THE famhp TIMES

2014 Annual Report

"Counterfeit and illegal medicines have not yet appeared in the legal supply chain in Belgium. The famhp is making every effort to keep it this way."

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What role is the famhp playing in combating Ebola?

P. 12

Extension of the moratorium on pharmacies. Is this a good thing or just out-of-date?

P. 15

Are e-cigarettes really so harmless?

The electronic cigarette or e-cigarette is gaining in popularity. However, how healthy or unhealthy are these "e-cigarette products"? A question mark still hangs around this issue. The famhp raised this issue in its 2013 annual report and once again it is setting out the current situation, namely, this topic continues to provoke debate.
The e-cigarette was proposed as an electronic alternative to smoking cigarettes. In the early days, they looked a lot like traditional cigarettes. Nowadays, these devices appear in all shapes and colours. Although they maybe appear to be innocuous, the devices often contain high quantities of nicotine.

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Note from the Chief Executive Officer

Dear Reader,

This year, we are presenting our annual report in a new guise. We have incorporated the topics that we would particularly like to highlight into a newspaper. We hope that this format will effectively convey that our agency is involved with matters that are of importance for you, too, every single day.

In the second part, we provide our yearly overview of the operations and results of the different divisions, entities, units and co-ordinations of the famhp. Charts and data tables offer a clear illustration of our activities and the results achieved.

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NOTE FROM THE CHIEF EXECUTIVE OFFICER

Up to the professionalisation of the famhp

We consider 2014 to be the year marking the next phase in the life-cycle of our agency. For myself personally, it was the beginning of my second mandate as Chief Executive Officer and for this period, a new, multi-year management plan has been created: the 2014-2018 Management Plan, which will allow us to further advance the professionalisation of the famhp.

I would like to summarise our ambition for the period 2014-2018 as follows: starting from our strategic goals, to consolidate our results and achievements and to provide our partners with the necessary support in order to face new challenges. I would especially like to emphasise two aspects here: meeting public health needs in relation to the fields of medicines and health products and reaffirming the central position of the patient.

We are going to have to confront numerous challenges, both external and internal: from increasingly critical patients with ever higher expectations, to the ageing population, Unmet Medical Needs, more "Europe" in the world, developments in the many fields falling under the famhp's authority, new advanced therapies and personalised medicine, to the internal policy on personnel, ICT, budget, quality and management.

I would like to conclude with my sincere thanks to all of the agency staff for their hard work. I'm pleased to be able to rely on your expertise and commitment. I would also like to thank our partners, patients, healthcare practitioners, the academic world, industry, the competent authorities and the political leaders of the member states and the European institutions for the constructive contribution they have made to the professionalisation of our agency.

Enjoy reading,
Xavier De Cuyper

Consultation with patients has begun

To further improve our provision of information to patients, the famhp has taken the initiative to organise a consultation with the parties involved. We have set up a discussion group with members of the current Patients' Platform and representatives from insurance companies, doctors, pharmacists, the National Institute for Sickness and Disability Insurance (RIZIV-INAMI), ethical committees, the Superior Health Council (HGR-CSS) and the King Baudouin Foundation.

In 2015, we anticipate an initial document that will set out the foundations for a long-term plan on the development of the information that we want to provide to patients.

A CHARTER FOR THE EXECUTIVE COUNCIL AND MIDDLE MANAGEMENT

The Executive Council and the Middle Management, in other words the Extended Executive Council, have decided to elaborate and apply a charter for operation and conduct.

We will behave in a **respectful manner**
We will show **empathy and actively listen** to others
We are assertive and have the courage to express our opinion and give advice
We **communicate** coherently and directly and we **share** information
We give each other **constructive feedback**
We respect a **decision**

By signing this charter, each member commits to becoming a creative, sympathetic, dynamic and responsible management team.

Charter concerning the performance and behavior of the Executive Council and Middle Management.

Your medicines and health products are our concern!

Mission

The famhp plays an essential role in the protection of public health with the following mission:

"Ensuring, from development to use, the quality, safety and efficacy:
- of medicines for human and veterinary use, including homoeopathic medicines and herbal medicines, pharmacy made and officinal preparations;
- of health products, including medical devices and accessories, and raw materials for the preparation and production of medicines.

Ensuring, from collection to use, the quality, safety and efficacy:
- of all operations involving blood, cells and tissues, which are also defined as health products".*

Role

To ensure the quality, safety and efficacy of medicines and health products in clinical development and on the market.

Values

The values nurtured within the famhp are carefully selected and form the unifying theme in our day-to-day activities:
- Integrity
- Commitment
- Adaptability
- Team Spirit

** Based on the law of 20 July 2006 (BS-MB 08.09.2006) concerning the establishment and functioning of the famhp.*

famhp
federal agency for medicines and health products

Dangerous, not dangerous?

Nicotine is an extremely toxic substance. The dose in a single refill is often sufficient to kill a child or even an adult. That is why the famhp and other organisations such as FPS Public Health and FPS Economy are also vigilant about the risks of products that contain nicotine.
Some people are in favour of e-cigarettes, others are against them. According to the first group, electronic cigarettes are healthier than regular cigarettes because users do not inhale tar or combustion by-products. This is a plausible assumption.
Those against e-cigarettes point to the dangers of propylene glycol. Although this substance is completely safe in food, it can create harmful substances when vaporised at high temperatures in e-cigarettes.

What do researchers say?

The debate has mainly raised further questions. For instance, are e-cigarettes a way to stop smoking? Or are they just a small step towards traditional cigarettes? Therefore, further scientific information is also essential. Only research will be able to determine how harmless or dangerous e-cigarette products really are.
The legal regulations around e-cigarette products begin with guidelines substantiated from research. This was why the Minister of Public Health asked the Superior Health Council for recommendations in 2013.

A lively debate at European level

Of course, the regulations do not just depend on Belgium. Even several years ago, votes were cast on adding provisions for e-cigarette products to the new European tobacco directive and so avoiding the pointless differences within the European free-trade zone.
There was an animated debate in 2013 between the European Council, the European Commission and the European Parliament. This led to a comprise text in 2014 on a number of important provisions:

- whoever brings e-cigarette products onto the market, must report this;
- the refill substances may not contain more than 20 mg of nicotine per millilitre;
- the liquid cannot contain toxic ingredients, either before or after heating;
- e-cigarette products and refills must be safe for children;
- e-cigarette products must be protected against fluid leaks when refilled by users;
- packages must contain warnings about the hazards of e-cigarette products and refills. A specific health warning should be included as follows: "This product contains nicotine, which is a highly addictive substance. Non-smokers are advised not to use this product";
- advertising for e-cigarettes and refills has been highly restricted;
- dealers must inform the government each year about their sales volumes, the types of consumers, sales methods, etc. Furthermore, they must identify the supposed harmful effects to health using a new system;
- the authorised institutions will take steps when they suspect that specific e-cigarette products are harmful. They will do this in consultation with the European Commission.

Hurdles and obstacles

What is the next step for the European member states? These provisions will be cast into national legislation. Member states have been given until 20 May 2016 to do this. The first obstacle is the question of whether the government considers e-cigarette products as medicines. The European directive actually permits this, if they meet the conditions of the legislation on medicines. The minister responsible for this in Belgium is currently studying the issue.
There are also hurdles for the institutions concerned. These include, whether people should be allowed to smoke an e-cigarette in public places. Or whether there should be age restrictions on the sale of e-cigarette products. Decisions on these and other issues are expected to be taken by 2016.

Is it a medicine?

In summary, the current situation is far from ideal. The traditional viewpoint about e-cigarettes as a medicine is diametrically opposed to the view about consumer protection.
In the majority of cases, the government considers e-cigarettes with nicotine or therapeutic findings as medicines. In other words:

- an authorisation is required to sell e-cigarettes as for any other medicine;
- the manufacture, distribution and sale of e-cigarettes will only take place through the pharmaceutical industry and public pharmacists.

