



# FAMHP Strategic Plan 2025-2027

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Your medicines and health products, our concern

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# 1. Introduction

The Federal Agency for Medicines and Health Products (FAMHP) plays a crucial role as the reference authority for public health protection. At the end of 2023, our new Chief Executive Officer took up office, bringing a new dynamic to our organisation. In 2024, we set up the Strategy Realisation Office, which played a central role in drawing up our new strategic plan.

The 2025-2027 strategic plan guides the way in which our mission will be executed in the coming years. It serves as a compass for monitoring and adjusting our activities in a VUCA environment (VUCA stands for Volatility, Uncertainty, Complexity and Ambiguity).

Our strategic (SG) and tactical goals (TG), as well as our action areas, have been defined in cooperation with our employees and stakeholders, through various surveys, workshops and feedback sessions. The opportunities and challenges they identified have been incorporated into the thinking process.

Our 2025-2027 strategic plan is based on **four pillars**.

1. We are continuing our efforts to offer quality service thanks to an a well-performing organisation.
2. We improve the visibility of our commitments by communicating effectively with our stakeholders, and especially the citizens.
3. As a partner in the health care ecosystem, we use our expertise to help improve public health in various ways.
4. We foster a great working environment, allowing our employees to live our motto, "Your medicines and health products, our concern" every day, daily through their expertise and dedication.

These pillars are part of our mission and are linked to the context in which we operate.

# 2. Mission, values and stakeholders

Our mission and values are at the centre of all our activities and partnerships with our stakeholders.

## Mission

Over the years, our mission has extended to include new developments and skills in the field of medicines and health products. Today, the availability of these products has become such a central issue that it has been explicitly added.

We play an essential role in the protection of public health with the following mission:

Ensuring, from development to use, the quality, safety, efficacy and availability

- of medicines for human and veterinary use, including homeopathic medicines and herbal medicines, pharmacy made and officinal preparations;
- of health products, including medical devices and accessories, and raw materials for the preparation and production of medicines.

Ensuring, from collection to use, the quality, safety, efficacy and availability

- of all operations involving human body material (blood, cells and tissues), which are also defined as health products.

Within its remit, the FAMHP also makes sure that:

- all patients and healthcare professionals have permanent access to objective, correct, complete and transparent information so that medicines and health products are used correctly;
- everyone can see which medicines are authorised in Belgium and consult the current patient information leaflet and summary of product characteristics of all medicines available on the market;
- the population is made aware through information campaigns on medicines and health products with tips to protect health and to help with the proper use of medicines in general and with children in particular.



## Values

Our culture is reflected in our values.

### **Integrity - Commitment - Adaptability - Team Spirit**

## Stakeholders

Given the diversity of our areas of competence, the existing technical and scientific expertise must be consolidated both internally and externally. This must be done through clearly defined and transparent partnerships with national, European and international authorities.

We interact with many stakeholders:

- Patients;
- Healthcare professionals;
- University and research centres;
- Industry;
- Competent authorities;
- Policy makers in the Member States and the EU institutions.

## 3. General context

As competent authority, we are in charge of ensuring the quality, safety and efficacy of medicines and health products for human and veterinary use.

These responsibilities are reflected in the various activities we carry out, both for products in clinical development and for those already on the market.

We are committed to continuously improving our internal processes and proactively managing our organisation. Managing business continuity and preparing for potential crises are among our priorities. The encouraging results of European audits and benchmarking exercises reflect our efficiency and rigour.

At national level, we work closely with our stakeholders, notably via the Consultative Committee, the Transparency Committee, the Patient Consultation Platform and other consultation structures.

Cooperating with public authorities such as the Federal Public Service of Health, Food Chain Safety and Environment (FPS HFCSE) and the National Institute for Health and Disability Insurance (NIHDI) is very important. We also work with Sciensano, the Belgian Health Care Knowledge Centre (KCE), the Federal Agency for the Safety of the Food Chain (FASFC), the Federal Agency for Nuclear Control (FANC), the Federal Public Service Economy, the Superior Health Council, the eHealth platform and other public bodies.

At European level, we are a strong partner within the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). We are active in the European Medicines Regulatory Network (EMRN) and closely follow its strategy. At European Commission level, we take part in initiatives and exchanges regarding medical devices and human body materials. We are also well represented in various working groups and scientific committees, and coordinate or participate in Joint Actions under EU4Health programmes. An up-to-date list of European programmes is available on our [website](#).

