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2023

famhp

federal agency for medicines and health products

CONTENTS

A WORD FROM OUR CHIEF EXECUTIVE OFFICER 4

IN THE SPOTLIGHT

Hugues Malonne: looking back on his first months as Chief Executive Officer 8

Xavier De Cuyper looks back on his years at the Federal Agency for Medicines and Health Products (FAMHP) 11

From meticulous analyses to concrete actions: how the FAMHP is addressing medicine shortages 14

From antibiotic dose fractionation to phage therapy: developments in the fight against antimicrobial resistance 16

PharmaInfo: an innovative website for citizens and patients with clear and reliable information about medicines and health products 20

Out with paper narcotic drugs order forms, welcome narcoreg.be 23

How the 'Meet the Expert' project encourages collaboration within the FAMHP 25

Building the future: positive results for the FAMHP during BEMA improvement exercise 27

Self-control and co-responsibility: a step forward in stakeholder involvement in control and inspection processes 29

OUR RESULTS PER SERVICE

Directorate General PRE authorisation 34

Directorate General POST authorisation 44

Directorate General Inspection 56

Transversal Support 66

A WORD FROM OUR CHIEF EXECUTIVE OFFICER

Dear readers,

The purpose of this annual report is to present the achievements, opportunities and challenges of the past year. In it we share the many successes of the Federal Agency for Medicines and Health Products (FAMHP), and highlight some of the individual and collective talents that have contributed to them. Throughout we ensure the complete transparency and reliability of the data shared.

Each year, we struggle to choose which subjects to highlight in this report, such is the intense and varied nature of the agency's work. 2023 was no exception. It even represents a pivotal time.

Indeed, in 2023, we experienced our first change of Chief Executive Officer (CEO) since the creation of the FAMHP. Xavier De Cuyper, CEO since 2007, made a huge contribution to our organisation. He notably extended his term of office to ensure continuity of service and, in particular, to participate in the collective effort to deal with the coronavirus crisis, before taking a well-deserved retirement.

On 1 September 2023, I succeeded him with an equal measure of pride and eagerness. On this subject, I invite you to read the article on my few months as Chief Executive Officer.

Another highlight for the agency in 2023 was participation in the fifth Benchmarking of European Medicines Agencies (BEMA V) exercise. The very positive conclusions of this benchmarking exercise reflect a high level of international recognition. These "top marks" in the areas of drug availability and our efficiency in managing critical situations, as well as in the areas of training and development, and internal audit, are the fruit of the exceptional work of our teams.

As you know, Belgium holds the presidency of the Council of the European Union in the first half of 2024. The preparation for this presidency also required a considerable amount of work on our part. One of the main themes of the presidency is the fight against antimicrobial resistance. In this context, the agency was once again able to demonstrate its engagement in this area, at both human and veterinary level, by taking part in numerous actions under the Belgian national "One World, One Health" plan.

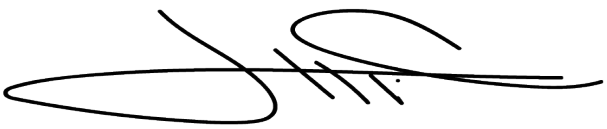
This focus on Europe has not made us lose sight of one of the agency's priorities: to make the day-to-day lives of healthcare professionals and citizens easier, in particular by offering them modern, easy-to-use and effective tools. To meet this objective, the FAMHP has launched Narcoreg, an application that enables pharmacists, manufacturers, wholesale distributors and FAMHP staff to declare transfers of narcotic drugs and psychotropic substances more quickly. To facilitate cooperation with our stakeholders, we also developed a web portal for dispensaries open to the public.

Citizens and patients, for their part, were able to discover PharmaInfo. It is an easy-to-use website offering official, understandable, reliable and impartial information on medicines and health products available on the Belgian market.

Finally, in terms of FAMHP operations, this year was also marked by internal collaboration thanks to the Personnel and Organisation Division and its "Meet the expert" project. The agency also saw some changes to its organisation chart. However, this report is presented according to the previous organisation chart, which was in effect for most of 2023.

I would like to thank all FAMHP staff for their conscientiousness and professionalism, and all our external partners for their support and trust. It is thanks to their commitment that we can maintain our essential role in protecting public health.

I hope you find this report an interesting read.



HUGUES MALONNE
Chief Executive Officer of the FAMHP

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HUGUES MALONNE

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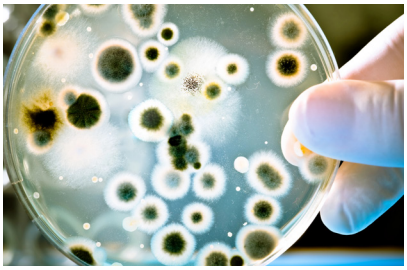

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PharmaInfo
une initiative de l'afmps

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HUGUES MALONNE: LOOKING BACK ON HIS FIRST MONTHS AS CHIEF EXECUTIVE OFFICER

In September 2023, Hugues Malonne took over as head of the Federal Agency for Medicines and Health Products. Having previously held the position of Director General of DG POST authorisation and then DG PRE authorisation, Hugues was well aware of the amount of work that lay ahead. This annual report is an opportunity to find out a bit more about our new Chief Executive Officer.

Hugues Malonne had an international pharmaceutical career before heading up the FAMHP. In 2017, he returned to Belgium and joined the agency. He then rose through the ranks, starting as Director General and eventually becoming Chief Executive Officer.

Hugues Malonnes

"I joined the FAMHP as Director General and successively managed the POST and PRE authorisation entities. The position of Director General enabled me to exercise a range of skills, such as a sense of responsibility, innovative thinking, strategic analysis, negotiation skills, human resources management and the creation of national and international networks as a public service. It was a key position with a major impact on the field. So I was already familiar with the agency's remarkable work and, above all, I was motivated and confident regarding this new opportunity. I know the importance and positive influence of our actions on the health of all our citizens, as well as on the organisation of all our institution's external partners at national and international levels. As soon as I took on the role, I knew that, with all my colleagues, I would be able to move this organisation forward and guide us into the future."

HOW WOULD YOU DESCRIBE THESE FEW MONTHS AS CEO?

"The start of my mandate at the FAMHP was marked by preparations for the Belgian presidency of the Council of the European Union. I am paying close attention to the FAMHP's involvement in the presidency and the Critical Medicines Act that the Minister wanted to highlight. Furthermore, as co-chair of the Joint Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA), I am involved in discussions concerning the level at which each measure should be implemented (regional, national, European or even international).

As a result, the Belgian presidency of the Council of the European Union in the first half of 2024 offers us a unique platform to address crucial themes for our agency, such as antimicrobial resistance, crisis management, unavailability and unmet medical needs. This is why our agency, through its various departments, has made extensive preparations for this presidency.

This opportunity will enable us to demonstrate Belgium's importance in the European public health arena, a status we will be seeking to reinforce given its essential role in global public health.

I am convinced that the presidency will help us to optimise our activities, advance our work and move towards ever greater collaboration.

At the start of my mandate, I decided to change the old organisation chart. So I set up a formal department for strategic support and chose the old model of separating general services and the CEO's services into two different entities. The CEO's services now include the Strategy Realisation Office, the Legal Affairs Division, the Quality Division and Organisational Management, the International Relations Division and the Communication Division. The general services, now under the management of Pascal Giloteau, include the Budget and Management Control Division, the Personnel and Organisation Division, the ICT Division and the Logistics Unit - Collaboration 1FM.

These organisational changes were also accompanied by changes in responsibilities. So I am delighted that Erik Everaert joined our team as Director General of DG POST authorisation on 1 November 2023. I am convinced that Erik will make a valuable contribution to our organisation thanks to his experience and expertise. I look forward to working with him in his new role and seeing what he will achieve. We will also be welcoming another person to take my place as DG PRE authorisation."

WHAT ARE YOU MOST PROUD OF?

"First of all, I am already proud of my career at the agency. Starting out as Director General of two entities has given me a wealth of experience and a better overview for my current role.

Secondly, I am proud that the Minister of Public Health, Frank Vandenbroucke, and the Council of Ministers have placed their trust in me to lead the agency for the next six years.

From the outset of my mandate as CEO, I knew I could count on the agency's staff to meet the challenges ahead. So I am also proud of all my colleagues. Through our work, we contribute to exemplary service by ensuring the quality, safety and efficacy of medicines from conception to use.

Not forgetting the agency's crucial role in integrating the Medical Devices Amendment (Medical Device Regulation, MDR and In-Vitro Diagnostics Regulation, IVDR) and finalising the new SoHO legislation (substances of human origin).

This amendment has three objectives: to extend the transition period for the IVDR, to allow for a gradual implementation of Eudamed (European database on medical devices), and to require notification in the event of imminent unavailability.

The SoHO legislation involves the introduction of new rules to protect citizens who donate or receive substances (blood, cells, tissues, breast milk or microbiota), and children born of medically-assisted procreation. On 14 December 2023, agreement was reached on the European regulation on standards of quality and safety for these substances intended for human application. The SoHO legislation is another example of our contribution to improved public health.

We have a direct and tangible impact on public health protection. The websites we have developed, such as PharmaStatut and PharmaInfo, help to fulfil this crucial role by providing citizens with understandable, reliable and impartial information.

Our teams are also committed to sharing knowledge and information with our external partners, as you can see from projects such as the development of a web portal for pharmacists.

There are more major projects to come, and I have every confidence in my teams' dedication and commitment to the agency's continued future development."

WHAT DIFFICULTIES DID YOU ENCOUNTER IN TAKING UP THIS MANDATE?

"There is no denying that our areas of expertise are highly complex. Particularly so in an ever-changing world with a considerable impact on public health.

To carry out our mission as well as possible, we need to recruit specialised profiles with solid skills in a variety of fields. But this is not always an easy task, as there are often tight deadlines involved, which should not be underestimated."

WHAT HAVE YOU DISCOVERED IN THE LAST FEW MONTHS THAT YOU NEVER IMAGINED YOU WOULD FIND IN THIS JOB?

"Although I was already familiar with the way the agency worked, this job introduced me to other facets I had never imagined.

Firstly, the complexity of European systems. Of course, I knew that the FAMHP was very involved at European level. In fact, the FAMHP is one of the few Belgian health authorities that is already well integrated into the European network. We often collaborate with the European Medicines Agency and take part in a number of European projects.

However, I also found that, in addition to this collaboration, more time was needed for feedback and evaluation from the European to the national level.

We also need to further develop our European projects, for example, in the field of Advanced Therapy Medicinal Products (ATMPs). These are highly complex products, and above all, it is a fast-moving field. We want to be major players in this field. I want the FAMHP to be a key player on a European and even global scale. We do not want to become a kind of 'subsidiary' of the EMA."

WHAT ARE YOUR MAIN OBJECTIVES AND CHALLENGES DURING YOUR MANDATE?

"As I explained earlier, we are in a constantly evolving field. So it is important to prepare for this, so we can adapt and use it to our advantage. The FAMHP will therefore have to evolve to meet future challenges, such as artificial intelligence, raw data, megadata and real-life data. What we do today is not the same as what we will do tomorrow. The need to evolve as an individual and as an organisation is essential. It is a major challenge, but an essential one.

Artificial intelligence is becoming increasingly important in various fields, but it is not a threat to us. I believe that our work will be enriched by this technology. We all need to play our part, making the right choices and investments to take advantage of these changes, and using them as tools to shape our future.

My aim is to support my colleagues through this change. This will inevitably alter our business, but without compromising it - on the contrary. We must make sure we stay at the cutting edge of our fields of expertise. This evolution will benefit us, as it will save us time that we can then devote to more rewarding tasks."

WHAT ARE YOUR STRATEGIC PRIORITIES FOR 2024?

"We should remember that Belgium will hold the presidency of the Council of the European Union in the first half of 2024. This will require a lot of energy, time and resources. But I do not want this to delay the new version of the FAMHP strategic plan. Nor can it hinder the implementation and monitoring of this plan by our employees and stakeholders. In my view, our strategic plan is the foundation of our institution. It is the means for our transformation into a future-ready organisation. It is up to all of us to make it happen!"

XAVIER DE CUYPER LOOKS BACK ON HIS YEARS AT THE FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

Xavier De Cuyper led the FAMHP from 1 May 2007. He was the agency's first chief executive officer, coming on board at its inception.In 2022, he reached the age limit for holding a mandate within the federal government, but his term was extended to ensure the FAMHP kept running smoothly, pending the appointment of his successor. He finally retired on 1 September 2023. His long stint at the head of the agency has left its mark on the history of our organisation. His departure gives us the opportunity to ask him a few questions about this period.

CAN YOU GIVE US A BRIEF RUNDOWN OF YOUR CAREER BEFORE THE FAMHP WAS FOUNDED?

"Over the course of my career, I've held a number of key positions in the Belgian public sector. I was Secretary General of the Ministry of Middle Classes and Agriculture, Managing Director of the Federal Agency for the Safety of the Food Chain, Director General of the DG Animals, Plants and Food of the FPS Public Health, as well as Chief of Staff to several Ministers with responsibility for Agriculture and two Deputy Prime Ministers. All these experiences have increased my desire to serve in very different fields, with a better understanding of our system of public governance.

In the early 2000s, I moved into public health, and when I joined the FAMHP in 2007, I helped define national policy on medicines and healthcare products. At a European level, I was a member of the Board of Directors of the European Medicines Agency (EMA) and I continue to sit on the Board of Directors of the Agence nationale de sécurité du médicament et des produits de santé (ANSM - the French national agency for the safety of medications and health products). I also played an active role in the network of European Heads of Medicines Agencies (HMA). I was born at the time when the EU came into being and have always been convinced that being actively present at this level is positive, not only for economic agents, but also for our fellow citizens."

WHAT HAVE YOUR SIXTEEN YEARS WITH THE AGENCY BEEN LIKE?

"There were so many projects that I hardly noticed the passing years. Our agency was set up by the legislature in 2006, with the support of successive ministers. The aim was to respond to the expectations of a range of stakeholders such as patients, healthcare professionals, academics, manufacturers and all parties involved in the distribution of medicines and healthcare products. By way of example, some of you will recall the early days of the agency, struggling with the demands of marketing authorisation

Xavier De Cuyper

applications for drugs. Our Minister had requested that this issue be resolved within two years. Thanks to the expertise of the departments concerned and our willingness to engage in dialogue, various proposals were drawn up, and a solution was proposed on schedule. Since then, we've stopped talking about 'backlogs' at the agency altogether.

Dialogue and consultation have been the driving forces, both in terms of internal management and managing the services the agency is required to provide. One of the successes I believe is worth highlighting is the willingness to present, discuss and consult with all our partners within platforms specific to each stakeholder group, starting with patients, who occupy a central place in the organisation.

Of course, we took advantage of the agency being set up to develop all the stages in the life cycle of medicines and products: not just inspection, but also research and development, monitoring, surveillance, etc.

A major strategic focus was to build an organisation recognised as a sectoral authority in the fields of medicines and healthcare products by our various target groups.

In the past, the medical profession had no knowledge of the agency. Thanks to our transparency and continuous exchange of information, especially during the various crises, and our use of informal platforms where everything can be said and discussed, this has changed dramatically.

What's more, I'm convinced that the COVID-19 health crisis has made the public more aware of the agency's work. However, you can't speak to a doctor, pharmacist or manufacturer in the same way as a citizen, so we had to adapt accordingly."

WHICH PROJECTS ARE YOU MOST PROUD OF?

"A difficult question. Above all, I'm proud to have achieved our objectives thanks to the support of our ministers, stakeholders and, of course, the commitment and expertise of the members of the agency.

Since its inception, the agency has grown from 200 employees to over 500 today. This growth is the result of fully justified needs and has been made possible by a special financing mechanism. The agency's public/private co-financing mechanism is quite unique in Belgium, at least in its scope, and is highly innovative. This financing system took a lot of energy to design, but where there is a common interest, it enables us to develop new projects. This is much more complex for an administration with a traditional financing model. This financing system is an opportunity that benefits everyone, while taking care to avoid conflicts of interest, of course.

The list of significant improvements would be long to go through here. I would, however, like to highlight the progress made in the provision of information, thanks to our new database, which centralises all information on drugs: instructions and summaries of product characteristics, RMA documents (Risk Minimisation Activities), DHPC (Dear Healthcare Professional Communication), etc. And, thanks to PharmaStatut, everyone can find out whether a drug is available. So there have been great strides forward. I'd be delighted if citizens looking for information on medicines and health products instinctively thought to visit the FAMHP website. These efforts have raised our profile. The agency has gained greater visibility, but this objective has not yet been achieved.

Without going into detail, I would also like to express my satisfaction with my contribution to the agency's recognition as a key European player. This has helped to build in-house expertise, although many Belgian experts are also sought after for positions with, for example, the European Commission or the EMA.

Indeed, I'm convinced that our agency will also be able to be satisfied with its performance during the 2024 European Presidency, thanks to excellent and ambitious preparations over the past two years or so."