Is this logical? Yes it is, considering the specific effect and toxicity of nicotine. So treating e-cigarettes as medicines also means controlling the risks more tightly.
There are currently numerous safety measures from the European directive for consumers. However, until these are transposed into national legislation, they will not have any legal force. That is why the famhp is working together with other authorised institutions to quickly clarify this area too.

THE ANATOMY OF AN E-CIGARETTE

Electronic cigarettes are composed of the following basic components: a fluid reservoir (TANK), a heating element (ATOMIZER) that vaporises the liquid and a BATTERY that provides energy to an electronic component (SENSOR) controlling the e-cigarette. Many models come with a red light on the tip which lights up (LED LAMP) when the user inhales, just like a real cigarette.
How about the liquid? This mainly consists of propylene glycol with flavourings and often also includes...nicotine. It is supplied in the form of refills.

Implementation of the Common Repository

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency (EMA) launched the Common Repository on 28 February 2014. This is a common system for the submission of applications to obtain a marketing authorisation through a centralised procedure. National competent authorities (NCAs) can now electronically submit, search for, consult and download common technical documents (eCTD) on medicines for human use that follow the centralised procedure.

Thanks to the Common Repository, the time needed to receive and validate incoming applications has been significantly reduced and up-to-date files are constantly and immediately available. The number of documents sent by applicants/authorisation holders will also be considerably reduced which will cause a significant fall in the time and costs related to submissions.

Belgium, as one of the first European member states, has been using the Common Repository as its sole source for submitting these types of files since 1 August 2014. By the end of 2014 the Common Repository was already in use by over half of the NCAs. The NCAs will be required to use the Common Repository as of 1 July 2015 in line with the e-Submission Roadmap of the network of European medical authorities or Heads of Medicines Agencies (HMA).

Once all of the NCAs have implemented the Common Repository, the applicants/authorisation holders should only submit their application to EMA. It will no longer be necessary to submit CDs, DVDs or files to individual member states, which will be submitted through the improved Common European Submission Platform (CESP).

Process reporting or greater efficiency

In order to deal with its tasks and powers in an even more efficient manner, DG PRE authorisation has moved to a new form of reporting to the Chief Executive Officer. This reporting complies with the key processes.

Concept trimesteriële rapportering DG PRE vergunning

Identifying the processes

All of the key processes have been listed. Each process has been flagged if a lean validation has been performed and a list has been drawn up of the existing quality documents and those which still need to be prepared, as described in the Working Instructions (WITs) or Standard Operating Procedures (SOPs). The list of all outputs related to a file that belong to a well-defined process can also be found here.

How does the famhp assess the recognition of expertise?

The consolidation of expertise is a set of targets that has been subdivided into three major sections:

- medicines for human use;
- Technical Scientific Advice (TSA) and Research and Development (R&D);
- medicines for veterinary use.

The targets will be reviewed each year depending on the number of European files. Subsidiary targets have also been set for certain targets in order to expand and continue to maintain expertise in important, strategic areas such as vaccines, oncology and endocrinology. These are monitored on a quarterly basis and adjusted where necessary.

How well are we performing?

We look every quarter at the number of files that have been closed and at how well the deadlines have been respected. In "2014 Results for each of the five entities" you can find the results from this for each division and unit.

How cost-effectively are we working?

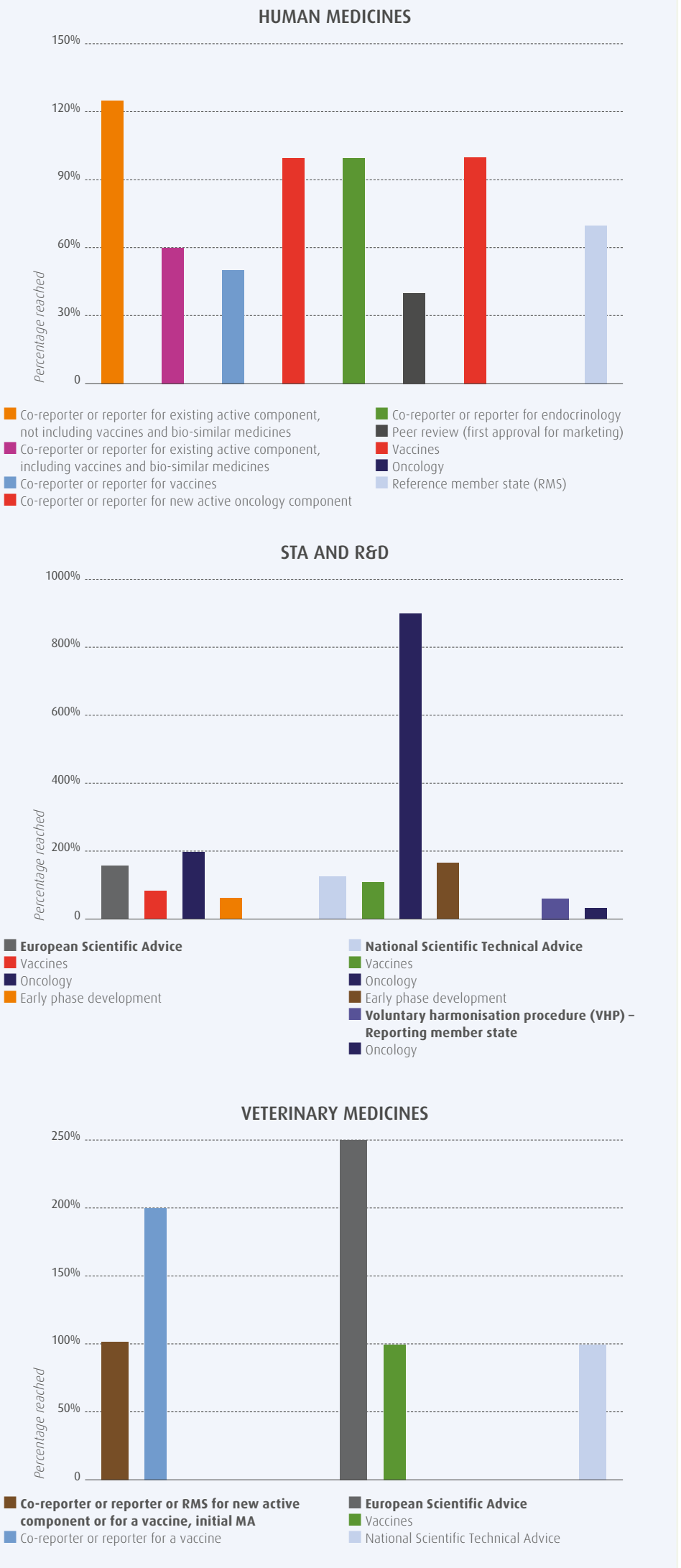
An estimate of the cost for each process enables the requested fees (or payments) to be justified or adjusted. This exercise is due to be further refined in 2015.

Open to further expansion

This quarterly reporting is a dynamic idea that DG PRE authorisation also wants to further optimise in 2015. We are ready to integrate new processes such as Unmet Medical Needs (UMNs). The strength of this reporting lies in the clear and objective representation of the data on the various divisions and units of DG PRE authorisation.

A basis for quality, efficiency and transparency

This new form of reporting enables the management to identify difficult areas and where necessary make timely adjustments. The constant optimisation of a high-quality, efficient, high-performance and cost-effective process is paramount for DG PRE authorisation. The quarterly reporting, together with the internal audits (and their corrective action plans or CAPA plans) and the risk management to be deployed remain priorities for 2015.



