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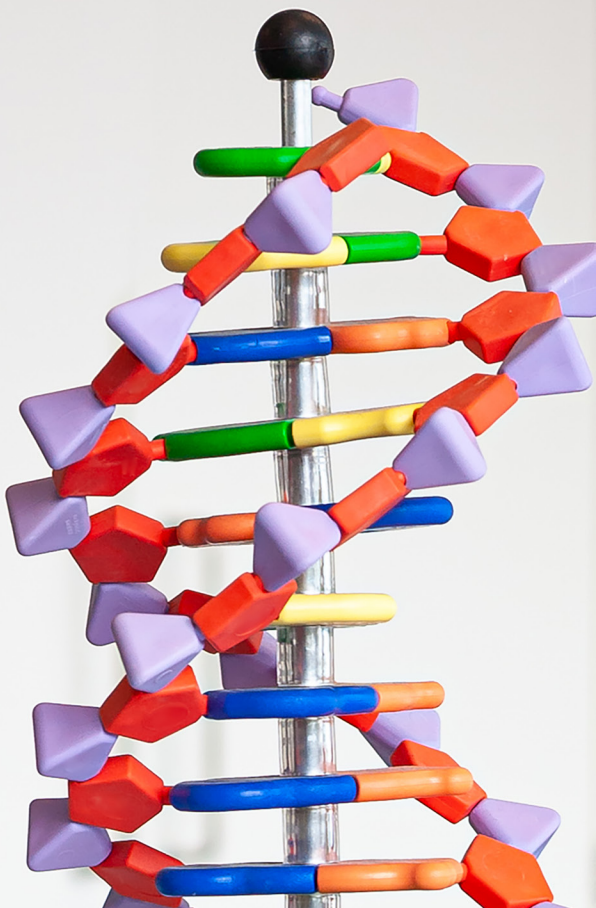

Belgium: Trends & Developments

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BELGIUM

Trends and Developments

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Van Bael & Bellis is a leading independent international law firm, headquartered in Brussels with additional presence in London and Geneva. For nearly 40 years, the firm has been at the heart of the EU and Belgian legal and regulatory ecosystem, representing some of the world's largest pharmaceutical, biotechnology and medical device companies. Its multi-disciplinary digital healthcare team combines longstanding life sciences and healthcare, data privacy, competition and regulatory expertise with experience advising on new and emerging technologies. The firm advises multiple clients on issues related to the access and use of data in the digital healthcare field and the impact of new and proposed competition and sectoral regulation and policy on existing practices. These include advising on the data protection implications of the use of new technologies, cloud-based services and analysis of Big Data and the re-use of personal data for AI, in particular machine learning.

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The Latest in Digital Healthcare in Belgium

The digital healthcare landscape in Belgium has experienced profound changes in recent years, propelled by technological advancements, evolving patient needs, and challenges brought on by the COVID-19 pandemic. The heightened need for remote care, telemedicine, and data-driven decision-making has underscored the importance of a robust and adaptable digital healthcare infrastructure.

Amid these evolving dynamics, a new federal government, formed in January 2025, has set a clear policy direction through its federal coalition agreement for 2025–2029 ("Coalition Agreement"). While the Coalition Agreement places digital transformation, especially within healthcare, at the heart of its vision for public service modernisation, it largely maintains the course set by previous administrations, with no major shift in healthcare policies. The Coalition Agreement recognises the potential added value of technology for patients and healthcare providers, provided it complements rather than replaces in-person care. Digital tools are viewed as a means to strengthen existing care relationships and support more personalised services. The federal government also recognises the growing role of artificial intelligence (AI). Belgium aims to complement EU legislation with national rules that safeguard medical confidentiality, therapeutic freedom, and patient safety, while leaving space for experimentation and innovation. A national AI and data strategy for public health is being developed, with cybersecurity as a core priority.

Similarly, the National Institute for Health and Disability Insurance (RIZIV/INAMI – NIHDI) has introduced its new interfederal eHealth Action Plan (2025–2027) (eHealth Plan) for integrated healthcare by establishing eHealth architecture in which the hundreds of existing ICT components and platforms are shared transparently with a wide range of stakeholders.

This review explores the key trends shaping Belgium's digital healthcare ecosystem and highlights the main challenges faced by healthcare organisations and policymakers.