WHAT WERE THE MOST COMPLICATED BRIEFS?

"I don't know if some briefs are really more complicated than others. I'd mention complicated situations, even crises, which the FAMHP has managed with great professionalism. In my experience, I've always seen crises as challenges to be overcome, and therefore as opportunities for us. Each challenge has its own characteristics, but coordination and communication are essential. I won't go through all the crises we've experienced, but generally speaking, we've been very active, available, organised, transparent and open to dialogue with all the partners concerned. The COVID-19 crisis, more than any other, demonstrated our ability to take responsibility.

At the start of the crisis, there were major supply difficulties for certain products. There was a bit of a panic on a global scale. At the start of the pandemic, there was a race for vaccines between different countries. I salute the work of the European Commission, which has put in place a transparent system that saves us an enormous amount of time and energy. The group purchase was a success. The European Commission has anchored this mechanism in a structure that will centralise these procedures. It doesn't make sense for countries to negotiate individually with suppliers, especially small countries that are at a disadvantage compared to large ones.

During the pandemic, the agency was responsible for supplying and inspecting vaccination centres, as well as distributing vaccines. Our aim was to offer our expertise to those who needed it. As soon as the pandemic broke out, we set up a task force at the agency to respond to the various needs. We never stopped providing support for hospitals when they were facing supply shortages, particularly for neuromuscular blocking agents in intensive care. Our collaboration with university hospitals and hospital pharmacists' federations has been remarkable. But I would like to add that this has never led us astray from our mission: to guarantee the quality, efficacy and safety of medicines and healthcare products made available on the market. We have issued press releases on the adverse effects of vaccines. A pragmatic and transparent initiative. We were pleased to note that

both practitioners in the field and the general public reported a huge number of undesirable effects. This is all the more essential in crisis situations, when evaluation procedures are accelerated to ensure that new products such as vaccines are available as quickly as possible.

The whole agency was undeniably under pressure during the health crisis. Our employees have had their work cut out for them, and I'd like to underline the huge personal investment made by dozens of employees over many months to help manage the pandemic in our country with skill and efficiency. So I can understand why a few people then left the agency - to get away from this pressure.

In the end, I was able to observe and confirm the effectiveness of our staff in managing this crisis, and the need for in-depth cooperation. We must pay tribute to them for rising to the challenge in such an extraordinary way."

WHAT ABOUT YOUR LIFE AFTER FAMHP?

"I didn't want to give the impression that I was hanging on. My time was full of satisfaction, and I'm glad to be able to devote myself first and foremost to my family and friends, but also to have time for interests such as travel and contributing wherever I can."

WOULD YOU LIKE TO SAY A FEW WORDS TO YOUR SUCCESSOR, HUGUES MALONNE?

"Hugues Malonne and I worked together at the agency for several years. He knows the place inside out, which is an advantage when it comes to pursuing the current objectives set by the Executive Committee, but also and above all when it comes to meeting the agency's new challenges. I'm thinking in particular of the major issue of supply shortages, and of finding solutions to the many problems that remain unresolved. I'm convinced that he will remain willing to enter into conversations and collaborate with staff and external partners.

Once again I wish him, and all my former colleagues at the agency 'Plain sailing and every success in future endeavours!'"

FROM METICULOUS ANALYSES TO CONCRETE ACTIONS: HOW THE FAMHP IS ADDRESSING MEDICINE SHORTAGES

Unavailability of medicines is a problem that affects many patients every year. This issue is therefore high on the agenda both at the national and international/European levels. In recent years, the FAMHP has invested in a multifaceted approach to unavailable medicines with both practical actions on the ground and legislative initiatives.

At the FAMHP, every indication of a possible shortage is taken seriously and thoroughly analysed to assess the potential impact on public health. The FAMHP experts use a decision tree to analyse each unavailability, with a duration of one month or more, reported by the marketing authorisation holder or parallel distributor in order to estimate the impact on public health. This allows the FAMHP to take appropriate measures to minimise the impact of the unavailability on patients.

In the event of critical unavailability, a task force is convened to make recommendations and set priorities. "That task force consists of experts for the specific medicine for which there is a shortage," explains Lara Wellens of the Unavailabilities Entity. "In the task force there are doctors (specialists), pharmacists, professional associations, patient organisations and other government departments. They can, for example, propose an alternative treatment, but sometimes priority is also given to certain indications and so the task force can decide what happens to the remaining stock of the medicine." Critical unavailability fortunately accounts for only a small portion of all unavailability. In 2023, a total of only 1.14 per cent of unavailabilities were critical.

Lara Wellens

"It is important to stress, however, that reports of unavailabilities happen per presentation of a medicine: in other words, based on the dose, route of administration, pharmaceutical form and pack size," adds Lara, "so an unavailability does not always concern the whole range of the medicine. If the pack of 30 paracetamol of 1 gram tablets from a particular manufacturer is temporarily unavailable, it does not mean that the medicine is unavailable. Other packs of paracetamol, for example, may still be available and may provide a solution for patients at that time."

The FAMHP is continuously investing in effectively addressing unavailability of medicines. In 2019, for instance, the agency launched the application PharmaStatus. Patients can use this to look up whether a medicine is available and they can register to be kept informed about the availability of a specific medicine or group of medicines. Authorisation holders and parallel distributors are legally obliged to supply wholesaler-distributors (within the scope of their own special obligations) and pharmacists within three working days. Partial or interrupted deliveries are automatically considered as an unavailability and must be reported through PharmaStatus. Since April 2021, pharmacists and wholesaler-distributors are also able to contact marketing authorisation holders and parallel distributors through PharmaStatus in the event they suspect a shortage or supply problems to occur. This system encourages companies to pass on their reports correctly.

If the problem cannot be solved locally, solutions are sought at the international/European level. "We therefore cooperate closely with European networks. In some cases, we have to create strategic stocks. Other services within the FAMHP, such as the inspection services and other government agencies are also often involved to get the situation under control. For example, a notification can be sent via the European Medicines Agency (EMA) to all members of a network whenever there is a significant shortage. It is then possible to check which countries still have alternative medicines on the market."

"A specific case that demonstrates the need for such measures

is the shortage of thrombolytics. Thrombolytics are medicines that actively dissolve blood clots and are used in life-threatening situations such as a blocked blood vessel. Thrombolytics are used in cases of heart attack, pulmonary embolism, stroke or thrombosis, for example. These medicines are therefore crucial for saving lives," Lara explains. "In late 2021, there was a quality issue with a widely used thrombolytic in Belgium that caused an acute shortage of this medicine in Belgium. Two alternative medicines could not provide a solution at that time because there was a global capacity problem. Belgium fell back on about fifty per cent of the need for thrombolytics at that time."

As other countries were also facing supply problems for thrombolytics, no stock could initially be imported from abroad. The FAMHP therefore set up a controlled distribution for these medicines, whereby hospitals were given a monthly quota based on their historical consumption. Hospitals had to report their stock on a weekly basis. If the hospital's stock fell below the threshold, they were able to receive a new supply. A task force was organised on a very regular basis during the period when the situation was very critical, even on a weekly basis for a certain period.

"It was a very uncomfortable situation for the hospitals because the consumption of thrombolytics can fluctuate from month to month," notes Lara Wellens, "but this way, we did manage to avoid a complete stock-out. Belgium currently has a strategic stock of the unavailable thrombolytic. Hospitals can order from the FPS Public Health, but of course there are quotas that apply. The company producing the other thrombolytics has also done a great deal to increase production. Hospitals had protocols to deal with limited supplies, and we communicated and collaborated closely to ensure that available medicines were used as effectively as possible."

The critical unavailability of thrombolytics was kept under control not only through the efforts of the hospitals, task force members and the FAMHP, but also through close contacts with pharmaceutical companies, other Member States and the European network. Other services within the FAMHP were also involved in this case: the inspection services and the experts of the directorate-general PRE authorisation have done a great deal of work. The National Institute for Health and Disability Insurance (NIHDI) also contributed through the task force. For example, they secured temporary reimbursement for thrombectomy devices, which can extract a clot from the blood.

"If there is one thing we are taking with us into the future, it is the importance of (inter)national cooperation and stock management. The pharma industry must continue to invest in diversifying manufacturing capacity. The experience of the thrombolytic shortage has provided a better understanding of the need for continuous monitoring, close cooperation between all players involved, and flexible solutions. Thorough coordination and collaboration in all aspects of this complex process, and effective crisis management are really essential to protect public health and save lives," Lara concludes.

OUR FAMHP EXPERTS

Lara Wellens is head ad interim of the Unavailabilities Entity within the Proper Use Division. Her team is responsible for daily monitoring of temporarily unavailable medicines or discontinuations of commercialisation of medicines. They work with various experts, both inside and outside the FAMHP. The unit also manages the PharmaStatus application, which was developed to collect information on the availability of medicines in Belgium.

FROM ANTIBIOTIC DOSE FRACTIONATION TO PHAGE THERAPY: DEVELOPMENTS IN THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) has been a major challenge for global human and animal health for several years. Therefore, the FAMHP is committed to fighting AMR with a number of concrete actions. The aim is to reduce and optimise the use of antimicrobial agents, particularly antibiotics, to prevent the development and spread of resistant germs.

In the fight against, a multisectoral approach is essential as humans, animals and the environment are inextricably linked. That is why the Belgian 'One Health' national action plan on the fight against antimicrobial resistance 2020-2024 has been set up. This plan, based on ten key lines of action, includes operational objectives and specific actions. Four objectives in the operational plan (FR/NL) directly concern the AMR team of the Proper Use Division.

Arnaud Selvais - Sarah De Clercq - Karim Tamseddak

REDUCING ANTIBIOTIC USE

One of the main objectives is to reduce antibiotic use in the ambulatory sector in Belgium. One of the options explored to achieve this is antibiotic dose fractionation. This means that patients receive the exact amount of antibiotics they were prescribed. "Together with the National Institute for Health and Disability Insurance (NIHDI), the DG Inspection of the FAMHP, the Belgian Pharmaceutical Association (APB) and the Office of Co-operative Pharmacies in Belgium (OPHACO), we have drawn up an exhaustive list of the additional steps this would entail for pharmacists," explains Arnaud Selvais.

For this measure to be effective, close cooperation between the various actors is essential. The NIHDI needs to allow unit pricing, and the FPS Public Health needs to oblige doctors to prescribe by substance name (international non-proprietary name, INN), by noting the name of the active substance, the dose and the precise duration of treatment in the prescription. The FAMHP will then be able to enforce the dispensing of the exact quantity of antibiotics through fractionation. Discussions are currently taking place with relevant actors to introduce this measure.

IMPROVING THE AVAILABILITY OF ANTIBIOTICS

A second measure taken by the FAMHP in the fight against AMR is improving the availability of antibiotics. The first step was to draw up a list of essential antimicrobials in the Belgian context. Karim Tamseddak explains: "We drew up the list based on the recommendations of the World Health Organization (WHO). This list was adapted to the Belgian situation through discussions with a panel of experts in the field who are involved in the Belgian Antibiotic Policy Coordination Committee (BAPCOC). In the course of these discussions, for each essential substance, we also defined the level of importance to work on in terms of improving accessibility. Based on this list, we prepared a state of play for the medicines linked to these essential active substances. We will continue our analysis using the data available, such as medicine life cycle and unavailability notifications, to assess the vulnerability of the supply chain for these medicines."

Sarah De Clercq adds: "Our analysis of the supply chain is based on a study carried out by the European Health Emergency Preparedness and Response Authority (HERA). In this context, we've recently entered into a dialogue with DG HERA to discuss the possibilities of exploiting our respective information." In parallel to this work, the FAMHP communicates to healthcare professionals when an antimicrobial innovation is introduced on the Belgian market.

DEVELOPING ALTERNATIVES

A third measure in the fight against AMR is the development of alternatives to antibiotics, such as phage therapy. This method uses bacteriophage viruses (also known as phages) which target only bacteria. Therefore, phages cannot target human cells. This method is already being used to treat certain bacterial infections in Belgium.

According to Arnaud: "Belgium is playing a pioneering role at European level in the use of phage therapy. The advantage of a bacteriophage is that it is highly specific, destroying only the targeted bacteria, which considerably limits the risk of adverse reactions. Unfortunately, phages are currently mainly used as a last resort, when antibiotic treatments have failed."

The choice of this treatment lies with the doctor, who may prescribe phage therapy.

In such cases, if the patient meets strict eligibility criteria, the Queen Astrid Military Hospital (QAMH) provides applicants with phages specific to the bacteria responsible for the infection, if it has them available. Furthermore, all phages supplied by QAMH are analysed by Sciensano laboratories to ensure their quality. The pharmacist then makes a magistral preparation (a dilution). The aim of phage therapy is not to replace antibiotics, but to be a complementary therapeutic tool.

In veterinary medicine as well, phage therapy can be a valuable complement to antibiotics, which can reduce their use. Therefore, there is regular consultation between colleagues working on human and veterinary AMR.

IDENTIFYING SUITABLE BUSINESS MODELS

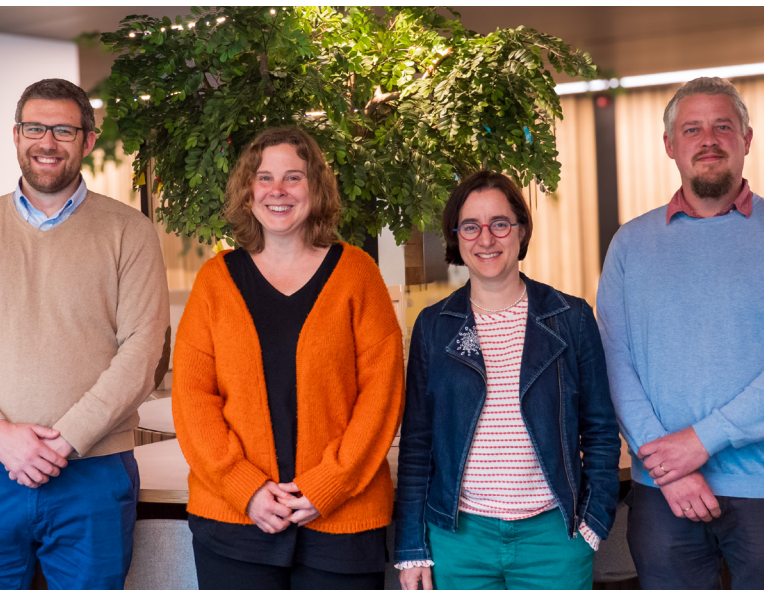
"It's often said that the antibiotics market is disrupted," Sarah explains, "because there has been almost no innovation for decades. To reverse this trend, it is vital to introduce incentives to stimulate investment by the pharmaceutical industry." To achieve this objective, we had to study existing business models and the various economic incentives available around the world.

"It's important to be able to access expertise on these different models to enable decision-makers to assess their feasibility for Belgium," says Karim. Sarah concludes: "In the context of the above objectives, we are also working together with other European countries, in a 'Joint Action' EU-JAMRAI 2 (European Union Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections). In fact, in collaboration with Sciensano, our team organised a three-day kick-off workshop for a work stream that we are contributing to."

FROM COVENANT TO VISIBLE RESULTS: COMBATING ANTIBIOTIC RESISTANCE IN ANIMALS

Antibiotic resistance not only affects humans; but also poses a serious threat to animal welfare. The Antimicrobial Resistance Entity of the DG PRE Authorisation is working closely with the industry in the fight against antibiotic resistance in animals. They too are basing their measures on the national action plan for AMR. "At the national level, as a follow-up to the first antibiotics covenant in 2016, a second antibiotic covenant was drawn up in 2021. This agreement was concluded between the Ministers of Agriculture and Public Health, represented by the FAMHP, the FASFC (Federal Agency for the Safety of the Food Chain) and the FPS Public Health, AMCRA (Antimicrobial Consumption and Resistance in Animals, the knowledge centre for antibiotic use and resistance in animals) and the stakeholders (agricultural organisations, veterinarian associations, the Order of Veterinarians, pharma.be, Belgian Feed Association, managers of specifications and animal health associations)," explains Antita Adriaens.

This covenant contains various strategic and operational objectives as well as general, numerical targets, which are mainly about an overall reduction in antibiotic sales. "By 2022, antibiotic sales figures for animals were down 58.2 per cent from 2011," notes Lies Van Nieuwenhove. "We are thus close to our goal of reducing sales by 65 % by the end of 2024, moving the total antibiotic use in animals in Belgium towards the median use in Europe. Cooperation between the industry and the government is very important in this regard. It's certainly not always easy, but by working together we can take important steps forward."