1. The targets will be reviewed each year depending on the number of European files where DG PRE authorisation wishes to take the role of a Reference Member State (RMS), reporting member state, co-reporter, reporter or coordinator of scientific advice.

Formation of an Audit Committee within the famhp

Auditing is an essential part of a modern organisation for measuring correct operation and guaranteeing high-quality service.

After we had established the Quality Division, organised the internal audits and brought together a team of auditors, our next step within the famhp was to set up an Audit Committee. This committee, together with the Federal Government Audit Committee (ACFG) enables our partners to contribute towards improving the operation of our agency. This initiative has been received positively by the famhp's Transparency Committee and the Minister of Public Health.

The fundamental objectives of the Audit Committee are as follows:
- to provide advice on improving internal operation;
- to develop a broad vision on the state of the famhp's management system;
- to optimise the organisation and coordination of the internal audits;
- to guarantee the independence required for the internal audit;
- to guarantee the efficiency and quality of the internal audits that are carried out.

Composition of the famhp's Audit Committee

The famhp's Audit Committee is made up of the following members:
- one member and a deputy member designated by the Minister of Public Health;
- two members and two deputy members designated by the Chief Executive Officer, following a proposal by the Transparency Committee;
- two members and two deputy members who are external experts in the field of auditing and/or quality who are designated by the Chief Executive Officer, following a proposal by the Transparency Committee;
- one member and a deputy member designated by the famhp's Quality Division;
- one member of the Executive Council acting as an observer, who is designated by the Chief Executive Officer.

Chairman: Richard Van Den Broeck, director of UNAMEC, the Belgian federation for the medical technologies industry.

Deputy chairwoman: Ann Adriaensen, general secretary of pharma.be, the general association for the medicines industry.

The other members are:
- Martijn Baeten (ordinary member) – WIV-ISP (Belgian Scientific Institute of Public Health);
- Christelle Beeckmans (ordinary member) – famhp;
- Patricia Cliquet (alternate member) – WIV-ISP;
- Brigitte Georges (alternate member) – FAVV-AFSCA (Federal Agency for the Safety of the Food Chain);
- Hans Hellinckx (alternate member) – UNAMEC;
- Pascal Guilmin (alternate member) – famhp;
- Déborah Gustin (alternate member) – cabinet of the Minister of Public Health;
- Olivier Lohest (ordinary member) – cabinet of the Minister of Public Health;
- Greet Musch (observer) – famhp;
- Guy Mommens (ordinary member) – FAVV-AFSCA;
- Davy Persoons (alternate member) – pharma.be.

Operation of the famhp's Audit Committee

The famhp's Audit Committee operates on a collective basis. Its most important tasks and responsibilities are:
- regularly informing the Executive Council and the Transparency Committee about the state of the internal control system using information obtained from the agency's various divisions;
- preparing an annual audit report that contains a general analysis or assessment of the audit activities performed and also recommendations or proposed improvements to the audited systems;
- working closely, in a fully transparent manner, with the famhp's Quality Division;
- approving the risk analysis that was performed by the Quality Division to create the annual internal audit plan that is based on the expectations of the Minister, the Chief Executive Officer, the Executive Council and the Transparency Committee;
- evaluating the annual internal audit plan submitted by the person responsible for the Quality Division;
- evaluating the interim audit applications submitted by the management;
- evaluating all changes to the annual audit plan;
- paying attention that the internal and external audit activities are performed according to the IA standards;
- approving the charter of the internal auditors;
- paying attention to the quality and effectiveness of the audits performed;
- providing advice to the internal auditors;
- together with the person responsible for the Quality Division, ensuring that the internal auditors get the appropriate training (continued training) and have the required objectivity, independence and competence both from the moment of their recruitment and during their assignments;
- drawing up a charter and regulations;
- formulating recommendations for the Executive Council about the organisation of the audit activities, the resources required for the correct performance of the audit activities and easy access to information;
- together with the person responsible for the Quality Division, ensuring that the formulated recommendations and nonconformities, including those which are part of the audit activities, are discussed in a timely manner and at the correct level of the organisation;
- focusing the attention of the Executive Council on the elements cited in the audit framework which were not considered in the Corrective and Preventive Action (CAPA plan).

The famhp's Audit Committee meets at least four times a year (once every quarter) in the agency's building. The first meeting took place on 30 June 2014. Two other meetings followed on 2 October 2014 and 18 December 2014.

The introduction of a new approach - Lean Management

In the current political and economic climate, we are considering changes to the services and processes to respond to the needs of users and government departments. Which approach did DG INSPECTION choose and what challenges did it face?

2014 saw a promising debut

This year was characterised by our wish to improve the work processes within DG INSPECTION thanks to the Lean Management approach. We want to improve the services we provide to our clients by developing rational management resources such as the avoidance of spillage and daily ineffectiveness. Cost efficiency is an integral part of this approach.

In line with this approach to improvement, DG INSPECTION decided to propose two concrete improvement projects to the Lean Academy that is working together with the Training Institute of the federal government.

The candidate files were put together in August 2012 and completed at the beginning of September 2014. The **OptiCellSang** project, supported by the Industry, Cell, Human Body Material & Blood Division and the **OptiPub** project, supported by the Distribution, Cell File Management Division came first in an initial selection performed by the Lean Academy during the final quarter of 2014.

We anticipate further discussions in 2015.

Is lean management a weight loss remedy?

The word 'lean' is used to characterise a theory for managing production and focuses on management without waste, frugal management or the most efficient management possible.

The lean management system was first used in Japan, in particular in the Toyota Production System (TPS). It is characterised by the pursuit of performance, in terms of productivity and quality, time frames and the costs which are achieved more easily through continual improvement and the elimination of waste.

Nowadays, lean management is used in administration departments to improve the service provided by organisations through greater efficiency in the management of processes. The intended result is a more efficient organisation that achieves faster results, spends less, provides better services, creates greater well-being in the workplace and generates greater customer satisfaction.

Lean Academy

On 7 February 2013, the Council of Ministers approved the project by the interdepartmental collaboration on the theme of the Lean Academy and the granting of the associated Optifed budget.

Lean Academy is a project proposal by FPS Mobility and Transport that aims to prepare civil servants working for various departments of the federal government to take on the role of internal lead consultant.

Areas for improvement and action plan following the external satisfaction survey

The 2013 annual report contained five initial areas for improvement that we need to address in order to meet our goal of continuously improving the quality of the services and products provided by the famhp. These areas were identified using the self-evaluation of our client-focused approach and the external satisfaction survey conducted among the famhp's partners in the industry.

We also conducted a second satisfaction survey in 2013 among the most important healthcare practitioners for famhp, namely doctors and specialists, pharmacists, vets and dentists. In October 2013, we sent the survey to 43,351 healthcare professionals. The most significant results were as follows:

Division of the response percentage by the profile of healthcare practitioners

	Number of people registered for the survey	Number of people who fully completed the questionnaire	Percentage of complete answers
Doctors	27,339	1,210	4.43%
Pharmacists	9,344	697	7.46%
Vets	2,542	162	6.37%
Dentists	4,126	168	4.07%
	43,351	**2,237**	**5.16%**

94% of respondents are professionally active in their area of healthcare.

Perception of the agency

70% of the healthcare practitioners were satisfied with the service provided by the agency. They perceived the famhp to be an extremely useful organisation (63%).

The famhp was considered to be a trusted and long-term partner that assumes its social responsibility and treats each client equally, but which is only moderately innovative and flexible.

Values

Adaptability, engagement, integrity, team spirit.

Out of the four values chosen by our organisation, integrity and engagement were seen as the strongest values with respective scores of 89% and 86%. Team spirit and adaptability scored lower.