Integrating Care and Advancing Data Sharing Systems in Belgium

The growing emphasis on healthcare data sharing and interoperability has emerged as a key trend in Belgium's digital healthcare landscape. Historically, Belgium's healthcare system was very fragmented, marked by minimal co-ordination across different providers and care settings. Patients frequently encountered gaps in care when moving between healthcare providers or settings, such as transitioning from hospital to home care. This lack of co-ordination and data sharing led to inefficiencies, and less-than-ideal patient outcomes. Interoperability efforts now aim to enhance continuity of care and improve communication across healthcare environments, facilitated by the rapid expansion of digital health technologies such as electronic health records (EHRs) and telehealth platforms (eg, myconsultation.be, Doctena, and Doktr). EHRs allow healthcare professionals to access and share patient information securely, ensuring continuity of care, while telehealth platforms enable remote consultations and monitoring, facilitating care co-ordination.

National strategy and the Belgian integrated health record

The eHealth Plan's central pillar is strengthening the core services of the federal eHealth platform and accelerating the rollout and operationalisation of the Belgian Integrated Health Record (BIHR). The BIHR is conceived as a comprehen-

sive, national electronic health record accessible to authorised healthcare professionals across the country. Its primary goal, supported by the Coalition Agreement, is to ensure continuity of care for every patient by providing a unified and secure platform for health data. The aim is for the BIHR to achieve full national interoperability by 2026–2027.

Existing Belgian initiatives illustrate this push for better data integration. For example, the Brussels Health Network (BHN) connects all public and private hospitals in the Brussels region, as well as the French and Dutch-speaking associations of general practitioners (GPs) in Brussels. These platforms allow healthcare providers to access and share relevant patient information, eg, medical history, test results, and medication lists, helping avoid unnecessary repeat tests. The federal eHealth platform, with its MaSanté patient portal and the eHealthBox secure messaging system, remains a cornerstone.

A recent concrete development is the Mult-eMediatt application. Developed by NIHDI in collaboration with the eHealth Platform, Medex (a federal agency responsible for conducting medical assessments for sick leave or workplace accidents), and the National Intermutualistic College (CIN/NIC), it allows GPs to electronically transmit medical certificates directly to health insurance funds or Medex, streamlining an important administrative process.

Alignment with European Health Data Space (EHDS)

Belgium's national data sharing initiatives are closely aligned with the broader European agenda, particularly the EHDS. The EHDS Regulation (2025/327), which entered into force on 26 March 2025, aims to give individuals greater control over their health data and facilitate secure cross-border data exchange for primary care purposes, as well as for secondary uses such as research, innovation, and health policymaking.

The eHealth Plan includes the planned interconnection of the BIHR with the EHDS, commencing in 2025. Belgium's proactive engagement is further demonstrated by Sciensano's involvement in preparatory projects such as the TEHDAS2 Joint Action (aimed at developing concrete guidelines for EHDS implementation) and the EHDS2 PILOT project (which concluded in October 2024 and focused on establishing infrastructure for secondary data use).

The Belgian Health Data Agency (HDA) and data governance

A key institutional development mandated by the Coalition Agreement is the formalisation of the HDA as a federal agency. HeDERA, a project co-ordinated by the Belgian Federal Public Service Health, Food chain safety and Environment (*Service public fédéral Santé publique, Sécurité de la chaîne alimentaire et Environnement/Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu* – FPS Health) in partnership with Sciensano, supports the HDA's mission to facilitate secondary use of health, healthcare and well-being data in a safe, uniform, and transparent environment, compliant with privacy regulations like the General Data Protection Regulation (2016/679) (GDPR) and the principles of the EHDS. Furthermore, health data managed by the Intermutualistic Agency (IMA/AIM) will be made accessible to authorised public and research institutions upon request, to support scientific research and inform health policy decisions.

Enhancing interoperability and data harmonisation

Despite significant progress, the full harmonisation of health data and comprehensive interoperability of digital systems remain ongoing objectives. Difficulties in exploiting data persist due to a lack of standardised data input and system compatibility, a concern highlighted by Belgian hospitals and research institutions. The Belgian government encourages the adoption of harmonised systems for structuring and encrypting medical data, such as SNOMED CT.

To address these challenges, FPS Health has launched initiatives like the "cross-over" call for projects. This programme is designed to finance projects aimed at strengthening the interoperability of digital systems within Belgian general and psychiatric hospitals. It seeks to overcome limitations of previous pilots, such as prototypes not reaching operationalisation, restricted scope, and insufficient transferability of solutions.