Guillaume De Cordes - Liesbeth Van Nieuwenhove - Inge Vandenbulcke - Cédric Maerckx

OBJECTIVES AND REPORTING IN VETERINARY MEDICINE

"One of the goals we still need to work on is reducing the number of alarm users. These are livestock farms with systemically high antibiotic use. The target for 2024 is to reduce the number of alarm users to one per cent. There is still some work to be done, but thanks to the support of the food animal sectors, we are already making positive progress," Antita explains. Therefore, in addition to antibiotic sales data reports, benchmarking reports are produced for livestock farmers and veterinarians of food-producing animals. The reports, which are prepared by AMCRA based on usage data for each animal category, are available to livestock farmers and veterinarians, with the intention of enabling them to consider together how to achieve sensible use of antibiotics on the farm. For example, based on this policy we can find out how many alarm users there are, what classes of antibiotics are being used and where best measures, such as mandatory coaching, are taken.

Since the implementation of Regulation 2019/6 on veterinary medicinal products in 2021, Member States are also required to report sales and use figures for antibiotics to the European Medicines Agency (EMA). With regard to sales, all marketing authorisation holders must enter the annual sales volume for each veterinary medicine into the European Union's veterinary product database (known as the Union Product Database or UPD). Member States are themselves required to report the sales volume of certain antimicrobials to the EMA in a timely manner. "The advantage of collecting and reporting sales data at the Union level is that it helps to monitor the EU's farm-to-fork strategy. This should achieve a 50 % reduction in antibiotic use in livestock and aquaculture within Europe by 2030," says Lies.

In terms of use, reporting is happening gradually, starting in 2024 for food-producing pigs, cattle and poultry (all chickens and turkeys). From 2027, reporting must be extended to all food-producing species (fish, goats, ducks, sheep, rabbits, and all horses, including non-food-producing ones). By 2030 at the latest, pet animal data should also be reported. To make this possible, the VetAMRtool project was launched with funding from an EU grant. The aim is to create an automatic link with the register IN and the register OUT of the depot of the veterinarian and pharmacy. This will enable data on sales and use of antibiotics to be obtained while minimising any additional administrative burden on veterinarians.

LIMITING THE USE OF CRITICAL ANTIBIOTICS

In the fight against AMR, both in humans and animals, it is also important to limit the use of critical antibiotics. Specifically within veterinary medicine, it is mandatory to perform an antibiogram or antibiotic sensitivity test before critical antibiotics can be administered to food-producing animals. Starting in September 2024, this requirement will be extended to companion animals and horses. This test must show which antibiotic is most appropriate for treating the bacteriological disease; a critical antibiotic should only be used if it is the best option or if it is the only appropriate antibiotic licensed in Belgium. This prevents bacteria from becoming resistant to antibiotics critical for humans and animals. Whenever possible, a non-critical antibiotic should be chosen. If the veterinarian decides to use a critical antibiotic, even if it is not substantiated by an antibiogram, he/she should always thoroughly justify it.

Antibiotic resistance knows no national boundaries and is an international problem. However, thanks to close cooperation with national and international bodies, the FAMHP continues to work tirelessly on systematic solutions and remains committed to the fight against antibiotic resistance. "All three of us are very passionate about this subject. I'm very proud of my team. Arnaud and Karim have put a lot of work into this issue, and all their research is very useful to us in our meetings with our partners," says Sarah. Antita and Lies agree: "The issue of AMR is very complex. That is why it remains important to adequately consult and communicate with all stakeholders. Together, we have already been able to achieve some great results, and we want to continue that in the future."

OUR FAMHP EXPERTS

Sarah De Clercq, Arnaud Selvais and Karim Tamseddak form the Antimicrobial Resistance (AMR) team, part of the Information Entity of the Proper Use Division within DG POST authorisation.

Sarah is head of the Information Entity and is Coordinator within the human medicines domain. Arnaud and Karim are file managers.

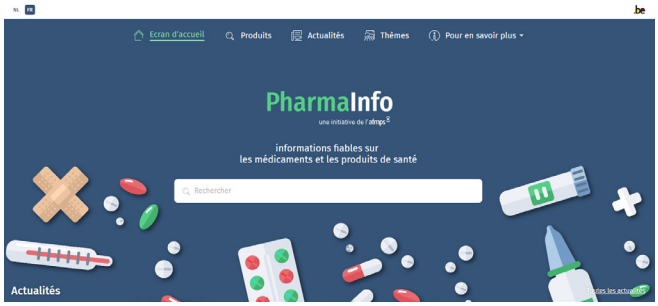
Antita Adriaens is head of the Antimicrobial Resistance Entity within the Medicines for Veterinary Use Division and works with Lies Van Nieuwenhove and her colleagues on rolling out projects relating to legislation, such as the new Regulation 2019/6 on veterinary medicinal products. They are also involved in implementing and coordinating actions on antibiotics included in the national action plan on AMR.

PHARMAINFO

An innovative website for citizens and patients with clear and reliable information about medicines and health products

In December 2023, the FAMHP launched www.PharmaInfo.be. A website tailored to citizens and patients had long been an idea of the FAMHP. As part of a multi-year patient information plan, this project became much more concrete, and thanks to the explicit support of the Minister for Health, it gained momentum. In the autumn of 2022, the FAMHP was officially able to begin development. It was the Proper Use Division that had to bring the project to fruition in just under a year.

Sarah De Clercq, Head of the Information Entity at the FAMHP, describes the process. “The final result is very similar to what we envisioned at the start, but we were able to refine a great deal during development. We listened to users’ needs and tried to respond to them. We received some valuable feedback from patient organisations, the Belgian Centre for Pharmacotherapeutic Information (BCFI/CBIP), the Belgian Pharmaceutical Association (APB) and from our colleagues at other government agencies. This was important because, although it was the FAMHP’s initiative, PharmaInfo is also a gateway to their ‘specific’ information.”



VERSATILE AND PATIENT TAILORED

The most important thing about PharmaInfo is the search engine. Type in the brand name or active ingredient of a medicine and you will find information on what packaging is on the market in Belgium, whether the medicine is available, what the price and reimbursement are, whether a prescription is required, as well as documents such as the patient information leaflet or additional materials for patients. For some active ingredients, you will also receive a special information sheet containing the most important elements for patients: practical information about the form of administration, how to take the medicine, when, for how long, at what time, etc. Whether you can stop treatment just like that and what to do if you forget a dose. What are the side effects, can you drive a car, what if you are pregnant or breastfeeding, etc. Each sheet is carefully structured so that you can search specifically for the information relevant to you. One hundred sheets were available at launch, and since then, more have been added every month.

FarmaInfo not only provides information about specific medicines, but also useful, general information. For example, what to do with expired medicines, how to report side-effects or how to find a pharmacist or (dental) doctor on duty. Finally, PharmaInfo keeps you up to date with the latest developments through news releases that focus on what patients need to know or do. This keeps patients informed and involved.

RELIABLE AND UNDERSTANDABLE

In times of fake news and disinformation, it is extremely important to offer citizens the right information so that they can actively participate in their own treatment. Laura De Meester explains. “Reliable and understandable are really the two main principles we always keep in mind. The information you can find on FarmaInfo is based on reliable sources. First, of course, the patient information leaflet, which contains the most up-to-date information about the medicine, but also the BCFI/CBIP’s drug repertory, which guarantees independent scientific information and is based on relevant international sources. But all that correct information is worth nothing if the patient cannot understand it. This is why we use a B1 level. A B1-level text consists of easy words that almost everyone uses. We avoid medical jargon or difficult sentence structures as far as possible. We want everything to be clear to everyone.”

Sarah De Clercq adds to this. “Reliable and understandable also goes beyond what we write ourselves. Fortunately, we don’t always have to start from scratch. For example, the independent Health and Science website developed by the Belgian Centre for Evidence-Based Medicine (CEBAM) has done a very good job of describing diseases and conditions in patients’ language. We make eager use of that and link through to it when we can. Patients

also need not fear that we are promoting particular medicines. No, we write our sheets starting from the active ingredients and also provide information on non-medicated treatments, such as in the ADHD care pathway or sleep medicines and sedatives."

But how to select which medicines or topics to write about? Ann Van Den Broucke: "Rest assured, we don't just decide by ourselves what information we're going to put out there as a priority. We base it on the patient's needs. First, of course, we look at what people themselves enter into the PharmaInfo search engine or the FAMHP website and the questions they send us by e-mail. We also receive regular feedback from patient organisations. Besides that, we review the press or parliamentary inquiries we receive at the FAMHP. Finally, other internal departments can also tell us what's going on in their fields. And of course, at the Proper Use Division, we also have our own expertise for pushing forward certain topics depending on the time of year, such as vaccinations during the winter season or travel pharmacy just before summer."

Ann Van Den Broucke

NOT JUST MEDICINES

The goal of FarmaInfo is to help patients with all types of products designed to support our health. Therefore, there is also information on medical devices. Anaïs Fauche was responsible for that part. "The information on medical devices is more limited because it involves hundreds of thousands of different types of products covered by differing legislation. It's far more difficult to make the same information – such as an patient information leaflet, manual or the price – available for all resources. However, you can search by the name of a product to find out whether it's a medical device and who is marketing it. But we mainly focus on information sheets according to the type of product. These include for example thermometers or hearing aids where we cover key things patients need to know, such as precautions, risks or when their use is discouraged."

POSITIVE START AND PHARMAINFO CONTINUES TO EVOLVE

In the first two weeks after the launch, thanks to a successful social media campaign and a great deal of press coverage, PharmaInfo had already had more than twenty thousand visitors. Feedback from individual patients, patient organisations and other FAMHP stakeholders was also positive.

Laura De Meester - Sarah De Clercq - Anaïs Fauche

The intention is for the website launched in late 2023 to continue to expand not only in terms of content – some new features will be added. Ann Van Den Broucke explains: "From the beginning, we made sure that the website was flexible enough to include information on other types of products too, such as food supplements or cosmetics. We're now looking at how to best process the information available to the government that can be useful to citizens. But the idea remains the same. A high-performance search engine will guide citizens to all the information about the product in question. In addition, we remain open to what patients want to see and are actively seeking out what we can add ourselves. What can be improved, what can be expanded, where is there a need?"

You will eventually see PharmaInfo popping up in other applications such as 'Myhealth' or 'Mymedicines'. Ideally, for example, when a patient views the summary of open prescriptions in those applications, he or she would have a direct link for each medicine to the relevant information in PharmaInfo. This should also be the case the other way around: from PharmaInfo, you should be able to report an adverse drug reaction with the most important details about the drug already entered.

OUR FAMHP EXPERTS

This project is coordinated by the Proper Use Division. Ann Van Den Broucke provides management support, but over the years has become the expert who helps implement innovative applications such as PharmaStatus, the medicines database and the internal Medicinal Product Management system.

Sarah De Clercq is Head of the Information Entity at the Proper Use Division. There, she works with Laura De Meester (for medicines) and Anaïs Fauche (for medical devices) to provide the correct content in understandable language as found on PharmaInfo.

OUT WITH PAPER NARCOTIC DRUGS ORDER FORMS, WELCOME NARCOREG.BE

In Belgium, any delivery or receipt of narcotic drugs and psychotropic substances must be registered with the FAMHP. This used to be done using paper narcotic drugs order forms. Since September 2023, Narcoreg has been put in place, an online application that digitalises the entire process with time savings for pharmacists, suppliers and the FAMHP.

Nur Demirci from the Narcotics Team explains how the system used to work: "In the old system, the pharmacist had to fill out a narcotic drugs order form for every purchase of narcotic drugs and psychotropic substances. That order form consisted of three identical pages. A pink copy for the pharmacist to keep, a yellow copy for the wholesaler and a white copy for the pharmacist to deliver to the FAMHP, which we kept for ten years. It was clear that digitising this process was necessary."

Nur Demirci

Both the experts from the Narcotics Team and the ICT Division worked at a fast pace to provide a high-quality and user-friendly application. Fortunately, they could also count on a select group of test users from the various sectors. Pharmacists and suppliers were thus already able to provide some valuable feedback during development. For example, the functionality of being able to add products not only through the narcotic code but also through the CNK code was a request that came from the field. For a while, a problem with the legal basis threatened to throw a spanner in the works, but in July 2023, www.narcoreg.be could finally be launched. Over the summer, all the users were able to test everything out for a while, and in September 2023, the application became legally mandatory.

But what exactly are the benefits? Nur Demirci: "The new system saves the pharmacist and wholesaler a great deal of time. The ability for pharmacists to upload data in bulk using a CSV file or the integration into the wholesaler's software so that everything is automatically recorded in Narcoreg are obviously very big steps forward for them. In addition, it is also quite an improvement for us at the FAMHP. Detecting excessively large orders or losses is now far easier to do. We also have a better overview of the market: what is being sold, in what quantities, what are the trends ... Moreover, we now also have easy access to both sides of the story, both pharmacist purchases and wholesaler sales. This is because the system works on the basis of 'matches'. If the pharmacist and wholesaler declare the same quantities, then there is a match and all the products are charged for."

Changing a way of working that has been around for decades is not something you do lightly. This is why the FAMHP has been working hard on communication and awareness-raising: consultation with and communication through, among others, the professional associations APB (General Pharmaceutical Union) and OPHACO (Association of the Cooperative Pharmacies in Belgium), mailings to individual pharmacists, interviews in the trade press and news items, manuals and FAQs on the FAMHP website and support for our services by e-mail or telephone. Nur: "Yes, we have seen in the first six months that there is still a learning curve among the pharmacists and so we are trying to give them maximum support. We see that mistakes are made unknowingly – for example, we have had to correct about eight thousand returns so far. But everyone is of good will; truly obstinate pharmacists who do not want to use the system despite the legal requirement can fortunately be counted on one hand. Thus far, it has only had to happen once, but enforcement measures such as an official report, with accompanying fines, are provided for in the law."

Such projects naturally require a great deal of effort from the FAMHP staff because the routine tasks remain. What does Nur think about that? "Despite the extra workload, I am still happy that I, along with many colleagues, was able to bring this project to fruition. Not only is following such a project from A to Z extremely instructive, it is also very satisfying. Getting positive feedback

from users and knowing that almost a million and a half returns have now been made in the new system, then you just know that all this work did lead to a decent result. But I do want to emphasise that this was really a team effort by a lot of people within our division, as well as in the ICT and Communications Divisions and even external partners such as SMALS, eHealth, pharmacists, hospital pharmacists and wholesalers. I should certainly not forget my division head Philippe De Buck, who took the first steps towards this project even before I was working at the FAMHP, and whose technical knowledge certainly added value. And the future? The work is not yet done. We will continue to look at how we can improve the system for users and how we can use the data even better."

Goedele Louwagie - Alain Dupont - Greet Declerck - Philippe De Buck - Nur Demirci - Hanne Lavrysen

OUR FAMHP EXPERTS

Nur Demirci holds a master's degree in biomedical sciences and is a member of the Narcotics Team and Precursors Team at the DG Inspection. She held a key role as a project manager in developing Narcoreg.

HOW THE 'MEET THE EXPERT' PROJECT ENCOURAGES COLLABORATION WITHIN THE FAMHP

Training and continuous development are crucial within the FAMHP. In a world that is constantly evolving both technologically and innovatively, it goes without saying that we cannot be left behind. The Personnel and Organisation (P&O) division therefore launched the 'Meet the expert' project in which employees are given the opportunity to follow colleagues for one or more days to get to know each other's work better.

Upon returning to the office after the coronavirus crisis, the P&O division, at the request of the Executive Committee, started looking for new ways to encourage employees to learn more about the specific roles and responsibilities of colleagues.

"Some colleagues have worked together for years without really knowing about each other's work. They are in regular contact via e-mail or phone, but don't know exactly what that other colleague is doing all day. The 'Meet the expert' project should put an end to this," explains Nathalie Wouters from the P&O division.

Nathalie Wouters

> **"Thanks to 'Meet the expert', I now have a better insight into the general workings of the FAMHP and have been able to expand my network within the agency. I can undoubtedly use the knowledge gained in the future."**
>
> Céline Thiry – Assessors division, DG PRE authorisation

The project was set up to offer a fun and interactive way to get to know colleagues and their responsibilities, in addition to the usual information sessions and integration process for new employees. "With this project, we especially want to encourage our employees to get to know their colleagues and their field of work a little better," Nathalie explains, "which will not only promote collaboration between the various divisions across entities, but will also ensure that we can increase our expertise and experience."

A first initiative came from the Directorate General Inspection with the project 'inspector for one day'. Employees from other divisions were given the opportunity to follow an inspection from A to Z: from the preparation about the inspection itself, to the final meeting with the drafting of the inspection report. This initiative gave colleagues from other divisions the opportunity to 'get into the field' and get a better idea of exactly what an inspection entails.

> **"'Meet the expert' not only allows us to share experiences among colleagues and strengthen ties within the organisation, but also allows you to discover other positions you may want to pursue in the future yourself."**
>
> Catherine Landrieu – P&O division

And it was a success! At the launch of the project, more than 25 employees signed up to follow an inspection, which was more than expected. There were some very different profiles from different divisions. The reactions were also very positive. Better knowledge of the work of colleagues involved in the same processes improves collaboration and quality of work, while allowing employees to expand their network.