Knowledge about the agency

65% of the healthcare practitioners questioned were familiar with the tasks of the famhp. However, on this point there was a considerable discrepancy between pharmacists (80%) and dentists (25%). 75% had little or no direct contact with the famhp. There is room to improve the famhp's visibility, publicity and media attention.

52% of the healthcare practitioners were able to easily find the famhp using the internet. 40% had a thorough knowledge about our website and found it easy to use. They also appreciated the simple forms and relevant information. However, these users expressed a preference for more rapid access to the information they look for.

The participants were extremely satisfied with our expertise (93%), availability (85%), rapid reaction to their queries (90%) and the fact that we share relevant information with them (90%). They know how to contact us using the various general email addresses (89%) and are quickly referred to the appropriate department or person (90%).

The healthcare practitioners were evidently unaware that they can lodge a complaint or the procedures that should be followed.

Information provided

Fewer than 50% of the healthcare practitioners knew about the wide range of information that the famhp provides, such as newsletters, the online database with package inserts and awareness campaigns.

The healthcare practitioners also wanted to be kept informed about changes to the legislation and the famhp's processes (50% and 39% respectively).

The survey also revealed that many healthcare practitioners search for other sources of information for medicines and healthcare products.

Inspections

The healthcare practitioners that are subject to routine inspections have sufficient information about these inspections and find these justified (96%). However, the announcement of the inspections was a negative point.

The healthcare practitioners were satisfied with the way our inspectors rapidly communicate information and about their expertise (97%) and availability (91%).

Conclusions

In addition to answering the questions, the healthcare practitioners provided us with 420 open-ended responses, many of which contained specific suggestions for improvements.

1,538 healthcare practitioners provided their address to receive the information electronically.

Using the results from these questionnaires, the Executive Council selected six areas where our client approach can be improved. These six areas have been fully brought into line with the initiatives listed in our new strategic plan. The opportunities for action, which are part of a project or improvement measures for the coming three to four years, are as follows:

AREAS FOR IMPROVEMENT	IMPROVEMENT MEASURES
Collect, save, process and use client data in a structured manner.	· Create a consolidated list with the contact data for communication with the famhp's clients. · Create a consolidated database with all existing client data.
Continue to monitor the quality that we offer to our clients.	· Promote the procedure for external complaints using a brochure that is specifically geared to our clients. · Decide on a client charter and communicate this to our clients. · Establish one or more Key Performance Indicators (KPIs) for each key process and determine the reporting frequency of these KPIs.
Improve our website and make it more user-friendly.	· Transfer the management of the Proper Use Division website to the Communication Division and appoint a new webmaster.
Improve the capability for the industry to monitor the current state of an open file.	· Set up a general call centre that is able to provide correct and relevant information.
Increase awareness and increase familiarity with our name.	· Clearly determine what we will communicate at national level following the meetings of the European scientific committees. · Distribute external reports more frequently.
Promote the dialogue with our partners (target groups) to be better able to determine which information we want to obtain from which channel.	· Analyse the gap between the target groups and the existing famhp platforms, such as by including the provision of adequate representation. · Analyse the information requirements of the various platforms. · Carry out benchmarking at European level on the various existing communication channels.

Procedure for portfolio meetings

The Scientific Technical Advice and Knowledge Management (STA-KM) was set up within DG PRE authorisation in April 2009. This unit offers applicants the possibility to request national scientific and/or technical advice (for instance, regulatory advice) about research and the development of medicines for human or veterinary use. The main aim of providing STA to applicants at a national level is to promote the development of new medicines as much as possible and to facilitate this from a regulatory perspective so as to increase the availability of innovative medicines.

We have found that additional procedures are necessary to better respond to the specific requirements of for instance companies, small or medium-sized businesses (SMEs), spin-offs, academic and clinical research centres during the preclinical and clinical development of new, innovative medicines and therapies, to enable early dialogue and to create a safe environment for open discussions with the famhp, namely before the submission of a file.

The STA-KM Unit implemented a new procedure for so-called portfolio meetings in 2014 after carrying out a number of trial projects in 2013. This procedure is free of charge for applicants.

What is a portfolio meeting?

For the famhp, a portfolio meeting is a high-level informative meeting with experts and divisional heads from the famhp that is organised by the STA-KM Unit.

At these meetings, applicants are able to provide information about their business and their various activities at European, national and international levels, developments in the area of medicines, the therapeutic areas in which they are active or which they wish to explore, the latest scientific developments and challenges and regulatory problems. A portfolio meeting may involve any of the therapeutic areas in which the applicant is involved or it may be limited to a specific field, such as oncology, early phase development and vaccines in line with the famhp's spearheads.

Why request a portfolio meeting?

This type of informal meeting offers medicine developers the unique opportunity to enter into an early dialogue with the famhp, to create a safe environment for the initial discussion of potentially critical problems of a scientific, regulatory or strategic nature and to reach mutual understanding and enter into a long-term partnership with the famhp. This is of key importance for the simplification of new innovations and for the accelerated entry of new, promising medicines onto the market.

Portfolio meetings can be particularly useful in therapeutic areas where there is an Unmet Medical Need (UMN). They are definitely worth considering before moving to the formal procedures such as those for STA, shared STA-HTA advice (Health Technology Assessment), in other words the combination with multidisciplinary research in which various aspects of a healthcare intervention are evaluated. They are also worthwhile for files to obtain an authorisation for a clinical trial or CTA (Clinical Trial Application), for the use of medicines without a marketing authorisation in compassionate cases or Compassionate Use (CU) or MNPs (Medical Need Programmes) and for early temporary authorisation (ETA) or early temporary reimbursement (ETR).

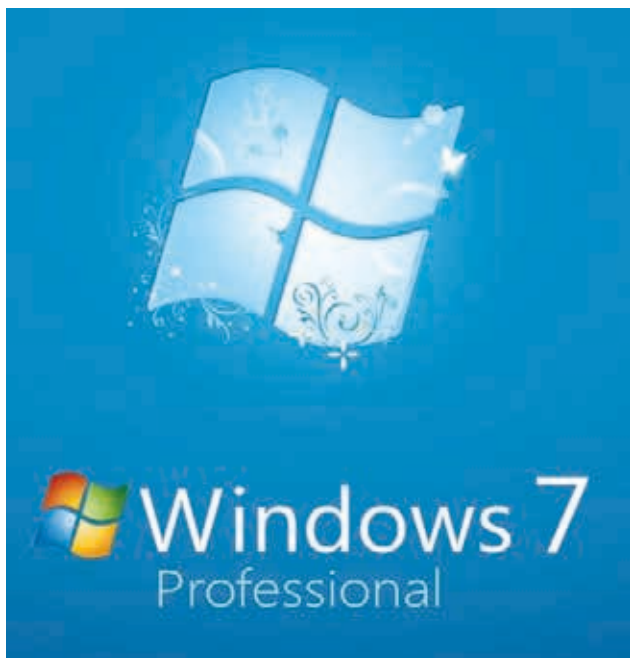
In this context, the STA-KM Unit offers the opportunity for experts from the National Institute for Sickness and Disability Insurance (RIZIV-INAMI) to attend portfolio meetings as an observer with the famhp where the applicant wishes to discuss problems that may also be relevant at a later stage from a HTA perspective. This approach can definitely be extremely useful where the intention is to submit a shared STA-HTA advice application to the STA-KM Unit at a later stage.

Applicants can also gain added value from portfolio meetings because through these meetings they can obtain a better insight into the various expertise domains for which the famhp is accredited and the various activities and scientific committees/working groups that the famhp is involved in, at European and national and international levels. In this way, applicants are able to obtain a better view of the potential role that the agency can play as part of future files and the ad-hoc expertise it possesses in terms of projects and strategies around the development of new medicines that may lead to scientific/regulatory discussions at European and national and international levels through the representatives in the various committees/working groups.