We anticipate and prepare for the impact of new EU regulations such as the implementation of the Regulation on quality and safety standards for human body material, the Regulation on artificial intelligence, the Critical Entities Resilience Directive and the Network and Information Security Directive (NIS2). At the same time, by taking an active part in negotiations and preparing for legislative initiatives, particularly as regards the revision of pharmaceutical legislation, we position ourselves as a major player in the evolution of regulatory policy.

By consistently reinforcing our expertise and strategies, we strive to maintain our strong position among the competent authorities and to collaborate efficiently with our national and international stakeholders in order to continuously improve public health.



## 4. Strategy

Our strategy embodies our vision and ambition for today and tomorrow.

Six key factors are central to our vision:

- Recognition at national, European and international level.
- Developing partnerships with the healthcare sector.
- Performing core tasks in a professional manner.
- Informing the population optimally.
- Developing transversality (cooperation across different divisions) within our organisation.
- Realising and establishing a learning organisation culture.

Starting from our mission and vision, four SGs have been defined. Each SG is divided into TGs, along with priorities in the field.

The actions implemented within this framework are part of programmes, projects, operational activities or day-to-day operations. These actions are crucial for achieving the strategy.



**SG 1 - A well-performing organisation**



**SG 2 - Visibility of our commitments**



**SG 3 - The FAMHP, a partner in today's and tomorrow's healthcare ecosystem**



**SG 4 - An excellent working environment**

## 4.1. SG 1 - A well-performing organisation



Providing quality services is one of our key priorities. We pursue continuous improvement to enhance our efficiency and flexibility. In particular, we invest in data security and process automation through a range of tools. It is essential to share information as easily as possible and to efficiently collaborate, both internally and with our stakeholders.

It is crucial to flexibly respond to developments in the medicines and health products sector. Therefore we continually invest in developing our expertise. We actively encourage knowledge sharing and exchange and we strengthen transversal cooperation.

### Strategic goal 1 - A well-performing organisation

#### Promote excellence and operational efficiency in our tools, processes and structures to deliver quality service

	Tactical goals	Priorities
TG 1.1	Our databases and processes are continually optimised using new technologies such as artificial intelligence to improve our services in terms of quality and efficiency.	1.1.1 Strategy and partnership on Artificial Intelligence (AI): develop an AI strategy and launch targeted pilot projects.
		1.1.2 Integrated governance and regulatory framework: establish data management governance as well as a legal framework for the ethical, secure and compliant use of AI at FAMHP.
		1.1.3 Training and skills development: implement training programmes to enhance our employees' AI skills and develop in-depth software expertise.
		1.1.4 Improve continuously the quality and efficiency of business and administrative processes: implement optimisation strategies for our processes and procedures.
TG 1.2	Reducing the internal and external administrative burden is a central consideration in all our initiatives.	1.2.1 Automation and digitalisation: accelerate the automation of our administrative processes and the digitalisation of our services to reduce the manual workload and improve efficiency (key success factor for TG 1.1).
		1.2.2 Standardisation and simplification of procedures: standardise and simplify our administrative procedures.
TG 1.3	Transversality and agility are deeply embedded in our processes, so that we can fulfil our mission efficiently.	1.3.1 Transversal coordination and communication: identify transversal priority themes, strengthen coordination and improve interdepartmental communication in these areas.
		1.3.2 Harmonisation and clarification of roles: clarify the roles and responsibilities of every Agency's service/division/unit, and identify related activities.
		1.3.3 Foster a culture of adaptability and flexibility while investing in transversal skills to enable us to quickly adapt to changes and new priorities.
TG 1.4	The performance, security and interoperability of our digital infrastructure guarantee our	1.4.1 Data maintenance and security: allocate resources to secure our databases and guaranteeing interoperability with European standards.
		1.4.2 Systemic integration and cooperation: ensure a smooth integration of systems and platforms for a consistent user experience.

	employees and stakeholders effective tools.	1.4.3	Transparent information management: create a centralised Business Intelligence (BI) system for single access and efficient report management, while sharing relevant information from various sources across the organisation.
		1.4.4	Information security: comply with current standards and strengthen IT security.



## 4.2. SG 2 - Visibility of our commitments



In fulfilling our mission, we always place the interests of public health at the heart of our concerns. Public health receives much attention from the public and the media. While the growing public and media interest is positive, it also brings challenges, such as reliable information available.