Consequently, the P&O division is continuing to brainstorm new ideas to improve knowledge between all divisions.

> **I was able to follow an inspection closely last year – I know now that there is a great deal involved. The whole process starts with thorough preparation. For example, inspectors and auditors should be aware of the findings from previous inspections. Afterwards, they must also evaluate corrective and preventative measures before they can issue a certificate.**

Olivier Pauwels, Authorisations Division, DG Inspection

Christophe Debruyne - Ethel Mertens - Jean-Michel Piers - Katelijne Van Keymeluen

The International Relations division also pitched in. Two colleagues had the opportunity to follow the activities of this division for a day, including attending a consultation with the cabinet on preparations for an important conference as part of the Belgian presidency of the Council of the European Union. This initiative demonstrated once again that the project improves the flow of information between divisions and contributes to the integration of expertise within the FAMHP.

> **As an inspector, I had the opportunity to introduce three colleagues from other entities to our inspections of medical device manufacturers. This gave colleagues a better idea of what impact their work has 'in the field' itself. For myself, it was also instructive to better understand the approach of the other divisions. Their expertise in relevant fields proved to be a clear added value.**

Arne Sunaert – Medical Devices division

"We will definitely continue to monitor this project," says Nathalie Wouters. This project is perfect proof that we can learn a lot from each other.

OUR FAMHP EXPERTS

Nathalie Wouters is head of the Employee and Organisational Development Entity within the Personnel and Organisation division. Along with her colleagues, she is responsible for knowledge policy, evaluation policy and policy around well-being and culture within the FAMHP.

BUILDING THE FUTURE: POSITIVE RESULTS FOR THE FAMHP DURING BEMA IMPROVEMENT EXERCISE

The FAMHP participated in the improvement exercise 'Benchmarking of European Medicines Agencies' (BEMA) in 2023. This improvement exercise gives the agency an opportunity to evaluate performance and then further optimise it. The FAMHP successfully completed the exercise and achieved positive results; also, the average score per area increased compared to the previous edition in 2016.

The BEMA exercise is organised on a regular basis by the Network of Heads of Medicines Agencies (HMA). All authorities competent within Europe for medicines, both human and veterinary, can participate.

"The FAMHP participated in a BEMA exercise for the fourth time in 2023," explains Annelies Cools of the Quality Division and Organisational Management. "BEMA offers our agency the opportunity to evaluate our performance, identify any bottlenecks in the organisation, learn more about good practices, and determine improvement actions."

In practice, the BEMA exercise consists of two parts. First, a self-assessment that was conducted through questionnaires. Forty areas were identified for the survey: from strategic planning and leadership, to clinical trials, pharmacovigilance and inspections. For each area, a coordinator within the FAMHP was designated who, along with a support team, gathered the necessary input. The self-assessment was followed by a visit to our agency by three BEMA assessors from medicines authorities from other European countries. During this visit, the assessors used the self-assessment to conduct several interviews of the coordinators and their teams.

QUITE A JOB

A great many services within the FAMHP participated in the BEMA exercise in one way or another. So proper coordination of the project was very important. Behind the scenes, the entire project was managed by the Quality Division and Organisational Management. "We provided both the overall organisation and coordination of the BEMA exercise, as well as support for the coordinators and their teams," says Kathy Cromphout. Because there was also a lot of preparatory work involved. "For example, to make the whole project run smoothly, we created a SharePoint website where all the information about the BEMA exercise was collected," adds Kathy Cromphout. "In addition, a roadmap was developed with the various steps and corresponding deadlines for this benchmarking exercise."

Christelle Beeckmans - Kathy Cromphout - Annelies Cools - Fleur Peten

POSITIVE RESULTS

And that good preparation was rewarded. The FAMHP has since successfully completed the BEMA exercise: the self-assessment was submitted on time and the interviews were very constructive. In late 2023, the FAMHP received the final BEMA report. The assessors noted a strong improvement in the FAMHP's performance. The average score per area evolved from 3.55/5 (in 2016) to 4.1/5 (in 2023). "According to the BEMA assessors, the FAMHP does an excellent job in medicines availability. Indeed, the agency is taking a leading role in addressing the unavailability of medicines at both national and European levels," explains Annelies Cools. Training and development also emerged as one of its strengths. Current knowledge and the need for expertise are regularly surveyed. "The FAMHP also scores strongly on internal audit, for which the Quality Division and Organisational Managementworks closely with auditors from other healthcare institutions and with the Federal Internal Audit Service," adds Fleur Peten.

CONTINUOUS IMPROVEMENT

Of course, the BEMA exercise is interesting not only to know our strengths, but also and especially to identify bottlenecks and

determine improvement actions. There is still room within the FAMHP for enhanced leadership support for quality management, more specifically for the implementation of improvement measures. More efforts can also be made to increase he FAMHP's staff's awareness of information security. This can be achieved through targeted training and exercises.

Based on the report from the BEMA assessors, an action plan was drawn up with some measures for improving the agency's operations. Improvement measures were formulated for fifteen different areas. Management will closely monitor the implementation of these actions.

"The BEMA cycle spans a period of several years. After the completion of the BEMA V cycle in the second half of 2025, we will have a clear picture of the position of the Belgian agency compared to the authorities of the other European countries. The FAMHP and all its staff can already be proud of the positive results achieved and the increase in the average score," concludes Christelle Beeckmans, Head of the Quality Division and Organisational Management.

Christelle Beeckmans

OUR FAMHP EXPERTS

Annelies Cools, Kathy Cromphout and Fleur Peten work in the Quality Division and Organisational Management under the direction of Christelle Beeckmans. Along with their colleagues, they support the FAMHP's various services to manage their activities properly, and carry them out efficiently and effectively. They do this by coordinating audits, handling external complaints, monitoring improvement actions, managing risks and managing declarations of interest, among other things. Together, they also coordinate improvement exercises to continuously improve the agency's operations.

SELF-CONTROL AND CO-RESPONSIBILITY: A STEP FORWARD IN STAKEHOLDER INVOLVEMENT IN CONTROL AND INSPECTION PROCESSES

Self-control and co-responsibility are the result of a new control policy implemented by the FAMHP Directorate General Inspection. This policy is adapted to the different stakeholders according to their sector, with the common goal of making these players more responsible and involved in optimising the inspections and controls carried out by the FAMHP.

The inspection departments are working to roll out this new control policy, which will eventually apply to all the players audited by our agency.

The first self-control system was set up for medical device distributors. The methodology was subsequently adapted and deployed in the public pharmacy sector and, more recently, in the field of medicine and active substance manufacturers. In parallel with these initiatives, the implementation of these principles is planned for medicine distributors in the near future (GDP - Good Distribution Practices) and a feasibility study for the clinical studies sector (GCP - Good Clinical Practices).

DIGITISATION AS A TOOL FOR EXCHANGING INFORMATION AND OPTIMISING CONTROLS

Digitisation plays a central role in information sharing and administrative simplification. The development of a dedicated web portal for each sector optimises the inspection process and its follow-up. The collection and analysis of relevant data exchanged with inspection services and the transmission of inspection reports and CAPA plans (corrective and preventive action plans) are automated, among other things. In this way, the IT system developed becomes a tool for optimising inspection planning and execution. These secure platforms also offer players centralised access to all the documents exchanged with inspection services, simplifying their interactions with the competent authority.

Digital transformation is no longer just a trend; it is an inescapable reality in all business sectors, including public health authorities. It is in this context that self-control and co-responsibility emerge as an essential concept.

FOR PHARMACISTS IN PHARMACIES OPEN TO THE PUBLIC: SELF-CONTROL

"For pharmacies open to the public, the emphasis is on self-control. 2023 marked the culmination of the pharmacy self-control project, carried out in close collaboration between the ICT division, Smals, the Dispensing Division and the legal department," explains Alain Denis.

This project led to the publication of a Royal Decree in September 2023, with various components.

Firstly, confirmation of the obligation for pharmacists to carry out a self-assessment. Pharmacists are required to carry out an annual self-assessment of their compliance with Good Pharmacy Practices. The conclusions of this self-assessment enable them to identify areas for improvement and put in place an action plan to further enhance quality within their pharmacy.

Secondly, every pharmacy is required to undergo an external audit once every four years. The agency is not involved in carrying out this audit, which does not replace a control or inspection. It is

Alain Denis - Margriet Gabriels - Alain Bya

carried out by auditors who meet the different criteria set out in the decree. This is part of a coaching approach, helping pharmacists to identify and implement areas for improvement.

Thirdly, pharmacists are now required to complete a form on the FAMHP web portal, covering the activities and structure of the pharmacy. The information collected via this form, along with other relevant data on each pharmacy, is integrated into a risk analysis tool developed by the agency. A risk profile of pharmacies is therefore drawn up to guide inspections, helping to rationalise the controls to be carried out and make them more efficient.

The Dispensing Division was heavily involved in this project. In addition to Alain Denis, three of his colleagues were actively involved. "This project is a good example of cross-functionality. Its implementation required the involvement of not only the inspection departments, but also the IT department, which developed the web portal module, and the legal department, which drafted the royal decree."

CO-RESPONSIBILITY FOR GOOD MANUFACTURING PRACTICES

Good Manufacturing Practices (GMP) are the principles and guidelines for the manufacture of medicines for human and veterinary use. This field covers a wide range of players, including manufacturers of active substances, production intermediaries and finished products (medicines), suppliers of the raw materials used in pharmacies and manufacturers of officinal preparations. In 2023, the implementation of the GMP co-responsibility project led to the development of a web portal for manufacturers of medicines and active substances. This tool was developed in close collaboration with the ICT department and Smals. Furthermore, the functionalities implemented have been tested with the involvement of industry stakeholders. Amanual has also been written to facilitate access to and use of this new tool by the different players involved.

The tool has been used for routine inspections of manufacturing sites since the end of 2023. The portal involves stakeholders in the entire inspection process, from planning to closing an inspection, including the transmission of the data used for preparation, the communication of reports and the review of CAPA plans.

It also enables relevant information to be collected for risk analysis purposes. In this way, the IT tool developed is used for optimising inspection planning and execution.

The GMP project will continue to evolve. Other functionalities will be added to the tool, such as the integration of investigations and inspections carried out as part of a manufacturing authorisation application, as well as administrative follow-ups such as the issue of GMP certificates, etc.

Karin Froidbise, Head of the Industry Division, believes that "this tool improves the control process while offering stakeholders an intuitive interface. This vast effort to dematerialise the inspection mechanism could serve as a basis for other sectors."

PROCESS OPTIMISATION FOR ALL

There are many benefits: process optimisation, improved data quality and processing, and consolidation of different information into a single interface. In addition, forms relating to controls and inspections are accessible to the inspected parties, access is secure and use is simplified and standardised across different sectors.

Feedback from stakeholders has been positive. Stefanie Scheerlinck from the Industry Division: "We have not had any negative feedback on the implementation of this system. Stakeholders are keen to centralise the information they pass on. The user aspect was taken into account and adaptation was easy."

Nicolas Mortier of the Industry Division points out: "It was essential to translate all our inspection processes into a single IT system. The work carried out with the ICT Division has proved essential. This digitalisation makes it easier for us to exchange data with our stakeholders and also enables us to manage our business more efficiently."

Stefanie Scheerlinck - Ethel Mertens - Karin Froidbise - Nicolas Mortier

OUR FAMHP EXPERTS

Alain Denis is an inspector in the Pharmacies Open to the Public Unit of the Dispensing Division within DG Inspection. This Division controls pharmacies open to the public, hospital pharmacies and veterinary depots.

Karin Froidbise is Head of the Industry Division within DG Inspection. She is responsible for self-control and co-responsibility projects in the fields of GMP and GCP.

Nicolas Mortier and Stefanie Scheerlinck are inspectors in the GM(D)P unit of the Industry Division. They are both involved in the GMP co-responsibility project.

OUR RESULTS PER SERVICE

DIRECTORATE GENERAL PRE AUTHORISATION

competent for all activities prior to approval of the first marketing authorisation for a medicine or a health product

DIRECTORATE GENERAL POST AUTHORISATION

competent for all activities following approval of the first marketing authorisation for a medicine or a health product

DIRECTORATE GENERAL INSPECTION

competent for all inspection and control activities

TRANSVERSAL SUPPORT

with the general support services of the agency which fall directly under the Chief Executive Officer

DIRECTORATE GENERAL
PRE AUTHORISATION

competent for all activities prior to approval of the first marketing authorisation for a medicine or a health product

Research and Development (human use) 35

Marketing Authorisation (human use) 36

Medicines for Veterinary Use 38

Assessors 39

National Innovation Office and Scientific-Technical Advice 40

Pharmacopoeia/Raw Materials Unit 43

DIVISION RESEARCH AND DEVELOPMENT DIVISION (HUMAN USE)

CLINICAL TRIAL AUTHORISATIONS

622
initial applications for clinical trials

2 926
substantial changes or amendments

COMPASSIONATE USE AND MEDICAL NEED PROGRAMMES

27
unmet medical need programmes submitted

27
unmet medical need programmes closed

41
reassessments of approved medical need programmes

19
substantial amendments to unmet medical need programmes submitted

116
urgent notifications of medicines for compassionate use

QUESTIONS CONCERNING CLINICAL TRIALS OR RESEARCH AND DEVELOPMENT

1 021
questions concerning clinical trials or research and development

ANNUAL SAFETY REPORTS

998
annual safety reports under the Directive

106
new indications as safety assessment Member State under the Regulation

CLINICAL INVESTIGATIONS OF MEDICAL DEVICES

51
new clinical investigations of medical devices under the new Regulation (EU) 2017/745

70
substantial amendments to clinical studies with medical devices under the new Regulation (EU) 2017/745

53
new performance studies with in vitro diagnostics under the new Regulation (EU) 2017/746 (since 26 May 2022)

21
new substantial amendments to performance studies with in vitro diagnostics under the new Regulation (EU) 2017/746 (since 26 May 2022)

NEW

In 2023, we entered a new period of transition from clinical trials to CTRs. From February 2023, it became compulsory to submit new trial applications via CTIS (CTR), while submission via the Directive was no longer possible for initial trial applications (only substantial modifications). .

TREND

With regard to compassionate use programmes (CUP/MNP), based on 26 approved programmes and an average programme duration of two years, it is estimated that some 2 908 patients will have free access to a medicine in a new, as yet unapproved indication. 44 % of these approved programmes are in oncology/haematology.

DIVISION MARKETING AUTHORISATION DIVISION (HUMAN USE)

FILES FOR OBTAINING MARKETING AUTHORISATION

1
new application for a marketing authorisation via the national procedure

171
new applications for a marketing authorisation via the mutual recognition procedure or the decentralised procedure

355
variations for which Belgium was rapporteur or co-rapporteur via the centralised procedure

8
renewals for which Belgium was rapporteur or co-rapporteur via the centralised procedure

629
files closed

1
file with Belgium as reference Member State

3
files with Belgium as rapporteur or co-rapporteur for new marketing authorizations via the central procedure

NEW

Concerning new marketing authorisations via the centralised procedure, Belgium was rapporteur or co-rapporteur for 2 'full application, complete* files' and 1 application for a biosimilar, and participated in 3 'multinational assessment teams' (MNAT)**

N.B.:
* 'a full application, complete file' is a file containing the necessary administrative, quality, non-clinical and clinical data.
** the 'multinational assessment team' makes it possible to set up an assessment team from different competent national authorities.

HOMOEOPATHIC MEDICINES

9
new applications for a marketing authorisation

2
new applications for registration

62
variations

3
five-yearly renewals

38
reference files with quality data on master products or pharmaceutical forms required to obtain a marketing authorisation for a complex homoeopathic medicine

90
files closed

HERBAL MEDICINES

3
new applications for a marketing authorisation or a registration

60
variations

5
five-yearly renewals

68
files closed

DIVISION MEDICINES FOR VETERINARY USE DIVISION

799

files closed

CLINICAL TRIAL AUTHORISATIONS

2

applications for clinical trials

FILES FOR OBTAINING MARKETING AUTHORISATION

51

new applications for a marketing authorisation

VARIATIONS

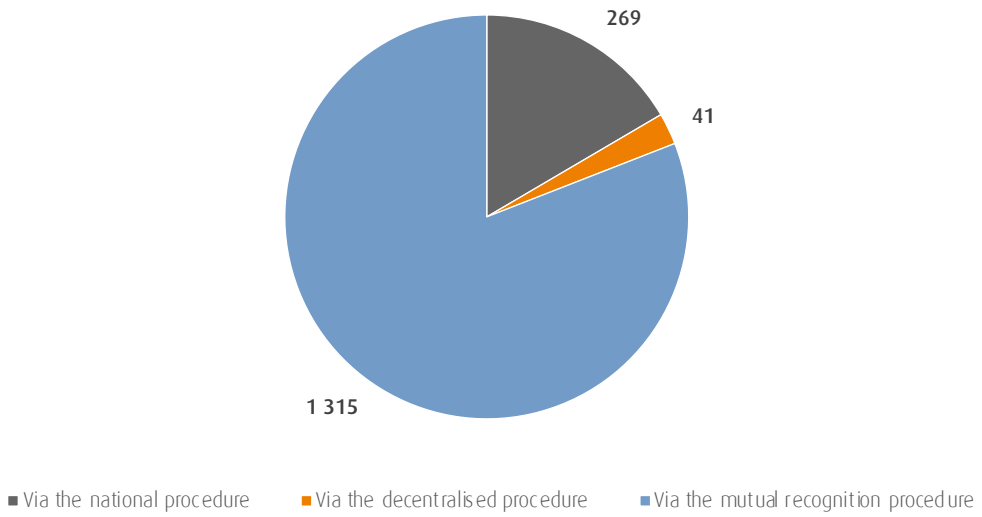
496

variations requiring assessment

1 076

variations not requiring assessment

Procedures for marketing authorisations or variations



NEW

The UPD (Union Product Database) continues to have an impact on the Veterinary Division in terms of file management (reception and closure). In 2023, the start-up of DTS production also had an effect on the division's performance. Staff are using new working instructions that will enable them to use DTS in a harmonised way.

