the patient's medical file to ensure proper care. The application/platform used for consultations must also meet certain requirements in terms of data security and confidentiality. Some mobile applications for remote healthcare monitoring (eg, remote physiotherapy) are also increasingly recognised and reimbursed. The August 2022

regime is, however, meant to be temporary and a new (permanent) reimbursement system for telemedicine is currently still in the works.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

Belgian hospitals mainly finance their operations through a dual remuneration structure. The first source of funding is the Budget of Financial Means (BFM), an annual national budget allocated to cover nursing and non-medical activities. This budget is distributed among hospitals based on various criteria, including pathology-weighted lengths of stay, with the aim of covering clinical operational costs through 'justified activities'.

The second source of funding comes from medical and medico-technical acts, such as consultations, laboratory tests, medical imaging, technical procedures and paramedical activities like physiotherapy, which are financed through a fee-for-service system. Hospitals can also invoice patients for a meals service, toiletries or room upgrades. Patients generally pay healthcare providers directly for these services and are subsequently reimbursed by their mutual insurance funds or additional private insurance. Reimbursement rates and conditions (including the applicable copayment amount) are defined in the national nomenclature. For additional details on the financing and reimbursement of medical services, medicinal products and medical devices, please refer to the relevant questions above and below.

9. How are the prices of such services determined? How is economic efficiency controlled?

The pricing of medical services provided in hospitals follows the same approach as when these services are offered in a healthcare provider's private practice. For more details, please refer to the answer to question 11.

For hospital stays, a 'nursing day price' is established by the FPS for Health. This flat rate includes the costs of accommodation and nursing care during a hospital stay and is calculated based on the BFM. Additionally, the patient's personal contribution to the nursing day price is legally regulated.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

The fee charged by healthcare providers consists of two parts: the amount reimbursed by mandatory health insurance and the copayment, which is the patient's personal contribution. The extent to which, and the amount by which, a service provided by a healthcare professional is reimbursed is determined by the nomenclature discussed above (see the answer to question 7). The remainder is paid by the patient.

Depending on the situation, the patient may either pay the full amount upfront and subsequently request reimbursement of the reimbursed part from their mutual insurance fund or pay only their personal contribution directly to the healthcare provider, with the remaining amount being billed directly by the healthcare provider to the mutual insurance

fund.

Certain individuals are also entitled to a reduction in the copayment or an increased reimbursement.

The copayment can, in some cases, also be reimbursed by the patient's additional private insurance.

11. How are the prices of such services determined? How is economic efficiency controlled?

The prices for medical services are established through an agreement ('convention') between representatives of healthcare providers, health insurance organisations and the government in the nationally established fee schedule (the 'nomenclature'), which serves as a basis for determining the rates for medical services. Private healthcare providers may choose to adhere to this agreement, thereby committing to apply the agreed-upon rates and fees as specified in the agreement. Providers who opt into this agreement receive a financial benefit.

Individual healthcare providers may also choose not to adhere to the agreement. In such cases, they are 'non-conventioned' and permitted to charge additional fees on top of the agreed-upon rates. These additional fees are not covered by the health insurance system and must be borne entirely by the patient. Additionally, some doctors only partially adhere to the agreed pricing. For example, they may apply the agreed-upon rates for hospital consultations during certain hours or days, but retain the freedom to set their own fees for home consultations or other services outside these times.