Data protection and patient trust

The protection of sensitive health data is paramount and is governed by a comprehensive regulatory framework in which the GDPR plays a central role. Public concern over data privacy remains a significant consideration in the development and implementation of data sharing initiatives. This sensitivity was underscored in February 2025 when patient associations, several psychologists' associations, and the League of Human Rights (LDH) lodged an appeal with the Belgian Council of State. The appeal raised concerns regarding the government's management of digitalised health data sharing, medical confidentiality, and the processes for informed consent. Ensuring robust data security measures, transparent governance structures, and maintaining public trust are therefore critical preconditions for the successful advancement of digital health and data sharing strategies in Belgium.

Data donation for research

The concept of "data donation" for scientific research is being actively promoted, supported by the Coalition Agreement. This aims to enable citizens to voluntarily share their health data, including anonymised or pseudonymised information from medical records, genetic data, and lifestyle information, for scientific research. This practice must be in full compliance with the GDPR, the EHDS Regulation, and the Data Governance Act (2022/868) (the Belgian implementing law for which was adopted on 15 May 2024).

Such data is viewed as a valuable resource for advancing medical understanding and innovation. Initiatives like the European Brain Data Hub, in which Belgium participates, already exemplify data altruism for specific research areas like brain health. Belgian authorities continue to study and refine the legislative framework surrounding medical data donation to ensure adequate safeguards, patient control, and transparency.

The Role of Multi-Stakeholder Partnerships

Another essential factor driving healthcare innovation in Belgium is the rise of multi-stakeholder partnerships. Diverse stakeholders play a role: government bodies such as FPS Health and the Walloon Agency for a Life of Quality (AVIQ), healthcare providers from hospitals to primary care centres and individual professionals, technology companies from multinational corporations to local startups, and research institutions including universities and academic medical centres. Patient organisations also play a pivotal part, advocating for patient needs.

These stakeholders combine to co-create digital health solutions that address real-world chal-

lenges. An example is HeDERA or at a more local level, the Antwerp Health Harbour initiative (AHHI), whose partners aim to share data, networks, and applications and to develop innovative health projects such as an integrated medical and socio-economic data platform.

Advancing Patient-Centric Care: Empowerment, Remote Technologies, and Personalised Medicine

Enhancing patient control and engagement

The digital healthcare revolution in Belgium continues to enhance patient empowerment. The introduction and expansion of telemedicine platforms, remote monitoring devices and wearable technologies have given patients greater control over their health information, allowing them to actively participate in their care journey. These tools enable remote access to healthcare services, monitor health metrics in real-time, and engage more effectively with healthcare providers. The Coalition Agreement supports the development of digital skills for citizens and psychosocial support to help them manage the influx of health data, further promoting patient empowerment.

Belgian startups remain at the forefront of this movement, developing innovative solutions for remote patient monitoring and disease management. For instance, smartphone apps employing photoplethysmography to detect atrial fibrillation have received CE marking and are now used by patients and healthcare providers nationwide. Similarly, wearable platforms capturing a wide array of physiological parameters continue to be tested in clinical trials and real-world settings, demonstrating the impact of continuous monitoring on patient outcomes.

AI and personalised medicine

The integration of AI into healthcare will also shape the future of digital health in Belgium. While Belgian companies and hospitals are actively developing and deploying AI-driven solutions, the establishment of a comprehensive national data and AI strategy specifically for the public health sector is an ongoing commitment for the Belgian federal government, as per the Coalition Agreement. The aim is to leverage AI for administrative simplification and care improvement, with an important emphasis on ensuring cybersecurity and ethical oversight. The new EU AI Act will significantly influence this, imposing stringent requirements on high-risk AI applications in healthcare.

Belgian companies are actively developing AI-driven solutions for personalised medicine, particularly in oncology and infectious diseases, promising improved patient outcomes and more efficient use of healthcare resources. For example, a Leuven-based company has devised AI algorithms for analysing brain scans, aiding neurological disorder diagnosis and monitoring. Hospitals like AZ Delta are being recognised for their innovative use of AI, and others, such as AZ West, are employing AI-equipped video capsules for digestive examinations. AI is also being developed for rapid diagnostic tests, for instance, to detect urinary infections more quickly.

As digital health solutions become more user-centric, patient engagement is expected to increase, leading to better health outcomes and a more sustainable healthcare system. Digital tools, such as patient portals, mobile health apps, and online communities, enable patients to take a more active role in managing their health and well-being. Initiatives like "C'est quoi, Doc?" aim to create accessible medical literacy

videos, further supporting patient understanding and engagement.