TREND

Marketing authorisation holders have made increasing use of the VNRA (Variation Not Requiring Assessment) system, and the number of VNRA dossiers submitted has doubled compared with 2022. The number of VRA (Variation Requiring Assessment) files increased by 40 %. The number of applications for new marketing authorisations remained on a par with last year. At present, Belgium does not have the capacity to assume the role of RMS (Reference Member State) for new marketing authorisation applications. The mutual recognition procedure accounts for the bulk of files, mainly due to the high number of VNRAs.

DIVISION ASSESSORS

MEDICINAL PRODUCTS FOR HUMAN USE

193
assessment reports for initial applications for clinical trial

27
assessment reports for compassionate use or medical need programmes

99
national and European scientific advices

52
assessment reports for new marketing authorisations

261
assessment reports for type II variations

265
questions on essential medicines and alternatives in case of unavailability

MEDICINES FOR VETERINARY USE

3

European scientific advice documents

33

evaluation reports for new marketing authorisations

136

evaluation reports for type II variations

NEW

The most important innovation for assessors in 2023 was the obligation to process clinical trial applications submitted via the CTR (Clinical Trials Regulation). This certainly played an important role, given that in 2023 the FAMHP was the Reference Member State for a large proportion of multinational applications and that the workload for processing applications under the CTR was higher than for applications submitted under the old legislation.

TREND

For veterinary medicines, there was a significant increase in the number of applications processed for variations. This is a consequence of the obligation to convert existing medicine product information to the current QRD (Quality Review of Documents) model.

NATIONAL INNOVATION OFFICE AND SCIENTIFIC-TECHNICAL ADVICE UNIT

NATIONAL SCIENTIFIC-TECHNICAL ADVICE

46

applications for scientific-technical advice for medicines for human and veterinary use submitted

50

applications for scientific-technical advice for medicines for human and veterinary use closed

SIMULTANEOUS NATIONAL SCIENTIFIC ADVICE

10

applications submitted and closed for simultaneous national scientific advice (SNSA) in collaboration with other national medicines authorities as part of the European SNSA pilot project of the EU Innovation Offices Network (EU IN)

QUESTIONS

189

questions and answers (including on existing legislation and guidelines, research and development, innovation and FAMHP's services)

MEETINGS

1

portfolio meeting

4

project information meetings with local promoters concerning a planned medicine development or medical device development project

CONSULTATION PROCEDURE FOR MEDICAL DEVICES WITH A MEDICINAL PRODUCT AS AN INTEGRATED PART OF THE MEDICAL DEVICE

1

consultation procedure submitted by a registered authority for medical devices with a medicinal product as an integrated part of the medical device

TSE CONSULTATION PROCEDURE

37

TSE consultation procedures for medical devices using animal tissues for their production that may cause transmissible spongiform encephalopathies (TSEs)

BORDERLINE PRODUCT CONSULTATION PROCEDURE

15

informal consultations for borderline products which were processed by the Borderline & Classification Working Group (BLCG) of the EU Innovation Offices Network (EU IN) between the competent national authorities

EUROPEAN REQUESTS FOR SCIENTIFIC ADVICE

88

European applications for scientific advice for medicinal products for human use processed by the EMA's Scientific Advice Working Party (SAWP-H) (i.e. 84 SAWP dossiers + 4 peer reviews)

1

European application for scientific advice for medicinal products for veterinary use processed by the EMA's Scientific Advice Working Party (SAWP-V)

NEW

Project information and portfolio meetings with the FAMHP National Innovation Office, which until now had been offered exclusively for the medicines sector, were opened up to developers of medical devices and in vitro diagnostics (IVD) to develop support for innovation in the MedTech sector in Belgium and thus facilitate accelerated access to innovative medical technologies and patient-friendly IVDs.

In 2023, the FAMHP National Innovation Office continued to develop its collaboration with the Commission for International Cooperation in Health 'CIS Health' to establish a partnership with funding bodies in Belgium and consequently support non-commercial (pre-)clinical research in Belgium in a more targeted way.

TREND

After a downward trend in 2021 and 2022, more applications for advice were received in 2023 (of which 26 % related to the FAMHP's vaccines area of excellence). The increase is mainly visible in the number of SNSA applications. This is the result of a more harmonised procedure and greater awareness thanks to active and passive communication through various channels. In addition to providing broader support for drug developers, the SNSA procedure also enables better communication between the different national medicines agencies.

The significant increase in the number of TSE consultation procedures (48 % compared to 2022) is a consequence of the implementation of the Medical Device Regulation (MDR) and indicates that it is being effectively followed.

PHARMACOPOEIA/RAW MATERIALS UNIT

RAW MATERIALS FOR PHARMACY-MADE AND OFFICINAL PREPARATIONS

101
new authorisation applications to be processed

including

101
new authorisations granted

278
authorisation modifications

including

45
modifications denied

7
new monograph applications

4
new applications for general authorisation to operate in raw materials

DIRECTORATE-GENERAL
POST AUTHORISATION

competent for all activities following approval of the first marketing authorisation for a medicine or a health product

Marketing Authorisation (variations and renewals) 45

Vigilance 46

Human body Material 48

Health Products 50

Proper Use 52

DIVISION MARKETING AUTHORISATION (VARIATIONS AND RENEWALS)

APPLICATIONS FOR VARIATIONS AND RENEWALS OF MARKETING AUTHORISATIONS

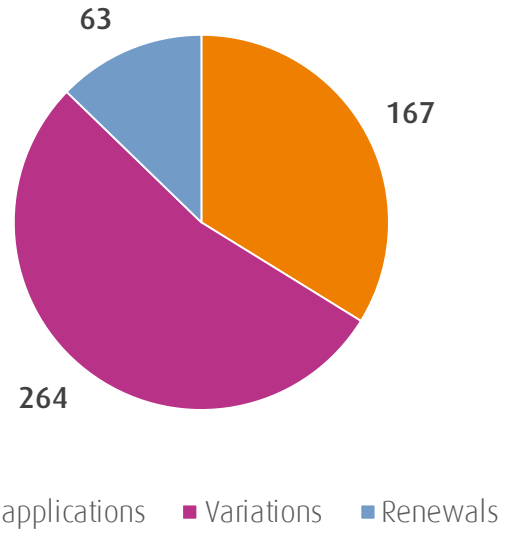
5 760

files submitted

5 048

files closed

Closed marketing authorisations for parallel import



CONTACT CENTRE

1 541

questions answered

DIVISION VIGILANCE

MEDICINAL PRODUCTS FOR HUMAN USE

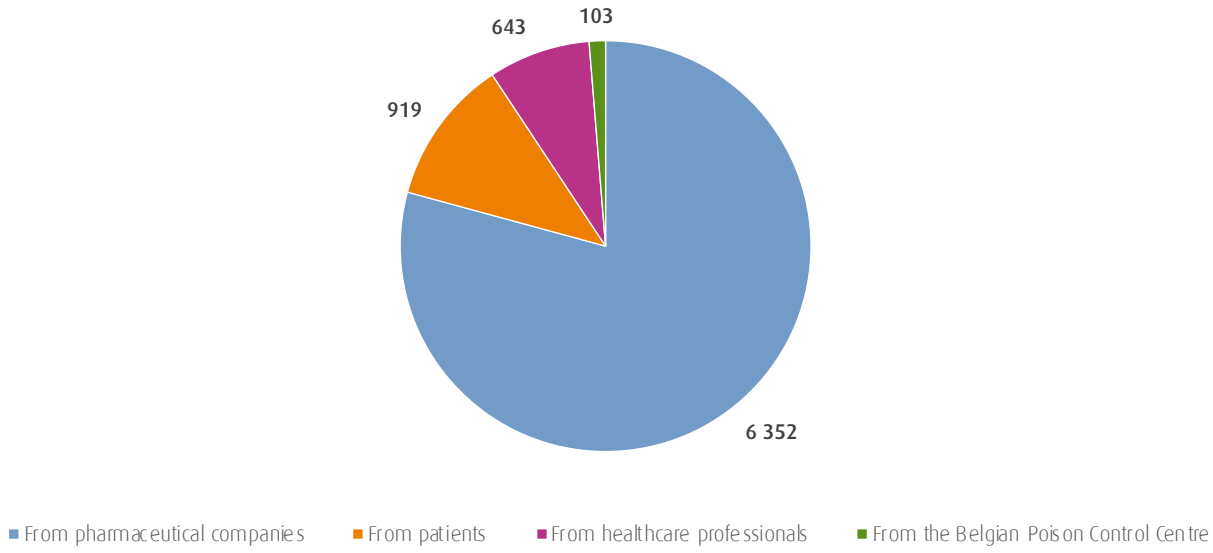
8 017

notifications received

127

updated safety reports received

Notifications of adverse reactions for medicinal products for human use



TREND

The number of notifications decreased compared to 2022 due to a lower number of notifications linked to the COVID-19 vaccination but remained higher than before the COVID crisis. The number of updated safety reports increased slightly.

ANNUAL SAFETY REPORTS

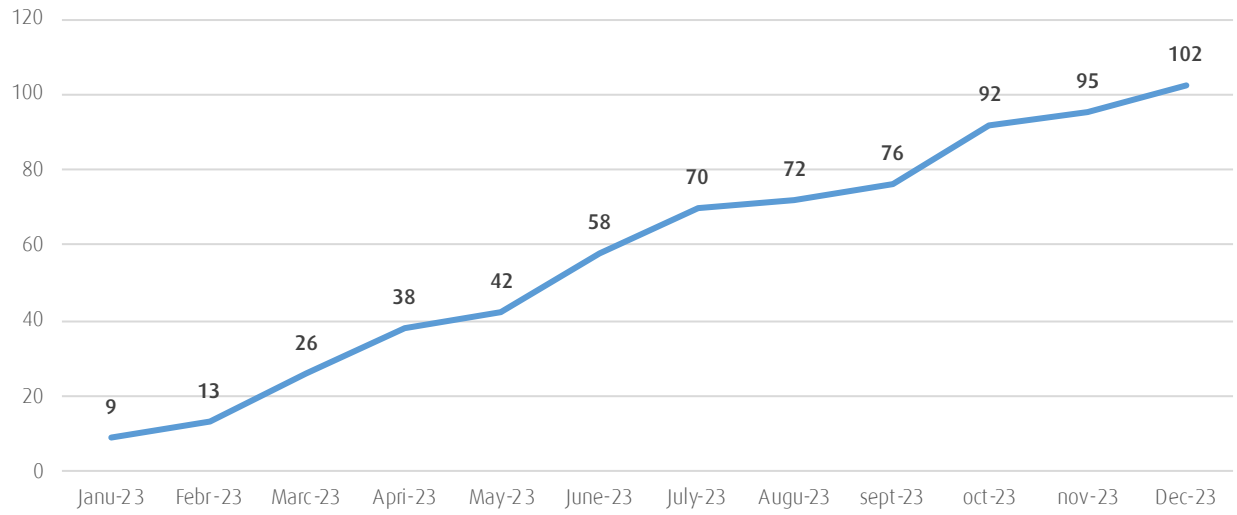
1 138

annual safety reports

SaMS

Change in the number of active substances for which Belgium is responsible for assessing safety data (SaMS), including the assessment of suspected serious and unexpected adverse reactions and annual safety reports.

Total number of SaMS



TREND

In 2023, there was a sharp increase due to the gradual allocation of active substances to European Union Member States under the new European Regulation.

MEDICINES FOR VETERINARY USE

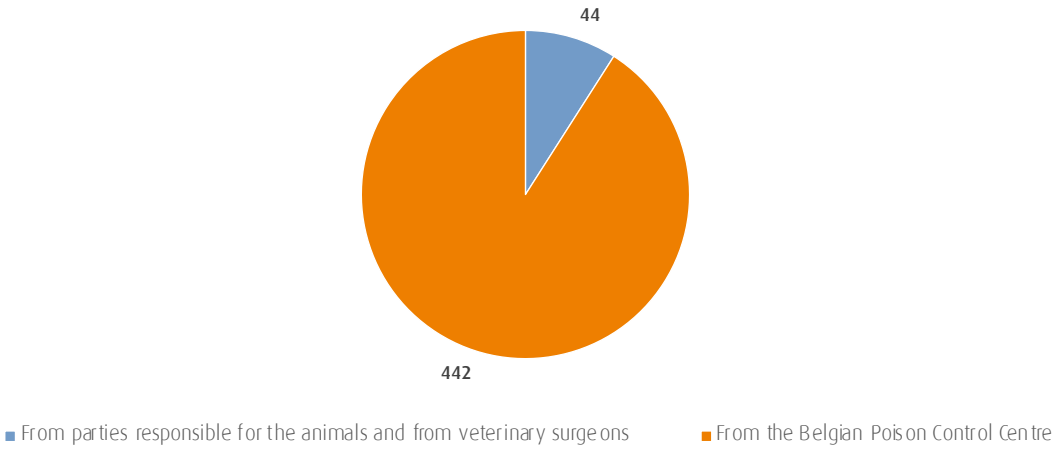
461

adverse reactions received

486

adverse reactions treated

Notification of adverse reactions for medicinal products for veterinary use



NEW

Vigilance is now shared between several departments.

Veterinary pharmacovigilance is now managed by the Assessors Division of DG PRE authorisation, and materiovigilance by the Health Products Division.

UNIT HUMAN BODY MATERIAL

HAEMOVIGILANCE (BLOOD AND LABILE BLOOD COMPONENTS)

1 196

reports of incidents and serious adverse events received

8

reports via the rapid alert system

BIOVIGILANCE (CELLS AND TISSUES)

303

notifications of serious adverse reactions and events received concerning cells or tissues intended for human medical applications

including

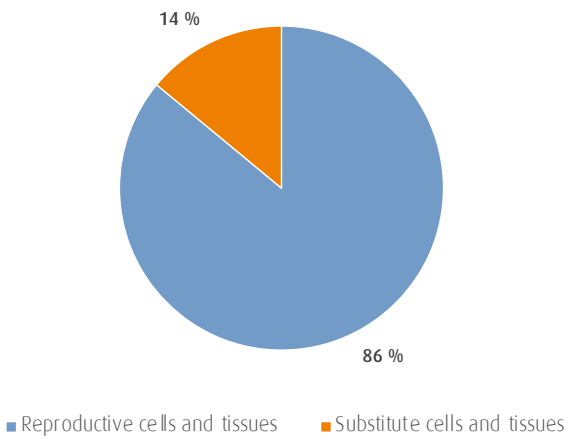
261

reports for reproductive cells and tissues used in medically assisted reproduction

42

reports for substitute cells and tissues used in the transplantation or transfusion of stem cells

Reports of serious adverse reactions and events



26

notifications received via the European Rapid Alert Tissues and Cells (RATC) platform

including

1

notification of a quality/ safety defect in a medical device relating to reproductive cells and tissues

18

notifications of a quality/ safety defect relating to reproductive cells and tissues

7

notifications for epidemiological opinions

3 notifications for substitute cells and tissues
3 notifications for haematopoietic stem cells
1 notifications for all types of cells and tissues

NEW

2023 saw a decrease compared with 2022 (-24%). The number of notifications received in 2023 compared with 2019 (pre-COVID period) still showed a significant increase (26 %).

TREND

Biovigilance:
In 2023 there was a further increase of approximately 9 % in the number of notifications (303 notifications), after a decrease in 2022 (280 notifications) compared to 2020 (327 notifications) and 2021 (334 notifications).