How to request a portfolio meeting?

Applicants can request a portfolio meeting by submitting a written request to the STA-KM Unit via sta@fagg-afmps.be. They should clearly describe the area of application of the portfolio meeting and provide reasons for the portfolio meeting in their request.

Migration to Windows 7



Microsoft gave each user until 8 April 2014 to switch to Windows 7 and Office 2007. Support for the Window XP and Office 2003 platforms, which are over ten years old, has been terminated and security updates have stopped. The famhp was also required to move to Windows 7 in order to avoid data becoming out of date.

We made a start with test migrations in the ICT Division during the final quarter of 2012. Various tests had to be carried out, such as the compatibility of software that had to work under Windows 7.

This update was only possible through a completely fresh installation on each user's PC. Together with this update, the agency decided to replace each desktop PC with a laptop and to terminate its support of desktop machines. To date, there are still only three desktop machines in use, to guarantee the functioning of the "Dataperfect" application.

We needed to update 450 workstations and to achieve this smoothly, the IT Helpdesk team was supported by two external experts who were later joined by two members of staff. The Infrastructure Team led by Nicolas Leroy, also provided a helping hand.

How did the update go?

Firstly, we made the most complete possible inventory of all of the programmes and applications that were installed on each PC for each user. The IT helpdesk contacted each user to confirm the inventory and to arrange a suitable time for the update to Windows 7. Although the IT Department does not guarantee the back-up of data stored on hardware, it made an exception this time. It created a back-up of the data on the hardware and the configuration was rolled out for everyone.

Since it can take up to two days to update a workstation, laptops were provided with the main programmes used at the famhp. After the migration, each user received his or her PC with Windows 7, Trucrypt encryption and the user configuration.

At the end of April 2014, the final PCs were updated and the number of laptops that had been migrated to Windows 7 stood at 480.

FURTHER EXPANSION OF THE ONCOLOGY AND VACCINES SPEARHEADS AND BUILDING EXPERTISE ON ENDOCRINOLOGY

In 2014, we noted for the ONCOLOGY spearhead that the evaluation of the first oncological file (Lynparza, ovarian cancer) for which Belgium was designated at European level as a co-reporter, had been successfully completed. Since then we have also been designated as reporters for several new applications of oncological medicines.

In line with the VACCINES spearhead again, in 2014 we were once again present and actively involved in the evaluation of all applications for the marketing of new vaccines.

Furthermore, we made extra efforts in the area of endocrinology where we performed the role of co-reporter in 2014 during the evaluation of a medicine to treat diabetes (Jardiance) and we were designated to a leading role for various new applications.

2014-2018 IT Strategy

The ICT Division has elaborated the 2014-2018 IT Strategy in conjunction with an external consultant.

A team of representatives from the various divisions of the famhp, including the ICT Division, performed a preparatory analysis for this during the summer of 2014.

This led to the following strategic guidelines:
- proactive publication of relevant information and the facilitation of direct input of information by the parties concerned;
- promotion of the underlying exchangeability with the internal and external parties involved (both linguistic and technical);
- incorporation of functional developments in order to optimise professional and supporting processes; simplify manual processes and make manual processes non-tangible.

Six axes of improvement that support this strategy were also identified:
- improve support for the majority of the professional processes, for the entry of common and specific systems;
- improve common functional modules;
- rationalise and review application architecture;
- harmonise data models;
- improve technical architecture and the computer network;
- draw up governance mechanisms.

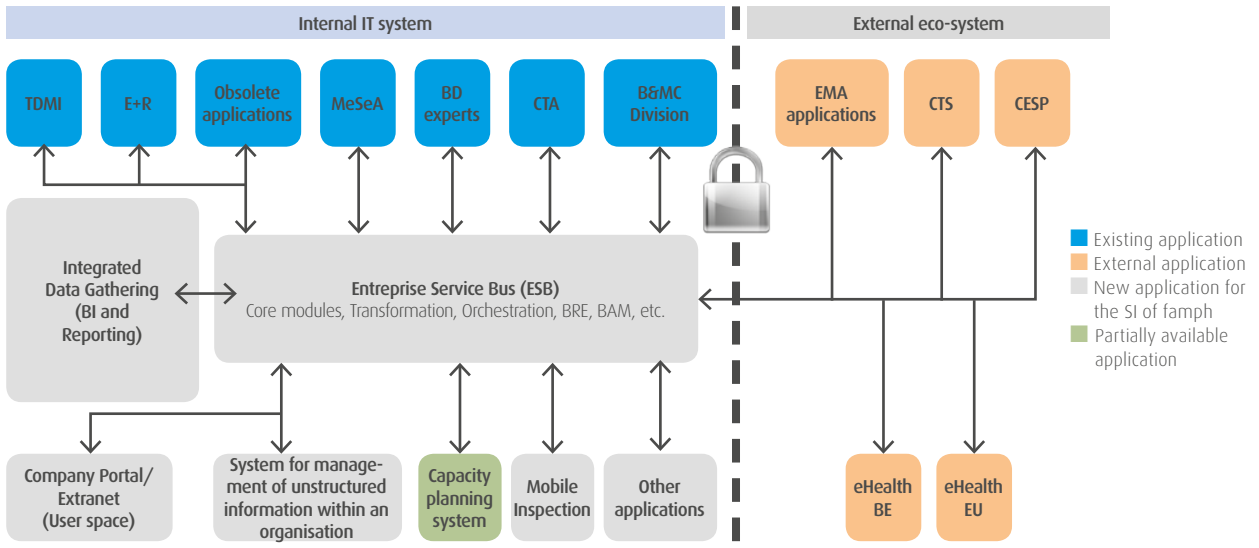
This strategy meets the need for greater transversality, by grouping applications/functionalities, which forms one of the strategic axes of our agency.

Another objective consists of making the technical systems "talk" to each another through the use of common modules. The structure of the current applications and IT services is extremely extensive. It is often developed on an "à la carte" basis for a particular and minor need, or developed directly by users to meet their immediate needs. The advantage of this situation is that the applications meet a particular need. However, the disadvantage is that resources are only concentrated on a couple of requirements. The fact that a specific solution is offered for each problem also creates "islands" which do not communicate easily with each other.

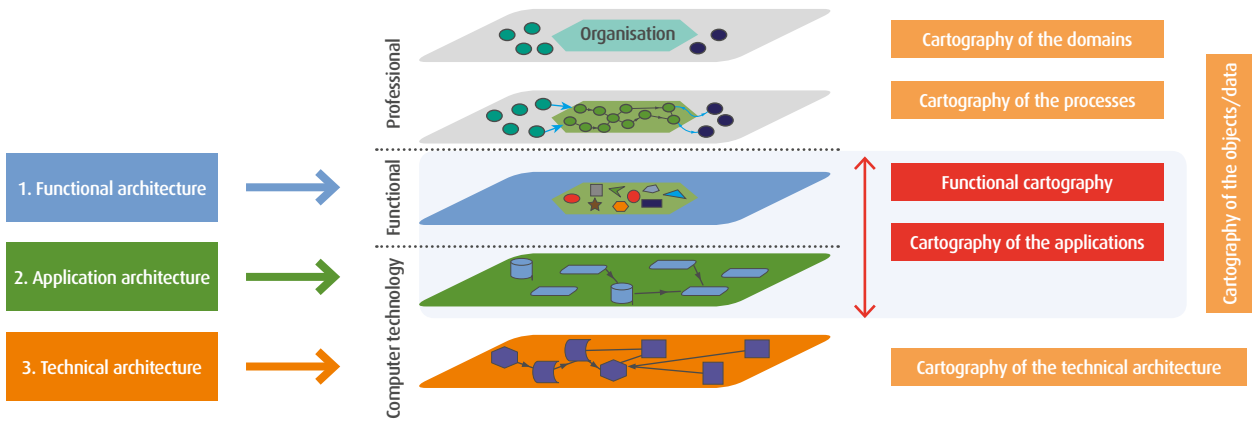
One way to approach the transverse aspects consists of building a single system that does everything.