In conclusion, while Belgium shows promising advancement in AI-driven personalised medicine, significant challenges remain. The absence of a comprehensive national data and AI strategy creates regulatory uncertainty. Ethical concerns around algorithmic bias and equitable access persist, potentially widening healthcare disparities if not properly addressed. Additionally, healthcare professionals face a steep learning curve in integrating these technologies into clinical workflows, requiring significant investment and resources in training and in developing skills to interpret AI outputs while maintaining their professional judgement. Without proper support, even the most promising AI technologies may face resistance or implementation challenges. For Belgium to fully realise the potential of AI in healthcare, these technical, ethical, and practical challenges must be addressed through thoughtful policy development and multi-stakeholder collaboration.

Regulatory Landscape

Efforts to cultivate a robust digital health ecosystem in Belgium are often challenged by the need to comply with complex European Union (EU) legal and regulatory frameworks, alongside national implementation and specific Belgian rules.

Evolving EU and national regulatory frameworks

Compliance with the EU Medical Device Regulation (2017/745) (MDR) and the EU In-Vitro Diagnostic Medical Devices Regulation (2017/746) (IVDR) continues to be particularly challenging for digital health companies, especially small and medium-sized enterprises. These regulations demand comprehensive clinical evidence, robust quality management systems, and continuous monitoring, which can be both resource-intensive and time-consuming. In recognition of these difficulties, the European Parliament adopted a resolution in October 2024 calling for urgent revisions to the MDR and IVDR to ensure the availability and safety of medical devices. The European Commission has subsequently initiated a targeted evaluation of these regulations, which closed for feedback on 21 March 2025, to identify areas for improvement and simplification. The European Medicines Agency (EMA) is also playing a growing role, having established a procedure for scientific advice on certain high-risk technologies and an ongoing pilot programme (until the end of 2025) for orphan medical devices.

A highly significant development is the EU AI Act, with enforcement projected to start mid-2025 and the Belgian Institute for Postal Services and Telecommunications as the designated national regulator. The AI Act introduces a risk-based framework for regulating AI systems, imposing stringent requirements for high-risk applications, a category that includes many healthcare AI systems used for diagnosis, treatment, or as medical devices. This legislation will notably influence the Belgian digital health sector, mandating specific controls for such systems. The Coalition Agreement sets out the plan to develop national frameworks to complement the AI Act, particularly focusing on care quality, medical confidentiality, and cybersecurity, while also creating safe spaces for experimentation through initiatives like AI regulatory sandboxes. A public tender was launched in late 2024 to study the framework for these sandboxes.

The GDPR continues to shape the sector by enforcing strict rules on personal data processing, particularly health data. Digital health com-

panies must design their solutions with robust data protection and privacy measures. Complementing this, the EU Data Governance Act facilitates data altruism and the creation of common data spaces, including in health. The EHDS Regulation, adopted in January 2025, will further revolutionise the landscape by governing cross-border health data exchange and secondary use for research and policy.

Belgium's strong position in clinical research (approximately 20% of all European clinical trials for cancer drugs occur in Belgium, with companies investing EUR15 million daily in R&D) highlights the importance of understanding these evolving regulatory frameworks. Challenges such as participant mobility and ensuring trust in medical research persist.

Cybersecurity: a critical imperative

Cybersecurity is another critical component of digital health regulation and a growing concern. The enactment of the NIS2 Belgian law (Law of 26 April 2024, effective 18 October 2024), aligning with the EU's NIS2 Directive (2022/2555), mandates stricter cybersecurity risk management measures, incident management, and supervision for entities in critical sectors, including healthcare. In-scope entities were required to identify themselves using tools like the Scope Test Tool and register via the Safeonweb@work platform by 18 March 2025. The Belgian Federal Agency for Medicines and Health Products (AFMPS/FAGG – FAMHP) acts as a sectoral authority for relevant health entities under this law. This framework is closely linked to the EU Directive on the resilience of critical entities (CER Directive, 2022/2557); entities designated as critical under the future Belgian CER law (for which the FAMHP will also be a sectoral authority) will automatically be considered essential under NIS2, even if they are not caught within the NIS2 scope.

As digital health technologies proliferate, ensuring strong cybersecurity protocols and mandatory notification of significant incidents to the Centre for Cybersecurity Belgium (CCB) are essential for protecting patient data, maintaining trust, and adhering to the evolving regulatory framework. Further supporting these efforts, the European Commission launched an action plan in January 2025 to strengthen cybersecurity in hospitals and healthcare providers across the EU, proposing that the EU Agency for Cybersecurity (ENISA) establish a pan-European support centre.