In response, we involve the citizen as a full-fledged stakeholder and continue to invest in clear communication tailored to different target groups and through various channels, including social networks. In addition, we focus on the visibility of our commitments and services. Our priority is to provide reliable information and maintain targeted communication with all our stakeholders.

### Strategic goal 2 - Visibility of our commitments

Strengthen our position as a reference authority in the medicines and health products sector through effective communication and trust-based relationships and partnerships

	Tactical goals	Priorities
TG 2.1	All our stakeholders consider us to be the leading partner in the medicines and health products sector.	2.1.1 Proactive and regular communication with our stakeholders about new developments in our areas of competence through the most appropriate channels.
		2.1.2 Targeted information to increase knowledge of medical devices.
		2.1.3 Strengthen communication in our areas of excellence ("spearheads").
TG 2.2	Dialogue is open with our stakeholders as we build our projects and develop our areas of expertise.	2.2.1 Stakeholders' commitments: organise consultations on a regular basis to gather information about their needs and expectations through existing platforms.
		2.2.2 Prior consultation: regulatory developments and our improvement projects are discussed on the consultation platforms before they are implemented.
TG 2.3	We disseminate clear, relevant and comprehensible information to target groups, and we position ourselves as a source of reference in our areas of competence.	2.3.1 Optimise the external communication strategy: strive for a clear, coherent communication policy for each of our areas of expertise and target audiences.
		2.3.2 Modernisation and updating of communication tools: continue to develop our website with a clear structure and modern tools.
		2.3.3 Communication protocol: develop a communication protocol and promoting it to all information providers.
		2.3.4 Optimise the internal communication strategy.
TG 2.4	Our recognition as a competent authority is reinforced through appropriate communication on our partnerships and projects with other administrations and European authorities.	2.4.1 Knowledge and updating of partnerships: map our partnerships and participation in projects to highlight potential synergies.
		2.4.2 Communicate about our participation in European projects and increase the visibility of our impact and priorities in these projects.
		2.4.3 Identify synergies: work in partnership with the NIHDI and the FPS Health to ensure joint communication on specific issues.





## 4.3. SG 3 - The FAMHP, a partner in today's and tomorrow's healthcare ecosystem



As a key player in the national, European and international health care ecosystem, we apply our expertise and skills to anticipate opportunities and meet future challenges. We also continue our efforts to facilitate access to innovative medicines, health products and therapies, while ensuring their availability to patients. With regard to availability, we ensure coordination at Belgian level and play an active and essential role at European level. We adopt a proactive policy to anticipate problems related to medicines and health products. Existing legislation will be strengthened to make all players aware of their responsibilities, and the measures taken will be evaluated and adjusted where necessary.

We also stand out in several areas where we make a lasting contribution at European level. We continue to invest in the Vaccines spearhead and aim to maximise our expertise in new areas such as Advanced Therapy Medicinal Products (ATMPs). We also explore opportunities in other fields of expertise, such as medical devices.

### Strategic goal 3 - The FAMHP, a partner in today's and tomorrow's healthcare ecosystem

By supporting innovative technologies and thanks to its expertise, the FAMHP is recognised as a proactive and major player in implementing policies in the medicines and health products sector.

	Tactical goals	Priorities
TG 3.1	We are recognised as a player and partner in the Belgian, European and international health care ecosystem.	3.1.1 Make cooperation between health authorities more agile in specific areas of competence.
		3.1.2 Promote network development at European level and expertise sharing between regulators through active participation in European projects.
		3.1.3 Promote access to and availability of affordable medicines and health products that meet the needs of Belgian patients by coordinating the efforts of all relevant authorities.
TG 3.2	We invest in spearheads to strengthen the Belgian health care ecosystem and increase our recognition as an influential organisation contributing to the advancement of the sector at European level.	3.2.1 Continue work regarding the Vaccines spearhead.
		3.2.2 Develop and implement a strategy for the ATMP spearhead.
		3.2.3 Initiate discussions on the development and implementation of a Medical Devices spearhead.
TG 3.3	The threats and impact of public health crises on the availability of medicines and health products and on our operations	3.3.1 Contribute actively towards adopting the Critical Medicines Act.
		3.3.2 Implement Business Continuity Management plans. Contribute to the drafting and implementation of the Business Continuity Management Plan (BCM).



	are identified and taken into account.	3.3.3	Prepare national legislation within our remit to contain the health impact of various crises and provide adequate powers for the competent minister and/or the FAMHP.
		3.3.4	Develop and maintain international collaborations in order to implement joint actions to tackle shortages of critical medicines.
TG 3.4	New developments are integrated into our organisation in terms of knowledge, processes and interactions with our stakeholders.	3.4.1	Set up horizon scanning to identify and analyse emerging trends.
		3.4.2	Implement EU legislation (regulations and directives).
		3.4.3	Develop strategies to accelerate research and innovation, and facilitate access to innovative treatments for patients.
		3.4.4	Monitor the market and, if necessary, adapt legislation to future developments (e.g. counterfeiting, AI and online sales of health products, etc.).