Due to the scale of our organisation, providing a single system is not recommended. Instead, several systems that meet multiple needs and exchange information smoothly should be provided. Technical modifications are required for the smooth exchange of information between applications and all of the data in the various systems must follow shared semantic rules and preferably the international standard.

In order to avoid placing unnecessary demands on the applications, the data that needs to be shared or used as part of Business Intelligence, in the broadest sense of the term, will be copied and grouped in one place.
We intend to move from a silo-based architecture to a service-focused architecture.



The strategy also emphasises the need for an overview of all of the famhp's activities in order to be able to control the entire IT system. Furthermore, this overview must be multi-dimensional and should take account of the various layers of the cartography, from "computer technology" to "business domains".



To summarise, the IT strategy will allow us to group matters together, make exchanges easier and maintain continual supervision.

What does that mean at project level?
The analysis shed lights on a number of steps which need to be taken as basic conditions for a better IT service. These are purely technical IT projects which do not have the immediate aim of directly creating added value for the core business. However, these should create the conditions for being able to offer a better service in the future to the core business.

This strategy also emphasises the fact solely implementing technical IT projects is not recommended. It is also important to make a start on several improvement projects related to IT, but at the same time to not neglect the improvement projects linked to the core business. This means that we need to find a balance between the improvement projects involving IT and those involving the core business.

The analysis also contains a proposed time scale, up to 2018 and a balance between business-focused and technical IT projects.
Given how current issues and the needs of the core business change rapidly, the Executive Council will review the balance between the various projects on an annual basis.

Online sale of medicines: easy or dangerous?

The online sale of medicines is a booming business. It is a phenomenon that has grown with e-commerce and new technologies. It offers greater comfort to patients. Unfortunately, illegal websites pose a danger to public health. The European Union and the famhp are taking action. There are a great many trustworthy, authorised online pharmacies. However, other platforms offer counterfeit medicines and/or illegal medicines. These are dangerous medicines that end up in the hands of individuals. Or they find themselves on a parallel market, for instance sex shops and gyms.

> *"Dangerous medicines are finding they away to individuals or onto a parallel market of sex shops and gyms via illegal websites"*

Europe launches a directive on counterfeit medicines
The European Union has adopted the Counterfeit Medicines Directive 2011/62/EU with a view to the safety of citizens. The directive only involves medicines for human use and was transposed into Belgian legislation by the law of 20 June 2013. The authorised institutions still need to attach concrete actions to the various provisions in this law.

Read more about the impact of the European Directive in the articles *"Europe joins the fight against falsified and illegal medicines"* and *"The famhp takes up arms against against international counterfeit medicines and illegal medicines"*.

Guaranteeing reliable online pharmacies
The law also contains new requirements for online pharmacies to the illegal sale of medicines online.
An overview of the obligations:
1. **pharmacy authorisation** in the member state of establishment;
2. compliance with the **regulations** in the member state of destination;
3. contact details and the website of the locally competent **medicines authority** should be mentioned on the pharmacy website;
4. display of this clearly recognisable European **logo**:

Click to verify if this website is operating legally

The last two provisions allow the population to verify the reliability of online pharmacies.
European member states must apply all of the new measures by 1 July 2016 at the latest.

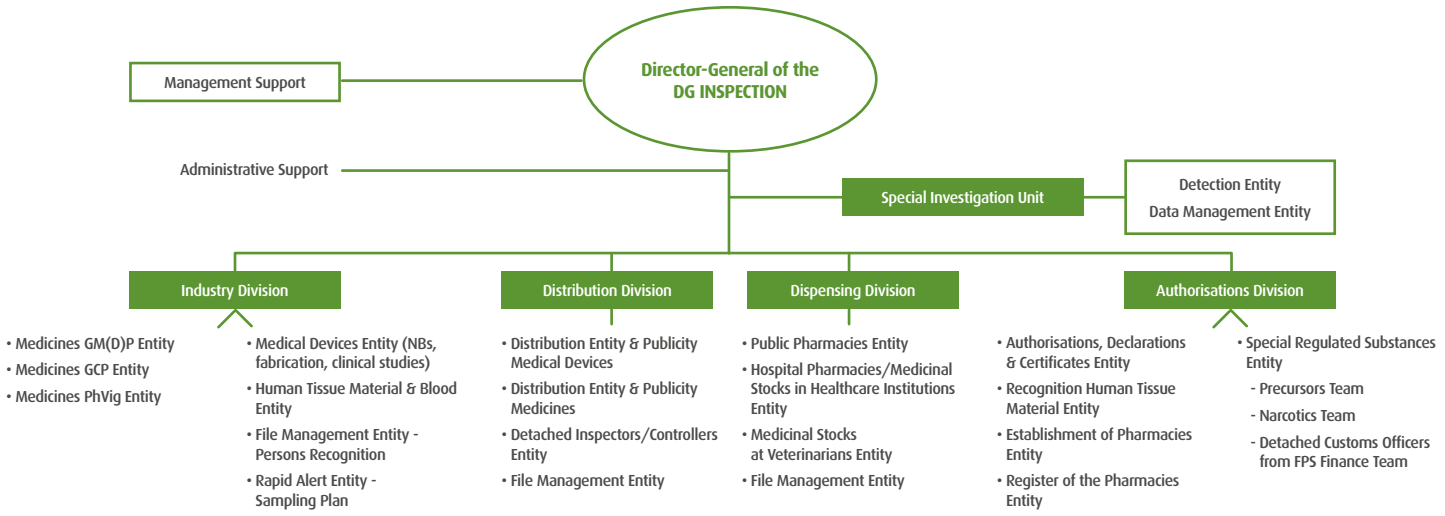
Does this control websites outside of the European Union?

Unfortunately, the new European provisions do not apply to medicine websites that are managed outside of the European Union. The internet makes the uncontrolled international sale of medicines possible which brings many risks for patients and users.

The famhp is closely monitoring the situation
The famhp recognises the problem in all of its complexity. That is why the agency has formed a working group within the INSPECTION Directorate-General. The aim is to reveal difficult areas and find appropriate solutions, with consideration of technical and regulatory developments.
Do you want to know more about the work being done by the famhp? Then read the article "*The famhp takes up arms against international counterfeit and illegal medicines*".

DG INSPECTION 2014 Structure

SOMETHING OLD, SOMETHING NEW, SOMETHING BORROWED, SOMETHING BLUE …



Although the basic structure of the famhp with its logical division of activities across the three cornerstones, DG PRE authorisation, DG POST authorisation and DG INSPECTION has been in place since 2009, DG INSPECTION has been actively and intensively searching for a structure that best links the reality of the inspection terrain and the core tasks of DG INSPECTION.

Its core tasks consist of performing inspections and checks at all stages of the life cycle of medicines and healthcare products (compliance), performing the associated authorisation activities (regulatory) and the combating of illegal practices (enforcement).

In the new structure we can make a comparison between the elements from the poem (around 1920) that traditionally brings good luck for a wedding:

- *Something old*, symbolising continuity and the link to the past;
- *Something new*, symbolising optimism and hope for the new future;
- *Something borrowed*, symbolising friends and family, in this case the internal and external partners;
- *Something blue*, symbolising modesty, purity and loyalty.