DIVISION HEALTH PRODUCTS

MEDICAL DEVICES

956

new actors (manufacturers, legal representatives, distributors, importers) were registered via the online registration system

1 837

free sale certificates of medical devices

433

free sale certificates of in vitro diagnostic medical devices

467

applications for marketing authorisations for class I medical devices received

1 999

applications for marketing authorisations for class I in vitro diagnostic medical devices received

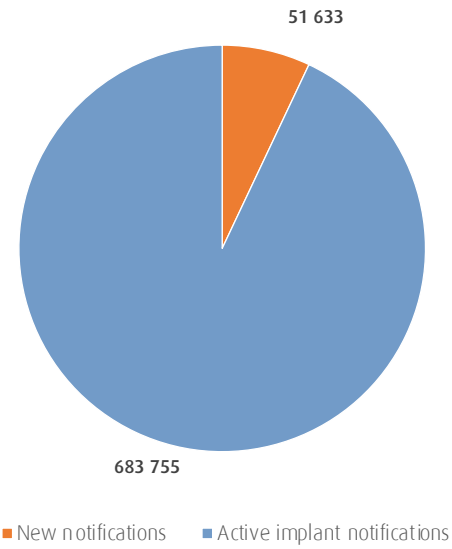
222

registrations of FAMHP-approved actors in Eudamed

1 654 215

reports of the implantation and explanation of medical devices in the central traceability register (CTR)

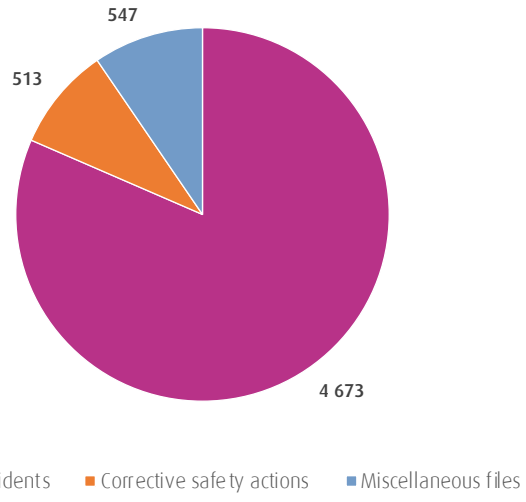
Implants and invasive medical devices notified to the FAMHP



5 733

vigilance notifications for medical devices

including



NEW

2023 saw another significant increase of over 25 % in the number of serious incidents, following a smaller increase in 2022 (10 %).

DIVISION PROPER USE

INFORMATION ABOUT MEDICINAL PRODUCTS AND MEDICAL DEVICES

569

questions from the public and health professionals answered

DATABASE

1 152

new authorisations for medicinal products in Belgium (in the Medicinal Product Management database)

886

concerning medicinal products for human use

266

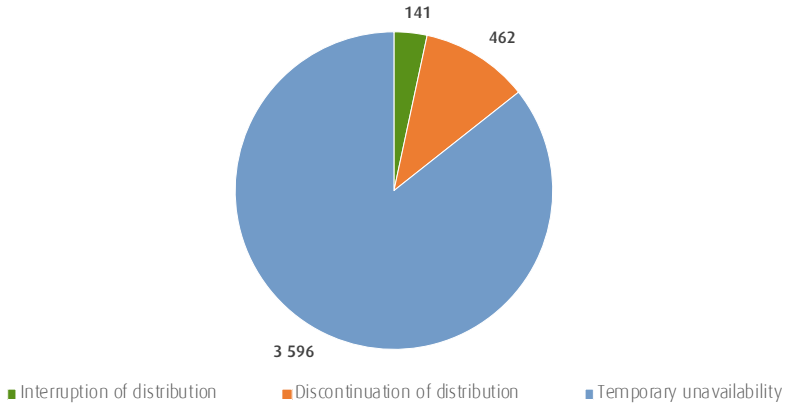
concerning medicinal products for veterinary use

724

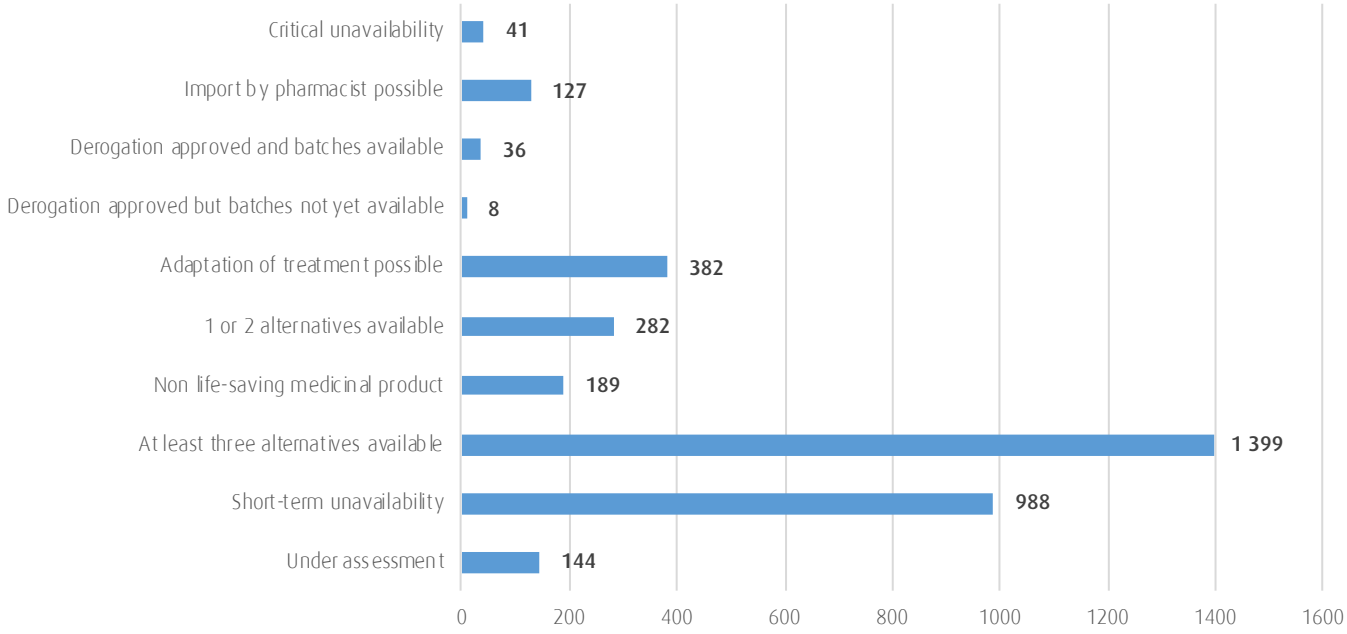
amendments to centrally authorised medicinal products (in the Medicinal Product Management database)

AVAILABILITY OF MEDICINAL PRODUCTS FOR HUMAN USE

Notifications on the unavailability of medicinal products for human use



Impact of new temporary unavailabilities



1 713

questions from the public and health professionals answered

9

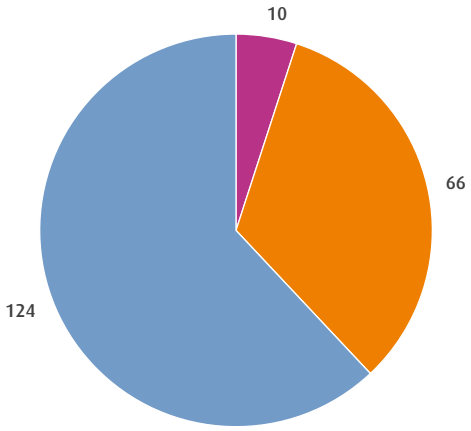
meetings of the task force in cases of critical unavailability

25

follow-up meetings of the task force in cases of critical unavailability

AVAILABILITY OF MEDICINAL PRODUCTS FOR VETERINARY USE

Notifications on unavailability for medicinal products for veterinary use



ADDITIONAL RISK MINIMISATION ACTIVITIES

70

dossiers for risk-limiting activities approved

ADVERTISING OF MEDICINAL PRODUCTS FOR HUMAN USE DIRECTED AT THE GENERAL PUBLIC

659

new notifications of advertising handled

110

renewals of notifications of advertising handled

61

new approvals for radio or television advertising issued

6

renewals of approvals for radio or television advertising issued

5

new approvals for an information campaign on radio or television issued

NEW

On 18 December 2023, the FAMHP launched PharmaInfo, a web portal for citizens and patients containing easily understandable and reliable information on medicines and health products.

- 97 new medicine information sheets published
- 5 new information sheets on medical devices published
- 28 new themes published
- 7 news items published

More information on this subject can be found in the "In the Spotlight" section of our annual report.

DIRECTORATE GENERAL **INSPECTION**

competent for all inspection and control activities

Industry 57

Distribution 57

Dispensing 60

Authorisations 61

Medical Devices 64

Special Investigation 65

DIVISION INDUSTRY

INSPECTIONS

120

good manufacturing practice inspections

46

good clinical practice inspections concerning medicines

RAPID ALERT SYSTEM

418

rapid alerts on the quality of medicines

ANALYSES OF PRODUCTS ON THE MARKET

150

medicines

314

preparations

17

raw materials

90

products seized

8

medical devices

DIVISION DISTRIBUTION

INSPECTIONS

64

routine inspections concerning good distribution practices

129

inspections concerning good distribution practices for medicines for obtaining or amending a distribution authorisation

22

pharmacovigilance inspections

32

inspections of human body material establishments

3

inspections of establishments importing human body material

2

thematic inspections of depots for human body material

12

inspections of blood establishments and donation centres

2

thematic inspections blood (mobile collections)

5

inspections of advertising and other promotional activities

INVESTIGATIONS

48

investigations concerning the distribution of medicines

1

pharmacovigilance investigation

2

human body material investigations

CHECKS ON ADVERTISING AND OTHER PROMOTIONAL ACTIVITIES FOR MEDICINES AND HEALTH PRODUCTS

25

checks on medicines

49

investigations on medicines

NOTIFICATIONS

309

notifications from the local pharmacovigilance officer

ACCREDITATION NUMBER OF RESPONSIBLE QUALIFIED PERSON

19

accreditation numbers awarded to people responsible for information

76

changes to the management of people responsible for information

SCIENTIFIC AND LEGAL QUESTIONS CONCERNING GOOD DISTRIBUTION PRACTICES

389

responses to scientific and legal questions concerning good distribution practices

71

responses to scientific and legal questions concerning human body material and blood

131

responses to questions on advertising and other promotional activities

NEW

In 2023, there was an increase in pharmacovigilance inspections, inspections of advertising and other promotional activities and of human body material establishments.

Pharmacovigilance: in addition to routine checks, the first pharmacovigilance inspections were also carried out this year in accordance with the provisions of the new European regulation on veterinary medicinal products (Regulation (EU) 2019/6) on holders of marketing authorisation for veterinary medicines.

Advertising and other promotional activities: these inspections were restarted again in 2023, following the COVID crisis.

DIVISION DISPENSING

INSPECTIONS

477

pharmacies open to the public

23

reinspections of pharmacies open to the public

60

hospital pharmacies for medicines

1

reinspection of hospital pharmacies for medicines

350

veterinary depots

INVESTIGATIONS

111

investigations on the dispensing of medicines (administrative dossiers)

86

investigations on the dispensing of medicines (legal dossiers)

FILES VETERINARY DEPOTS

301

files veterinary depots

QUESTIONS

2 908

questions on the dispensing of medicines

NEW

Of the 477 inspections of pharmacies open to the public, 81 were carried out as part of an operating license application.

The new legislation on pharmacies open to the public, in particular the entry into force of the Royal Decree on autocontrol in pharmacies, and the new legislation on veterinarians (updated in the 2016 Royal Decree) have raised many more questions in the sectors concerned.

TREND

In 2023, 1.5 FTE inspectors were added to the Retail Pharmacies unit. This has enabled a greater number of inspections.

DIVISION AUTHORISATIONS

HORMONES AND ANTIBIOTICS

45
new authorisations

123
renewals

4
letters of no objection

107
extensions/amendments of authorisations

NARCOTICS AND PSYCHOTROPIC SUBSTANCES

15
new activity authorisations

76
amendments to authorisations

5 786
authorisations for import and export

823
inspections as part of import and export authorisations

6
additional inspections

3 552
narcotics order forms (per 100 forms)

34
letters of no objection

458
validations of Schengen declarations

92
new or renewed end-user authorisations

8
amendments of end-user authorisations

PRECURSORS

16
new authorisations

51
renewals or amendments

8
import authorisations

1 196
export authorisations

41
suspicious orders and transactions

8
inspections of authorisations

5
letters of no objection

MANUFACTURING AND DISTRIBUTION AUTHORISATIONS

203
authorisations for the manufacturing/ distribution of medicines

31
registrations for the import/manufacturing/ distribution of pharmaceutical raw materials

30
certified copies

255
certificates for good manufacturing practices/good distribution practices

2 152
copies of certificates for good manufacturing practices/ good distribution practices, authorisations for the manufacturing/distribution or registrations for the manufacturing/distribution of pharmaceutical raw materials

1 674
certificaten voor farmaceutische producten, waarvan 201 dringende

1 717
e-legalisations of documents

HUMAN BODY MATERIAL AND BLOOD ESTABLISHMENTS

71

accreditations for human body material establishments

25

preliminary accreditations for human body material establishments

1

amendment to accreditations for human body material establishments

10

accreditations for establishments importing human body material

14

accreditations of biobanks

PHARMACIES OPEN TO THE PUBLIC

288

new applications before the Commission for establishment of pharmacies open to the public

838

cadastral registration forms of pharmacies open to the public

PHARMACISTS-CLINICAL BIOLOGISTS

27

authorisations of pharmacists-clinical biologists

DEPOSITARY VETERINARIANS

329

notifications of a veterinary depot

NEW

The sharp decrease in the number of narcotics order forms is explained by the switch to a new electronic system from 1 September 2023.

DIVISION MEDICAL DEVICES

14

inspections concerning good clinical practices involving medical devices

119

inspections of manufacturers of medical devices in Belgium

1

inspection of notified bodies abroad

3

inspections of notified bodies in Belgium

215

inspections of medical device distributors

28

inspections of hospitals concerning medical devices (including sterilisation divisions)

10

inspections of European authorised representatives

5

inspections of importers

1

inspection as an expert for Belac (Belgian Accreditation Body under the authority of the FPS Economy, to which Belgian companies and organisations can turn to obtain accreditations)

353

investigations into medical devices

333

questions about medical devices

NEW

Reports on two thematic actions were published in 2023. The first concerned unregistered medical device distributors, and the second the distribution and rental of oxygen concentrators.

TREND

The number of inspections of medical device distributors has increased by over 49 %, from 144 to 215.

The number of questions and investigations into medical devices increased in 2023.

SPECIAL INVESTIGATION UNIT

679

closed investigations into illegal medicines in illegal circulation

48

investigations into illegal health products in illegal circulation

142

cases in which assistance was provided to police and public prosecutors

608

cases of advice given to other (domestic and foreign) authorities

3 551

blocked postal packages sent from outside the European Economic Area to a Belgian addressee. The packages contained non-compliant medicines, medical devices and in vitro diagnostics

175

controls of consignments in transit (destined to another EU Member State)

NEW

In 2023, the SIU actively participated in writing two articles published by Sciensano.

In 2022 and 2023, the SIU provided Sciensano with samples of sildenafil and ivermectin in order to learn more about the risks posed by these substances.

Based on these samples, Sciensano was able to provide detailed reports to the SIU, and to draw up documents relating to the analyses carried out.

Overall, it was concluded that the majority of these samples present a health risk. Under- and overdosing are frequent. Some samples (both sildenafil and ivermectin) were bacteriologically contaminated. On the basis of these two findings, it would appear that hygiene conditions at the manufacturing sites of certain products in third countries are poor.