The Belgian Data Protection Authority (DPA) stressed the importance of adequate security measures in a decision of 17 December 2024, imposing a EUR200,000 fine on a Belgian hospital. This fine followed a 2021 ransomware attack that compromised the personal data of 300,000 people. The DPA found significant deficiencies in the hospital's data protection measures, including a lack of an appropriate data protection impact assessment (DPIA) and inadequate technical security.

The Belgian healthcare sector remains a prime target for cyberattacks, with reports in the second quarter of 2024 indicating a 31% increase compared to the same period in 2023, and the healthcare sector being the most targeted. High-profile incidents at various hospitals in recent years illustrate the persistent threat and the substantial financial and operational impact of such attacks, with recovery costs sometimes running into millions of euros.

Reimbursement and Funding: Persistent Challenges and Future Directions

One of the most significant remaining barriers in Belgium is the reimbursement and funding of digital health solutions. Reimbursement is for many digital health companies key to success and sustainable growth. Although certain innovations have seen progress in securing support, many others still struggle to obtain adequate reimbursement, hindering their broader adoption and integration into the healthcare system.

Scaling the pyramid: reimbursement of mobile health apps in Belgium

Belgium is one of the few countries in Europe that provides for reimbursement for mobile health apps. The mHealthBelgium validation pyramid, introduced in 2018, was designed to facilitate their reimbursement. It categorises apps into three levels: M1 (CE marking as a medical device), M2 (meeting interoperability and connectivity criteria), and M3 (demonstrating socio-economic value for reimbursement). Level M3 has remained a high hurdle, with only a few apps able to demonstrate sufficient socio-economic impact. As of April 2025, eight health apps have reached Level 3+, entitling them to regular reimbursement – a significant increase in comparison with last year.

While recent progress is encouraging, significant challenges remain. In October 2024, the Belgian House of Representatives introduced a draft resolution aimed at improving the accessibility and affordability of digital health applications. The resolution suggests that a process such as that of the German "*Fast-Track-Verfahren*", a fast-track procedure which allows digital health applications to be approved for reimbursement within three months, could be a significant improvement on the current approach proposed by the NIHDI, marked by unclear timelines and non-binding deadlines. This is particularly relevant given the challenges in demonstrating the socio-economic value of health applications, which often takes considerable time. The German model addresses this by allowing immediate approval and reimbursement if patient benefit is proven or granting companies up to 12 months post-inclusion in the central register to demonstrate added value.

New reimbursement framework for telemonitoring

The NIHDI has implemented a new reimbursement framework to support the use of telemonitoring in the follow-up care of patients hospitalised for heart failure. Under this initiative, hospitals that have established agreements with the NIHDI are eligible for reimbursement when providing remote monitoring services through dedicated telemonitoring teams. As of April 2025, 30 healthcare institutions had such agreements, and eight telemonitoring applications (FibriCheck, Remecare, moveUp, Healthentia, Comunicare, and BeWell@Home, CareLink System and Comarch), the majority of which are Belgian-developed, are approved for reimbursement under this scheme. This policy is based on the NIHDI's assessment that integrating telemonitoring into the care continuum for heart failure patients can significantly improve both the quality and efficiency of care delivery.

Setback for teleconsultations

While other areas are moving forward, teleconsultations have seen a setback. As of 15 February 2025, telephone consultations by GPs are no longer reimbursed. Video consultations remain permitted but are strictly regulated under the Royal Decree of 27 March 2025 which sets out the legal basis and guidelines for remote medical care under the compulsory health insurance scheme. This decision, made primarily for budg-

etary reasons, is provisional. The measure is set to expire by the end of June 2025, allowing time for a working group to define a clear framework for teleconsultation, including reimbursement criteria and safeguards against misuse.

Conclusion: Market Outlook and Strategic Trajectory

Belgium continues to make notable strides in digital healthcare, underscored by its leading e-health maturity ranking within the EU. The nation's digital health market is projected to reach EUR754.53 million in 2025, with anticipated growth to EUR991.91 million by 2029 at a 7.09% compound annual growth rate. This trajectory is bolstered by the eHealth Plan and Coalition Agreement's focus on digital transformation.

Despite these promising developments, Belgium faces significant challenges in navigating a complex regulatory landscape. Regardless of recent positive developments in cardiac telemonitoring, reimbursement pathways remain difficult for many digital health innovations.

Ultimately, Belgium's success in making the most of digital health will depend on how well it balances innovation with strong oversight, making sure that new technologies lead to real improvements in people's health and help create a more sustainable healthcare system for all citizens.

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