Until 2012, only the Industry (production and distribution), Delivery and Special Investigation Unit Divisions existed (something old). The decision was taken at that point to create the Authorisations Division (something new), because it was better in terms of "purity" (something blue) to separate responsibilities between the departments that perform the inspection and the departments that delivery the associated authorisation activities.

For the sake of clarity, there was no conflict of interests because it was the file managers and not the inspectors who issued the authorisations. Now for the sake of overall transparency, we have chosen a logical division. Furthermore, another argument was that the management of authorisations has evolved its own framework through constant increases in computerisation and globalisation so it was right to choose an autonomous management and policy for authorisations.

Attempts were also made in 2012 to completely renew this through a wake-up call on the format. The reason for this was the incident involving the manufacture of Poly Implant Prosthetic (PIP) breast implants which were an inferior quality medical device that were distributed with fraudulent intentions. This incident revealed that apart from the checks on medical products, for which we had years of experience, there was also a need for a sharpening of checks on medical devices.

Following this scandal, the Minister of Public Health implemented the Medical Devices Plan. This plan envisaged more thorough checks on the notified bodies and on the manufacture, clinical trials, distribution and supply and publicity of medical devices and also a curbing of illegal practices.

Additional resources were made available by the partners (something borrowed), the capacity of DG INSPECTION was boosted considerably and additional inspectors and scientific file managers were recruited. This recruitment made it necessary to restructure DG INSPECTION.

Where in the past the Industry Division was responsible for the inspections of both production and distribution, the decision was taken to split this division by processes. This was how the new Distribution Division came into being and it has been operational since 1 September 2014.

The Distribution Division specifically monitors the distribution and publicity for medicines, medical devices and base materials. The checks and inspections performed as part of this focus on the following:

- good distribution practices (GDP) of medicines;
- distribution of medical devices;
- distribution of active substances or active components in medicines or Active Pharmaceutical Ingredients (APIs) and base materials for preparations in pharmacies;
- advertising and promotional activities of medicines and medical devices.

The division is also responsible for the recognition of the person responsible for pharmaceutical information (RIP).

DG INSPECTION currently has four divisions, namely the Industry, Distribution and Delivery Divisions and the Authorisations Division for inspections on the legal supply chain (compliance and regulatory). The Special Investigation Unit (enforcement) has been more clearly placed in a transverse role.

DG INSPECTION is now ready to move at cruising speed based on its past foundations with optimism for the future, in partnership with the sector and in a fully transparent manner.

The 2014-2018 management plan, towards a professionalisation of the famhp

If we look back at the initial years of the famhp and the first management plans, we think mainly about the installation of the famhp, the removal of backlogs, the introduction of the spearheads and the numerous developments in the areas of vigilance, clinical trials, the combating of illegal practices and the traceability of medical devices.

We can summarise our ambition for the period between 2014 and 2018 as follows: starting from our strategic objectives, **consolidating the results and projects we have accomplished** and **providing the necessary support to our partners to embrace new challenges**. We have given special attention here to two aspects: **addressing the needs of public health with regard to medicines and healthcare products** and **keeping the patient in first place**.

The famhp is facing a great number of challenges, both externally and internally. This could be due to more critical patients who have ever increasing expectations, the ageing population, unmet medical needs (UMN), more "Europe" in the world, developments in the many areas where the famhp is involved, new advanced therapies and personalised medicine or internal policies on HR, IT, budget, quality and management.

The new 2014-2018 management plan consists of the 2014-2018 strategic plan and an annual operational plan.

We have already begun to take a number of concrete actions in order to achieve this ambitious plan, including:

- improvement of the decision making procedures by the Extended Executive Council;
- a strengthening of the service provided to all members of staff of the famhp through the presence of the person responsible for the P&O Division at meetings of the Executive Council;

- optimisation of the IT infrastructure and service provision through the organisation of a strategic IT committee;
- the formalisation of the information exchange through the internal communications network.

Each entity of the famhp has translated the operational plan into a version that is relevant to its activities with specific targets. In this way we should arrive at a consolidated and dynamic management plan for the famhp on the basis of the strategic and operational objectives and the various initiatives.

The Farma Trade Fair, a first for the famhp

"It's good that pharmacists and the pharmaceutical industry see the famhp as a partner and not just as a government body that acts in a controlling and repressive manner. Since dialogue between partners is crucial, the famhp sees its presence at the biannual Farma Trade Fair as an opportunity."

The Farma Trade Fair, the place where pharmacists and the industry meet

The Farma Trade Fair is organised exclusively for pharmacists. Many stakeholders ranging from representatives of pharmaceutical companies and other companies related to the industry to pharmaceutical associations that inform pharmacists about their products and services had stands at this trade fair.

An impression of the famhps stand.

The presence of the famhp at the Farma Trade Fair is essential

The famhp had its own stand at the trade fair in order to promote dialogue with stakeholders. This enabled it to inform pharmacists and companies about their rights and obligations, to update them about what the famhp stands for and to introduce them to the information that the famhp makes available to them.

The public was able to meet the inspectors from the Dispensing Division that inspect dispensing pharmacies. Due to their daily contact with retail pharmacists as part of their inspections, the inspectors were nominated to provide information and answer questions.

The management of the DG INSPECTION also attended which demonstrated their engagement to professional collaboration with the industry.

An extremely positive experience...

De aanwezigheid van het fagg werd door ieThe presence of the famhp was received very positively by everyone, from exhibitors to the professional associations for retail pharmacists.

At the famhp, we learnt a lot from our first trade fair experience in the world of pharmacists! We will be able to optimise the visibility and accessibility of the stand and our interaction with the visitors for future events.

The famhp has a lot to tell you

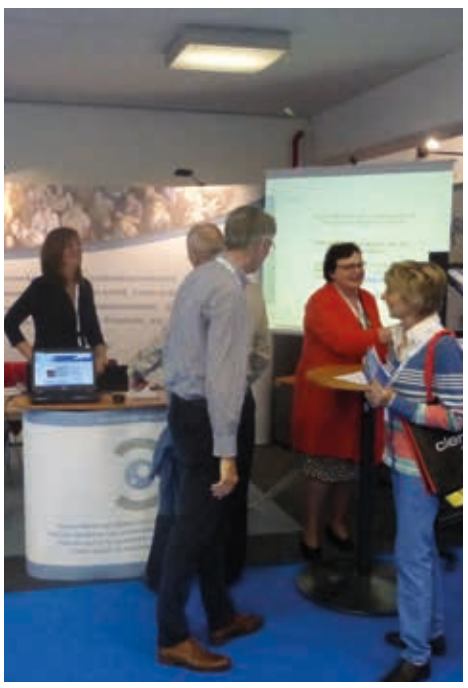
Visitors to the Farma Trade Fair were also able to obtain a wide range of interesting publications from the famhp. Alongside general brochures and brochures from the various awareness campaigns, we also had two brochures designed especially for this trade fair.

...that gave us an appetite for more!

The positive reactions and the conversations we had in the corridors convinced the management of the DG INSPECTION and the famhp of the importance of the presence of the famhp.

This was the famhp's debut attendance at the Farma Trade Fair but the famhp also took part in a trade fair before 2014. The inspectors from the veterinary depots (Dispensing Division of DG INSPECTION) and experts from DG PRE authorisation and DG POST authorisation were also present at the Libramont agricultural trade fair in July 2014.
We decided to continue this dialogue at other trade fairs, for both broad and specific target audiences. Therefore in the future, the famhp will also be seen at various trade fairs.

> ***"Congratulations, the famhp is here! Where it belongs, AMONG the pharmacists."***
>
> *Professor R. Kemel – University of Antwerp.*



Representatives in conversation with some visitors.

Regulations? The patient comes first

In 2014, the renowned TOPRA (The Organisation for Professionals in Regulatory Affairs) conference was held in Brussels and was jointly organised by the famhp. These three days were a resounding success and were able to count on the attendance of over 600 international participants, which was the highest attendance to date.