All doctors are required to clearly inform their patients about whether or not they adhere to the fixed-fee agreement. This information is typically provided through notices displayed in their waiting rooms. This still allows patients free choice.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

In Belgium, pharmaceuticals (medicinal products) and medical devices are governed by complex financing and reimbursement rules. For medicinal products, compulsory health insurance reimburses only those listed as reimbursable pharmaceutical specialties, following the positive reimbursement list approach. The Minister of Health determines which products are included based on recommendations from the Commission for Reimbursement of Medicinal Products. This decision considers factors such as the product's therapeutic value, price, proposed reimbursement basis, relevance to medical practice in addressing therapeutic and social needs, impact on healthcare expenditure, and the cost-benefit relationship between healthcare costs and therapeutic value. Reimbursement amounts are categorised into seven groups (A, B, C, Cs, Cx, Fa and Fb), which specify the percentage reimbursed by health insurance and the patient's copayment. For example, vital medicines in Category A are fully reimbursed, while those for symptomatic treatment in Category C are reimbursed at 50 per cent. These rates are applied to the reimbursement basis, which is the public price or, if unavailable, the ex-factory price, and the amount payable by the patient is legally capped.

Reimbursement for medical devices is equally complex, with procedures and levels of reimbursement depending on the type of device. Certain devices, such as implants, may be

reimbursed individually, while others are included in the general expenses of the hospital where they are used (eg, bandages). Rules also exist to regulate the payment or copayment levels required from patients, ensuring a structured approach to cost-sharing.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

The prices of medicinal products in Belgium are determined through a pricing procedure managed by the Price Department of the FPS for Economic Affairs via its 'mediprices' website. Pharmaceutical companies can only market a medicinal product after an official maximum price has been set. The Minister of Economic Affairs establishes this maximum ex-factory price, representing the sales price (excluding VAT) that companies may charge to wholesalers or pharmacists based on scientific and economic data submitted by the applicant. This pricing process runs parallel to the reimbursement procedure and varies depending on whether the medicinal product is reimbursable or non-reimbursable. The ex-factory price forms part of the maximum public price, which is the final price paid by the patient and includes the ex-factory price, predefined profit margins for wholesalers and pharmacists, a pharmacist's fee (for reimbursable products), and VAT. To ensure cost control, these profit margins are legally capped.

In Belgium, the pricing of medical devices is generally unregulated, allowing manufacturers to set prices freely. However, certain categories of medical devices, such as implantable devices and hearing aids, are subject to specific regulation. These devices are treated similarly to medicinal products, see above. Additionally, in some instances, maximum profit margins may be imposed.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

[Note that a lot of case law in Belgium is not published.]

Supreme Court Judgment No S.17.0031.F dated 20 May 2019

This case concerned a dispute over reimbursement for medical treatment received in Germany. The patient sought full reimbursement, even though the treatment cost exceeded Belgian rates. The Court of Appeal initially ruled in favour of the patient, requiring full reimbursement (minus the patient's contribution). The Supreme Court overturned this decision, ruling that under Belgian and European Union law, reimbursements for cross-border healthcare are capped at the amount the treatment would have cost in Belgium. This ensures the financial sustainability of the healthcare system.

Constitutional Court Judgment No 44/2024 dated 11 April 2024

The Constitutional Court reviewed a law prohibiting non-conventioned healthcare providers from charging additional fees for outpatient care provided to low-income patients eligible for increased reimbursement. Providers and associations argued that the law unfairly restricted their ability to set fees, jeopardised their financial viability and limited patient choice. The government defended the measure as essential to ensure equitable access to healthcare for

vulnerable populations and to address disparities in access to care. The court ultimately upheld the prohibition, finding it justified and proportionate to the goal of promoting financial accessibility for low-income patients.

Constitutional Court Judgment No 31/2012 dated 1 March 2012

The Constitutional Court addressed alleged discrimination in the rules on the importation of medicines to Belgium. The case arose when the NIHDI denied reimbursement for a medicine imported by a pharmacist for a patient with Still's disease. The medicine had been authorised in Belgium, but was not yet available on the market. NIHDI argued that the medicine should have been purchased directly abroad by the patient instead of through a pharmacist. The court examined the law, which allowed pharmacists to import medicines that were not authorised for sale in Belgium, but did not permit them to import medicines that had been authorised, but were not yet commercially available. The Court found this distinction unjustified and discriminatory. It noted that the rule placed an unreasonable burden on patients, forcing them to travel abroad to obtain medicines that could otherwise be safely imported by a pharmacist. This also denied patients the benefits of pharmacists' expertise in ensuring the proper storage, transport and usage of the medicines, which could compromise public health and safety.