TRANSVERSAL SUPPORT

with the general support services of the agency which fall directly under the Chief Executive Officer

Management Support 67

ICT 67

Budget and Management Control 70

Communication 71

Legislation and Litigation 72

Personnel and Organisation 73

Quality 74

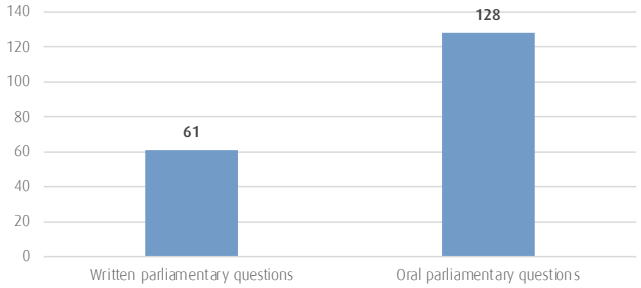
International Relations 77

Project and Portfolio Management Office Coordination 78

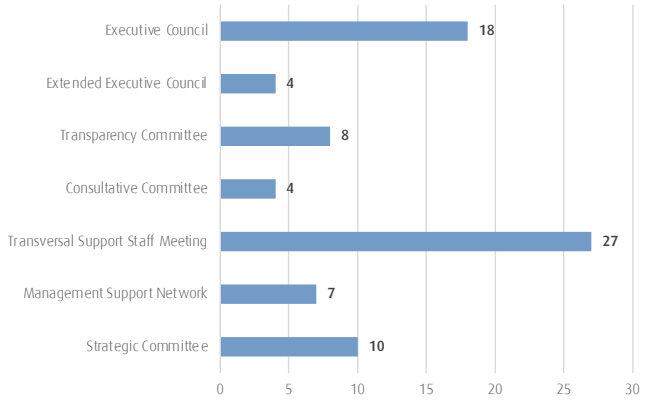
Spearheads 79

MANAGEMENT SUPPORT

Answered parliamentary questions



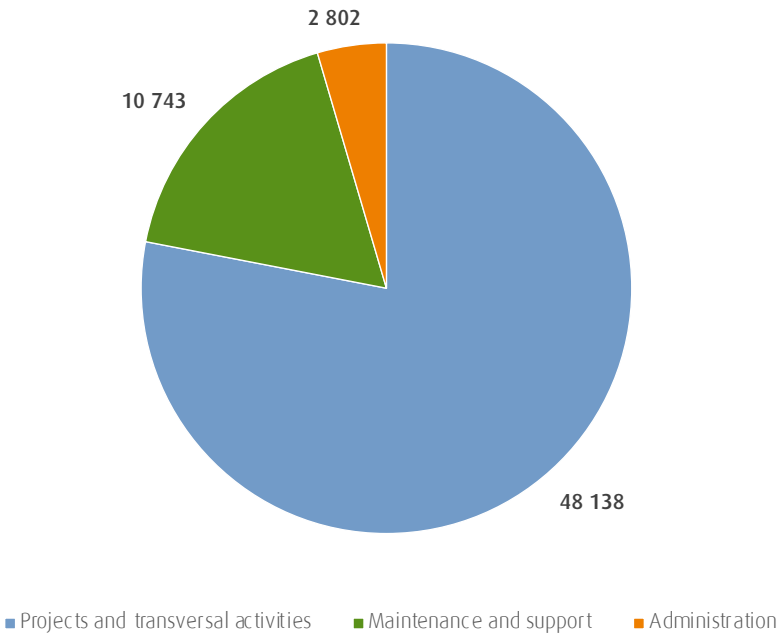
Organised meetings



DIVISION ICT

PROJECTS AND DEVELOPMENT ENTITY

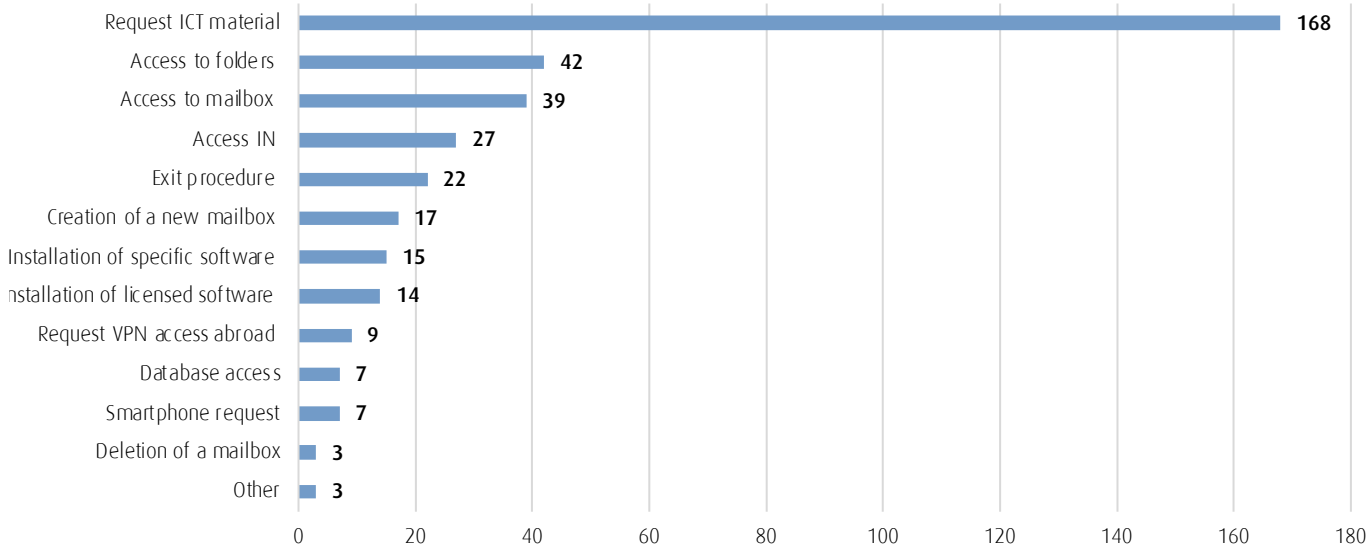
Distribution by activity (in number of hours)



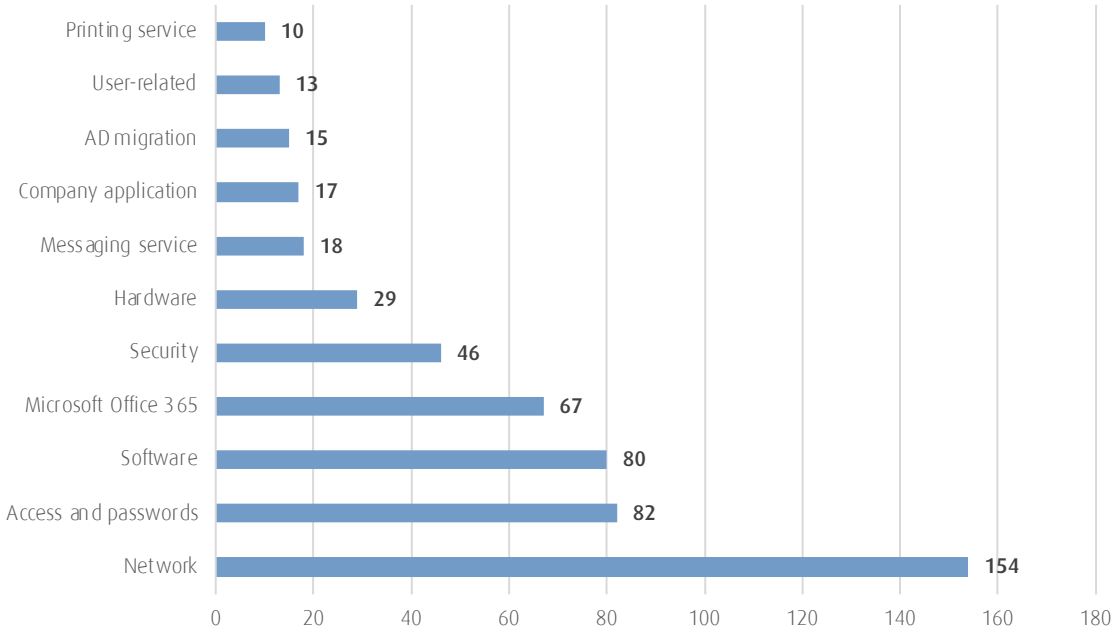
OPERATIONS ENTITY

SERVICE DESK TEAM

Requests handled through the ServiceNow ticketing system

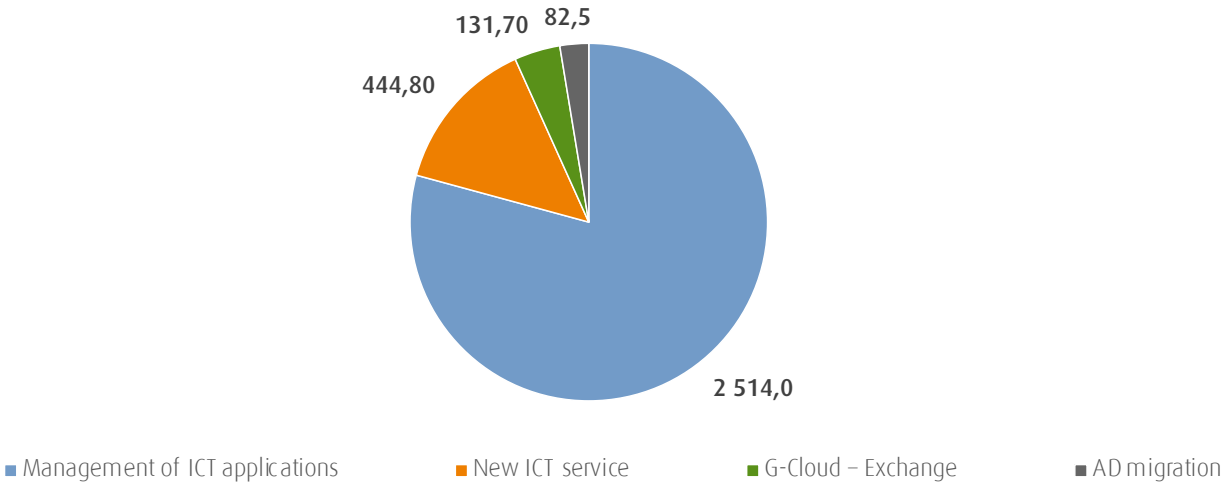


Incidents handled through the ServiceNow ticketing system



INFRASTRUCTURE TEAM

Distribution by activity (in number of hours)



NEW

Our mission is to manage and implement the FAMHP's ICT tools in line with the agency's strategic objectives. We would like to thank all the FAMHP staff who helped us better understand their needs. This has enabled us to provide solutions that effectively support our users in their daily work.

With the development of Agile, we worked iteratively and collaboratively, actively involving our colleagues from other entities throughout the development cycle of each application.

The ICT division contributed to many projects this year.

1. PharmaInfo
2. Narcoreg
3. Autocontrol in pharmacies
4. Fertidata
5. Data Tracking System

The first three projects mentioned above are described in the 'In the spotlight' section of this annual report.

DIVISION BUDGET AND MANAGEMENT CONTROL

Expenses	Budget 2023 (€)	Implementation 2023 (€)	Balance 2023 (€)	Percentage
Personnel expenses	65 733 105	60 711 628	5 021 477	92 %
Other personnel costs	720 926	681 080	39 846	94 %
Sciensano's expertise	7 997 787	6 371 421	1 626 366	80 %
Other expertise	3 195 148	1 228 789	1 966 359	38 %
ICT investments	12 650 357	12 833 497	- 183 140	101 %
Other investments	4 939 565	3 354 610	1 584 955	68 %
Allocation 1FM	2 470 437	2 396 437	74 000	97 %
ICT capital expenses	212 639	11 268	201 371	5 %
Non-ICT capital expenses	183 547	331 084	- 147 537	180 %
Subsidies for NAT blood tests	9 901 249	9 901 249	/	100 %
Subsidies and other expenses	10 370 281	9 924 067	446 214	96 %
Reimbursement to the Federal State	/	3 333 459	- 3 333 459	/
	118 375 041	**111 078 590**	**7 296 451**	**94 %**

* ICT Information and Communication Technology
**1FM Joint Facility Service of the FAMHP, the RIZIV-INAMI and the FPS Health
***NAT Nucleic Acid Amplification Test – Blood test using the nucleic acid amplification technique

Revenue	Budget 2023 (€)	Implementation 2023 (€)	Balance 2023 (€)	Percentage
Fees for medical devices	15 510 345	16 334 721	- 824 376	105 %
Fees for packaging	18 408 450	19 494 186	- 1 085 736	106 %
Fees marketing authorisations	12 294 384	7 005 448	5 288 936	57 %
Fees inspections	6 057 025	6 580 799	- 523 774	109 %
EMA revenues	7 659 161	7 754 780	- 95 619	101 %
Revenues from clinical trials	4 731 061	3 627 035	1 104 026	77 %
Revenues from registrations	11 501 385	10 820 185	681 200	94 %
DSUR revenues	/	1 106 908	- 1 106 908	/
Revenues from clinical research	2 029 749	564 892	1 464 857	28 %
RIZIV-INAMI revenues	3 617 751	3 599 750	18 001	100 %
Other revenues	6 282 468	5 137 303	1 145 165	82 %
Revenues from European projects	1 623 915	398 822	1 225 093	25 %
Allocation	28 659 347	28 653 760	5 587	100 %
	118 375 041	**111 078 589**	**7 296 452**	**94 %**

*EMA European Medicines Agency
**DSUR Development Safety Update Report

In the first half of 2024, Belgium will hold the presidency of the Council of the European Union. In this context, the FAMHP is taking numerous initiatives such as organising conferences. The agency has set up a cost accounting system to carefully track the expenses and revenues (allocations) resulting from this role.

To ensure the correct and efficient collection of all fees and contributions due, the revenue accounting team worked to make invoicing procedures more efficient in 2023. A reminder module and the establishment of a partnership with FPS Finance will help the FAMHP to recover unpaid invoices and spread the financial burden fairly among all economic operators.

NEW

The Belgian Pharmaceutical Association (APB) has an analytical laboratory whose activities contribute to the dispensing of quality medicines by pharmacies (and depositary veterinarians). This Medicines Control Laboratory (SCM) is financed by pharmacies. Their fees are proportional to the quantities of medicines they purchase. Companies supplying medicines to pharmacies report their sales quantities to the FAMHP each quarter and pay their contribution into a separate FAMHP account to finance the SCM. Since this is not the only tax on the number of packages sold, there has often been ambiguity in the past. In 2023, the FAMHP provided clear and complete information to all companies concerned. This immediately translated into a significant increase in revenue, and thus into fairer and more adequate funding for the SCM.

After several years of preparatory work and consultation with representatives from the sector, the system for financing the market surveillance of actors operating in the medical devices sector was reformed in 2023. To compensate, an activity tax was introduced. The nature of the activities, the classes of medical devices involved and whether or not they participate in the autocontrol programme largely determine the contribution of each actor, reflecting the risk to public health and the workload for the FAMHP. At the same time, we reduced the annual turnover tax by a quarter, removed the minimum contribution due and introduced a minimum threshold which will now mean that companies that have a limited turnover from medical devices are exempt from paying the turnover tax.

DIVISION COMMUNICATION

368	69	220	>3 500
answers to press questions recorded	news items on the website	internal newsletters	new followers on social media

TREND

In 2023 we received 33% more press requests than in 2022. The average response time was half a day.

77% of press questions were answered within one working day, and 17% of press questions were answered after one working day.

Only 6% of press questions were answered after more than one working day.

The questions most frequently answered concerned:

- medication shortages;
- temporarily unavailable medicines;
- Ozempic (unavailability, recommendations, side-effects, falsification).