## 4.4. SG 4 - An excellent working environment



Maintaining a quality working environment is one of our main priorities. Our employees are the very essence of the FAMHP. It is therefore crucial to continue investing in their well-being at work and in developing their expertise and skills. We attach great importance to integrity and transparency. Integrity and ethics initiatives aim to make this aspect even more visible. Transversal cooperation is strongly encouraged as a key element of the Agency's culture.

### Strategic goal 4 - An excellent working environment

**Foster a culture of continuous learning, autonomy and well-being. Our employees have the skills and abilities needed to fulfil their responsibilities effectively and meet the evolving challenges of the sector.**

	Tactical goals	Priorities
TG 4.1	Our workforce and expertise are adequate to meet today's needs and tomorrow's challenges.	4.1.1 Use horizon scanning (see 3.4.1) to determine future skills to be acquired or developed.
		4.1.2 Human resource planning: draw up a recruitment plan to fill skills gaps and set up training and development programmes for our current employees.
		4.1.3 Skills management: ensure that each key position has trained and competent employees and backups to guarantee continuity of operations.
TG 4.2	Our employees can count on a strong leadership that fosters a positive working atmosphere and clearly communicates expectations.	4.2.1 Explain our mission and vision, strategic goals and expected results, by defining expectations at every level, by evaluating and updating our values and by integrating them into our daily operations.
		4.2.2 Feedback and appreciation: systematically integrate constructive feedback and promote a culture of recognition and respect for the participation of all our employees.
		4.2.3 Team dynamics and leadership at all levels: organise intervision sessions, leadership initiatives and group dynamics activities to strengthen commitment and trust.
		4.2.4 Strategy coordination and planning: coherently and clearly establish a link between our strategic plan, our operational plans and our other plans and projects, and at the same time draw attention to our day-to-day activities.
TG 4.3	The development prospects offered to our employees are adequate to anchor the	4.3.1 Provide our employees with the necessary resources and options for continuing education.
		4.3.2 Develop career plans for our employees, based on the mapping of job descriptions.



	expertise acquired in the organisation.	4.3.3	Develop support and initiatives to guide our employees through change processes and reinforce adaptability in a culture of continuous growth and development.
TG 4.4	We place respect, trust, autonomy, employee well-being and work-life balance at the centre of our staff policy, and we are recognised in that regard.	4.4.1	Implement the right to disconnect in our teams.
		4.4.2	Implement absenteeism and return-to-work policy.
		4.4.3	Integrity and deontology: implement our integrity policy and deontology framework and translate it into understandable messages and initiatives, with structural monitoring and evaluation.
		4.4.4	Cooperation and team agreements: actively support and stimulate team work through appropriate initiatives and tools such as coaching and team agreements.



## 5. Relevant information

<a href="#">About the FAMHP</a>	<ul style="list-style-type: none"> <li>- The FAMHP and European projects</li> <li>- Our core business</li> <li>- Our stakeholders</li> <li>- Our values</li> </ul>
Regulatory initiatives	<ul style="list-style-type: none"> <li>- Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.</li> <li>- Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).</li> <li>- Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC.</li> <li>- Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive).</li> </ul>

## 6. Abbreviations used

FANC	Federal Agency for Nuclear Control
FAMHP	Federal Agency for Medicines and Health Products
FASFC	Federal Agency for the Safety of the Food Chain
BEMA	Benchmarking of European Medicines Agencies
BI	Business Intelligence
SHC	Superior Health Council
NIS 2 Directive	Network and Information Security Directive 2, NIS2
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
HMA	Heads of Medicines Agencies
AI	Artificial Intelligence
IT	Information Technology
NIHDI	National Institute for Health and Disability Insurance
KCE	Belgian Health Care Knowledge Centre
TG	Tactical goal
SG	Strategic goal
BCM	Business Continuity Management
FPS HFCSE	FPS Health, Food Chain Safety and Environment