Constitutional Court Judgment No 114/2007 dated 19 September 2007

The Court reviewed a challenge brought by Merck Sharp & Dohme, a pharmaceutical company, against provisions in Belgian healthcare legislation imposing levies on pharmaceutical companies based on their sales of reimbursable medicines. These measures included sales-based contributions, additional discounts for exceeding sales thresholds, and retroactive application of the levies. Merck argued that the measures were discriminatory, disproportionate and unfairly targeted pharmaceutical companies, while other healthcare actors, such as hospitals and insurers, were exempt. They also claimed that the retroactive nature of the levies created legal uncertainty.

The government defended the provisions as essential to maintaining healthcare affordability and financial sustainability. The Court agreed, stating that the measures reasonably sought to protect patients from being limited to higher-priced original medicines if generics disappeared from the market. Adjusting the reimbursement basis to the public price set by the company was deemed a rational and effective way to manage healthcare budgets. The Court also noted that pharmaceutical companies remained free to increase prices, but would be encouraged to align them with reimbursement levels to stay competitive.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes or trends for healthcare financing and reimbursement, and briefly indicate how these may foreseeably affect the medical sector in the near future.

Belgium has implemented and is currently carrying out several reforms and innovations to improve its healthcare system and adapt it to modern needs. Some of these include the following:

Reform nomenclature

Belgium is currently modernising the nomenclature (ie, the coded list of medical services wholly or partially reimbursed by compulsory health insurance) that defines and classifies reimbursable medical services. Indeed, the existing structure has been criticised for its complexity, outdated design and inability to reflect recent developments in medical care, such as telemedicine and interdisciplinary collaboration. The reform should introduce a shift in the classification system, where medical acts will be categorised based on the anatomical area treated rather than the physician's specialisation. The reform consists of three phases: Phase 1, restructuring service descriptions, has been completed; Phase 2, establishing relative value scales for the professional section, is ongoing; and Phase 3, developing fees, will begin afterwards, distinguishing professional costs from intellectual services in physician fees.

Medicine reimbursement procedure

In 2022, Belgium commenced the reform of its medication reimbursement procedure, led by the NIHDI, with the goal of modernising the system to ensure faster, more transparent and patient focused processes.

In the context of this reform, on 12 May 2024, a new law was introduced in Belgium aiming to ensure faster and more sustainable access to medicines. Key changes include the introduction of mechanisms for early and fast access programmes, such as fast-track reviews for urgently needed medicines and expanded provisions for unmet medical needs. The law also emphasises greater patient involvement, requiring pharmaceutical companies to include patient experience data in applications and integrating patient representatives into the decision-making process. Additionally, reimbursement procedures have been streamlined, allowing shorter timelines for medicines with no perceived added value.

Hospital reform

Belgium initiated a major reform of its hospital system by establishing loco-regional hospital networks to ensure the sustainability of healthcare delivery, while addressing budgetary constraints. Since 2019, all hospitals have been required to join one geographically defined network, with the goal of improving resource efficiency, sharing investment and promoting task specialisation based on expertise. These networks aim to provide basic care as close to home as possible, while concentrating highly specialised care in fewer supra-regional reference centres. By centralising complex services, like advanced stroke care or burn centres, the reform seeks to optimise the allocation of resources and enhance the quality of care.

The reform reflects a dual approach: offering accessible local care for general medical needs and consolidating specialised services to improve outcomes. Hospitals are encouraged to collaborate by pooling resources, such as shared services or joint equipment purchases, leading to significant cost savings. While the reform emphasises improving healthcare delivery, it is also driven by the need for a more sustainable financial model, ensuring that investments and operational costs are better managed in the face of growing healthcare demands.