LEGISLATION AND LITIGATION DIVISION

74

publications in the Belgian Official Gazette

13

TRIS procedure with the European Commission

210

offence reports prosecuted

70

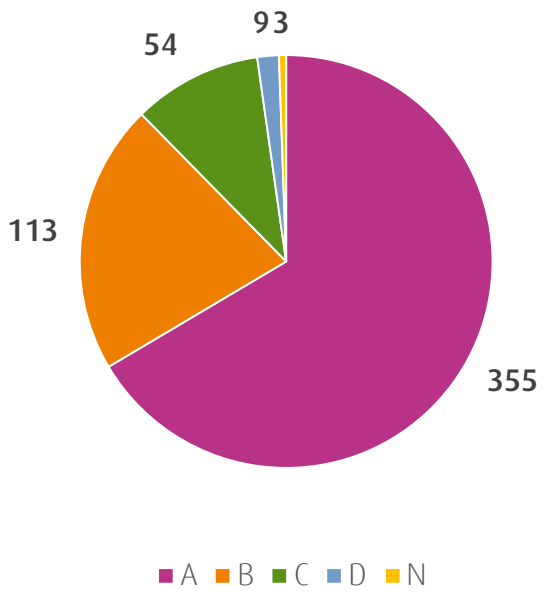
litigation in progress, including 13 new cases arriving in 2023

20

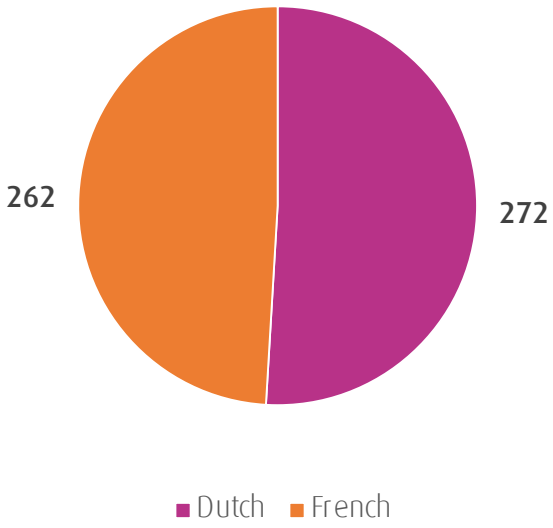
passive advertising requests

DIVISION PERSONNEL AND ORGANISATION

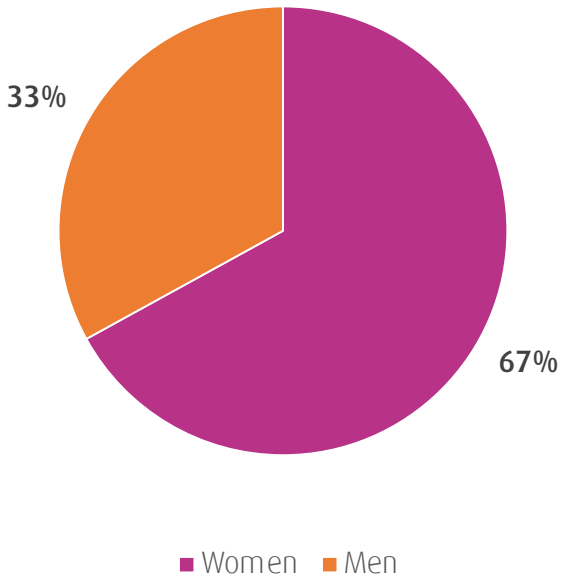
Distribution by level



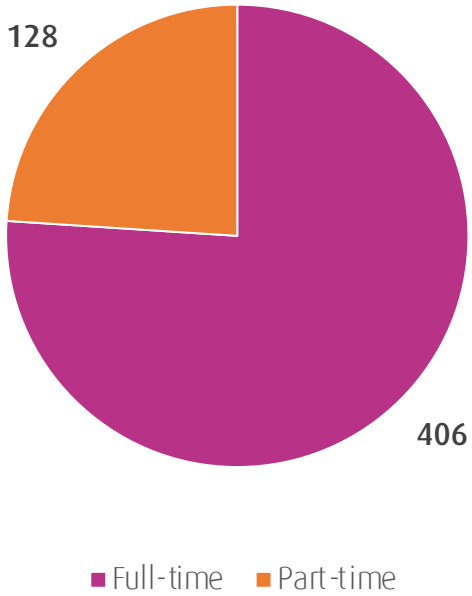
Distribution by language



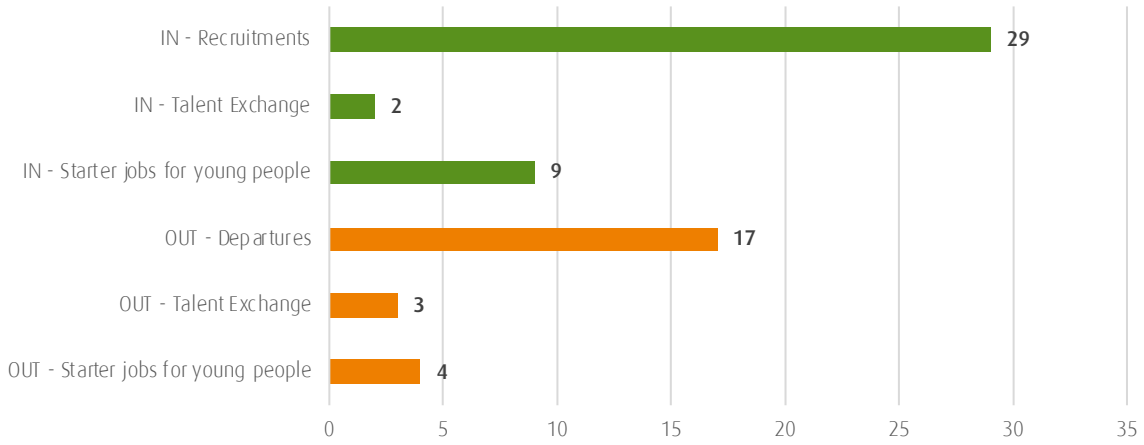
Distribution by gender



Distribution by working regime



Staff turnover



NEW

In the distribution by level, we have also added 'authorised representatives' as a separate category, as provided for in the Royal Decree of 16 November 2006 on the designation and exercise of management and supervisory functions in certain public-interest bodies.

During the summer months of July, August and September 2023, we welcomed 35 student workers. The students were employed in the agency's various divisions, as well as in 1FM's support services. The linguistic distribution was proportionate: 17 French-speaking student workers and 18 Dutch-speaking student workers. The average age of the student workers was 18. For legal reasons, four external students were also recruited in 2023. These are students who are not family members of FAMHP staff.

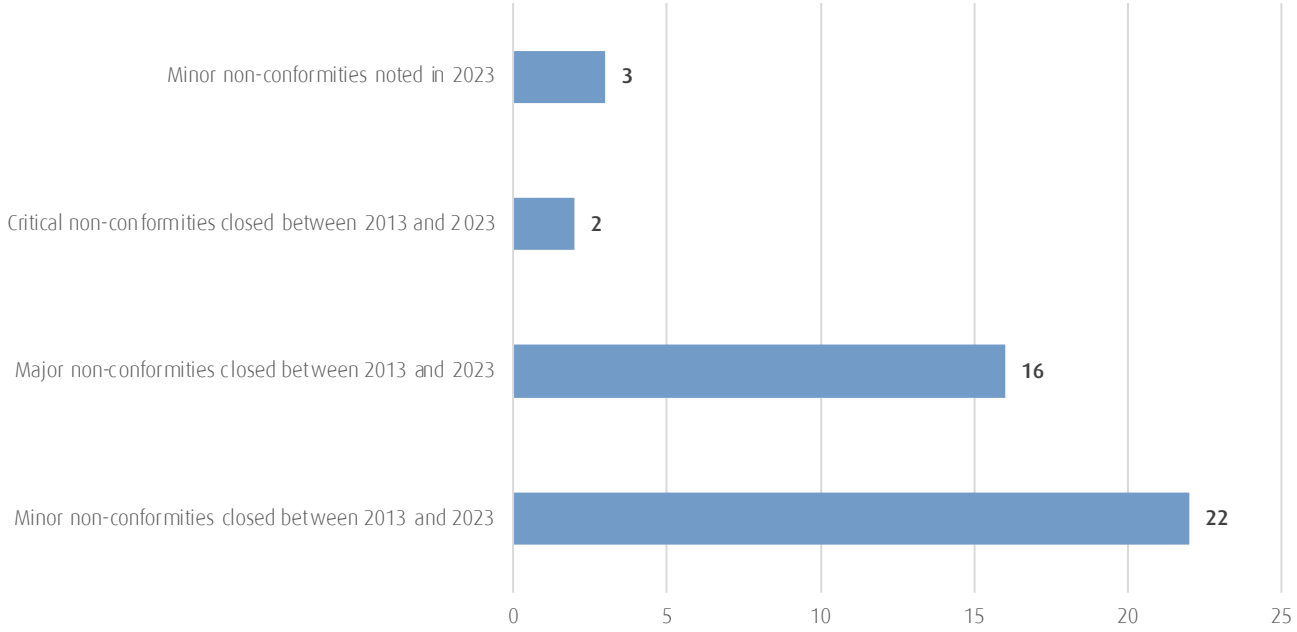
QUALITY DIVISION

QUALITY AUDITS

1

quality audit conducted by the FAMHP: human pharmacovigilance system

Non-conformities in internal audits



INTERNAL AUDIT BY THE FEDERAL INTERNAL AUDIT SERVICE

1

audit on the Inspection Services of the Federal Agency for Medicines and Health Products

1

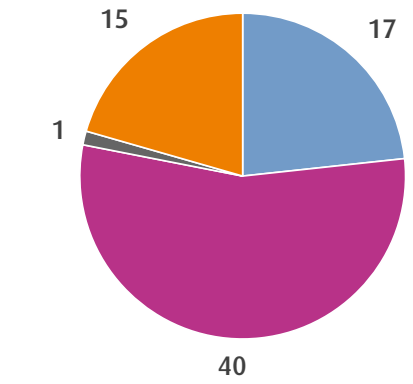
follow-up audit on the recommendations from the 2018_13 'Certification of accounts – From established law to cash management' audit

1

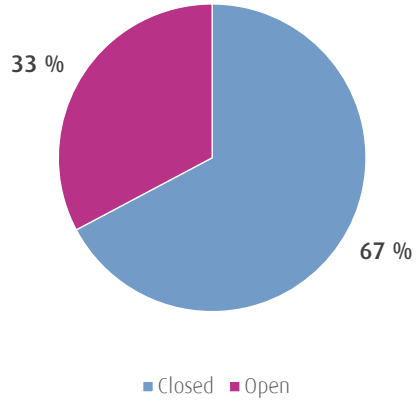
follow-up audit on the recommendations from the 2019_13 'Certification' audit

EXTERNAL COMPLAINTS

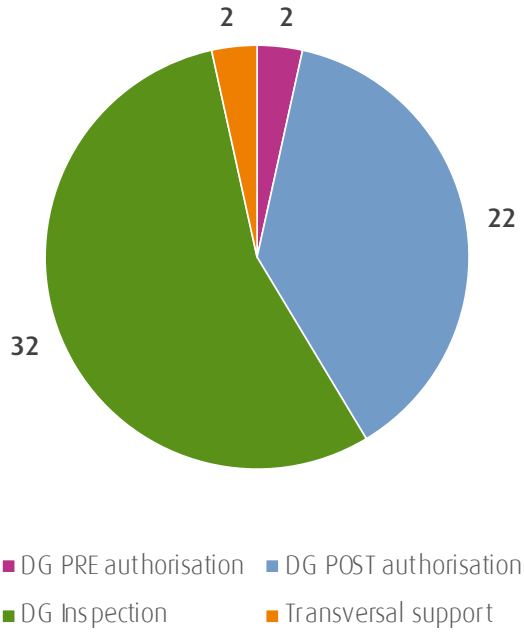
Received complaints



Status of the received complaints



Distribution of complaints by entity

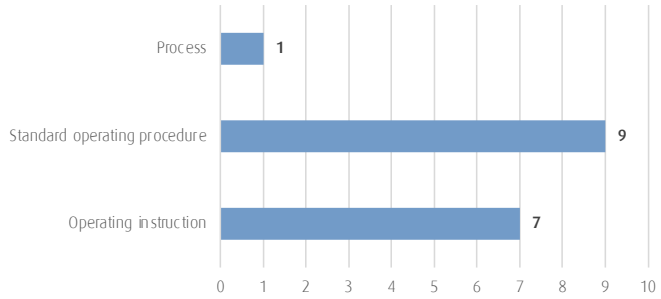


QUALITY DOCUMENTS

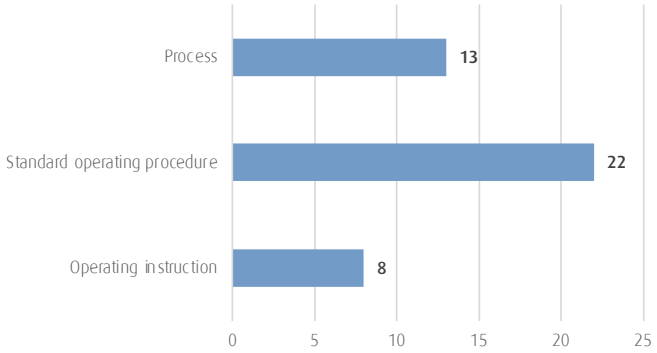
17
new quality documents

43
modified quality documents

Types of new quality documents



Types of modified quality documents



NEW

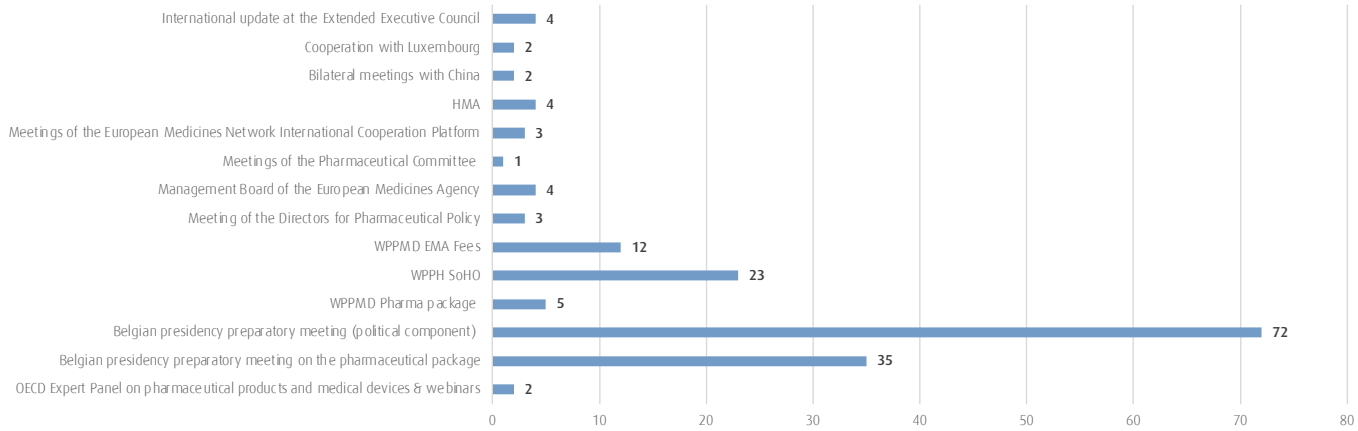
The Network of Directors of European Medicines Authorities (HMA) is organising a fifth benchmarking exercise for the period 2022-2025, called Benchmarking of European Medicines Agencies (BEMA V). In 2023, the FAMHP participated for the fourth time in this improvement exercise. Learn more in this article.

TREND

In 2023, the 'quality' audit schedule was limited to mandatory audits. The organisation of BEMA V involved a large number of teams in this exercise to assess the management maturity of our services and activities.

INTERNATIONAL RELATIONS UNIT

International cooperation in 2023



NEW

2023 was an extraordinary year in more ways than one for the International Relations Unit. Preparations for the Belgian presidency of the Council of the European Union in the first half of 2024 were naturally a large contributor to this, but they are not the only important factor.

There was also intense legislative and political activity. On the legislative front, we reached agreement in less than one year on the revision of the regulation on fees payable to the European Medicines Agency, and finalised the Council's position on the new SoHO regulation in less than eighteen months. It is also worth noting the adoption, in record time, of a proposed regulation amending the transition period of Regulations 2017/745 and 2017/746 for certain devices.

On the political front, Belgium stood out internationally as the driving force behind European action on medication shortages with the launch of a non-paper on medicines shortages (Non-paper – Improving the security of medicines supply in Europe), which was supported by 23 Member States and followed in October of the same year by a communication from the Commission (addressing medicines shortages in the Union).

Finally, the FAMHP continued and developed its bilateral activities with Luxembourg, following the entry into force of the cooperation agreement between the Kingdom of Belgium and the Grand Duchy of Luxembourg on medicines and health products in December 2022, and implemented the framework cooperation agreement on medicines and health products between the FAMHP and ENABEL through a specific agreement relating to support for the Senegalese Agency for Pharmaceutical Regulation to achieve and maintain WHO Maturity Level three.

PROJECT AND PORTFOLIO MANAGEMENT OFFICE COORDINATION

26

projects supported by our experts

NEW

In 2023, ten projects were delivered or entered their final testing phase, including several major projects such as:

- the delivery of the basic functionalities of
  - MPM (FAMHP central database for medicines);
  - DTS (electronic dossier tracking application);
  - HIRS (research and reports based on data from the two applications above);
- the digitisation/autocontrol of narcotics order forms (Narcoreg);
- the electronic document transmission and approval processes;
- the new quality system (replacing DMS Quality).

Other ongoing projects will continue to occupy our resources in 2024.

SPEARHEADS

EARLY STAGE DEVELOPMENT

158

applications for phase I clinical trials or phase I/II clinical trials

38 under the Directive and 120 under the Regulation, including 22 transitional trials

which

80

applications are for first-in-human trials

24 under the Directive and 56 under the Regulation, including 15 transitional trials

ONCOLOGY

233

applications for clinical trials with oncologic medicinal products

15

for a paediatric population

14

with advanced therapy medicinal products

VACCINES

15

applications for clinical trials with vaccines

NEW

The Vaccines Spearhead management group was relaunched with an increase in membership.

Participation in Flanders Vaccine symposia, including 'Immunity for Health'.

Participation in IABS workshops:

- workshop on 'Ethical approval for Controlled Human Infectious Models (CHIM) clinical trial protocols';
- workshop on 'The role of real-world evidence for regulatory and public health decision-making for accelerated vaccine deployment'.

Collaboration launched with the 'Leading International Vaccinology Education (LIVE)' MSc programme, offering internships to MSc LIVE students.

Launch of a project on knowledge of and attitudes towards Human Challenge trials.

famhp

Your medicines and health products, our concern

Federal Agency for Medicines and Health Products

Avenue Galilée 5/03, 1210 BRUSSEL - BELGIUM
+ 32 2 528 40 12
comm@fagg-afmps.be
www.famhp.be

Concept and realisation: Mtea Digital Solutions , Ooigem