Specific attention was devoted this year to the views of patients. The central theme "Matching Modern Regulation with Modern Medicine - a Patient-Centred Approach to Regulatory Affairs?" enabled a number of extremely interesting themes to be raised.

https://www.topra.org/TOPRA/TOPRA_Member/Regulatory_Rapporteur.aspx

Dynamic dialogue

New for this year's TOPRA was the possibility for participants to actively engage in the debates. National and European policy makers from the healthcare sector, the academic world and patients' organisations were given the opportunity to fruitfully exchange ideas with each other.

Contribution from the famhp was universally appreciated

Even if we say so ourselves, the contributions from the Belgian experts both as the chairman, speaker or representative in a panel were excellent. This certainly contributed towards a broad and international recognition of the famhp.

The famhp explained the patient-focused approach with a number of interesting presentations:

- the Chief Executive Officer outlined the famhp's 2014-2018 strategic plan;
- the new national legislation about unmet medical needs;
- the spearheads of EARLY PHASE DEVELOPMENT and VACCINES with the recent issue of combating the Ebola virus;
- combating the counterfeiting and falsification of medicinal products.

Successful veterinary conference

The Medicinal Products for Veterinary Use Division scored top marks for its contribution at this conference. Its contribution over two days was able to count on large numbers of attendees, namely 110 visitors who accounted for a sell-out conference. Representatives from national and international industries, the academic world, governments and research institutions were present at the conference.

The following topics were dealt with:
- the draft law on the new directive concerning veterinary medicines;
- vaccines for veterinary use;
- the issue of antimicrobial resistance;
- the harmonisation of the requirements between Europe and the United States for bringing animal medicines onto the market,
- the requirements for small and medium-sized companies and products intended for MUMS (minor use, minor species).

Medical devices in five sessions

A specific conference dealt with medical devices from a number of different perspectives. The famhp played a crucial role here and shared its knowledge with the public. The new European regulations, the market supervision and the pre and post-marketing assessment of medical devices were topics in this conference.

You can find more information about this subject in the Regulatory Rapporteur, The International Journal for Professionals in Regulatory Affairs, December 2014.

SEVERAL TOPRA THEMES IN 2014

1. The safe and early access to medicines for Unmet Medical Needs (UMNs).
2. The new directive on clinical trials.
3. Data transparency.
4. The experiences of patients' representation in the European Pharmacovigilance Risk Assessment Committee (PRAC).
5. Expectations concerning:
   - personalised medicines;
   - biosimilar medicines;
   - medicines for children.
6. The facilitating role played by authorised institutions towards small and medium-sized companies.

OVER 100 PARTICIPANTS ATTEND THE SECOND PHARMACOVIGILANCE DAY ORGANISED BY THE FAMHP

The famhp organised the second pharmacovigilance day on 9 December 2014. This year's event also proved to be a success and attracted over one hundred participants from various fields, including healthcare practitioners, the pharmaceutical industry, professional associations such as the Co-ordinating Federation of the Belgian professional Associations of Independent Retail Pharmacies (APB), government bodies such as the National Institute of Health and Disability Insurance (RIZIV-INAMI) and FPS Public Health and other organisations such as the Belgian Anti-poisons Centre.

The programme was an opportunity to explore a variety of themes, such as:

- the specific risks when using medicines in geriatrics;
- test-case studies as a tool for pharmacovigilance;
- the experiences of a retail pharmacist with pharmacovigilance or as a representative of healthcare practitioners within the Pharmacovigilance Risk Assessment Committee (PRAC);
- the collaboration between the famhp and the not-for-profit association, the Belgian Centre for Pharmacotherapeutic Information (BFCI).

The pharmacovigilance day was brought to a close with a debate that enabled a constructive exchange of viewpoints. This included debates about the effectiveness of risk-reducing measures such as more frequent letters sent to the healthcare practitioners by the pharmaceutical companies to inform them about potential risks of medicines, or Direct Healthcare Professional Communication (DHPC).

An event of this nature fits perfectly with the objective of the famhp to raise the awareness of the various groups involved about pharmacovigilance. This increased awareness should lead to improvements in notifications and a better integration of pharmacovigilance in daily practice and in this way, avoid adverse reactions.

The participants were asked about the organisation and the programme in a satisfaction survey. This revealed that the participants would like to see subjects offered which are even more relevant to their daily practice.

During the opening of the second pharmacovigilance day, our Chief Executive Officer announced that a third event will be held in 2015.

The famhp takes up arms against counterfeit and illegal medicines

The counterfeiting and falsification of medicines is a global problem. Despite national and international measures, the threat is on the rise. Collaboration across national borders is essential to effectively tackle this. In Belgium, this remains one of the priorities for the famhp.

Summary of the situation: falsification is a global problem

Belgium is increasingly having to contend with the illegal trade in counterfeit and illegal medicines, particularly online. Fortunately, counterfeit and illegal medicines have not yet appeared in the legal supply chain. However, this has occurred in other countries.

Police agencies intercept all possible types of medicines. For a long time, this has involved more than just anabolic steroids, erectile dysfunction medications or slimming products. What is the reason behind this increasing criminality? There is a relatively low risk of prosecution, but huge profits to be made. Furthermore, the internet makes it very easy to distribute counterfeit and illegal products. That is why the problem has assumed global proportions. And no country is safe from this.

> *"Counterfeit and illegal medicines have not yet appeared in the legal supply chain in Belgium. The famhp is making every effort to keep it this way"*

Breakthroughs in international criminal law

The international scourge of falsification urgently demands a broad, multidisciplinary approach. The famhp is convinced of this. It took part in three pioneering projects over the last year:

• European directive on falsified medicines
The famhp is closely involved with Falsified Medicines Directive 2011/62/EU by the European Commission. This Directive has since been transposed into Belgian law. However, the practical implementation is a challenge for 2015.
Furthermore, the famhp is part of working groups on safety features for medicines. These take place under the aegis of the European Commission and the network of the European medicines authorities or Heads of Medicines Agencies (HMA) and want to prevent counterfeit and illegal products from entering the legal distribution chains. Read more about this in the article "*Europe joins in combating counterfeit and illegal medicines*".

• Medicrime Convention of the Council of Europe
The Medicrime Convention is the first judicial instrument against falsified medicines at international level. The late lamented head of the famhp's Special Investigation Unit Division (SOE-USE), Roy Vancauwenberghe, was one its architects. The famhp has also promised its unswerving support in the initiative and even promotes it to other states. For instance, the famhp organised training courses on the Medicrime Convention in countries with high levels of need. These were held in the Democratic Republic of Congo in 2013 and in Morocco in November 2014. Two courses were held in collaboration with authorities including the Council of Europe. What was the objective? To stimulate communication between authorities who are tackling medicine crime through a network of Single Points of Contact (SPOCs).

• Model Legislative Provisions on Medicine Crime (UNODC)
The United Nations Office on Drugs and Crime (UNODC) was tasked with drawing up Model Legislative Provisions (MLPs) for combating counterfeit medicines. This was instructed by the International Commission on Crime Prevention and Criminal Justice (CCPCJ). The famhp played a part in this.

The MLPs have a multi-faceted role. They should make it easier for member states to take measures against counterfeit and illegal medicines. These are not binding directives, rather preconditions. States can adapt them to their needs, the principles of their constitutional and criminal laws and the requirements of the international conventions that they have signed.

Challenge: safeguarding legal trade

Counterfeit and illegal medicines have not yet appeared in the legal supply chain in Belgium. The famhp is making every effort to keep it this way.

THE MEDICRIME CONVENTION IN A NUTSHELL

- **Initiative:** the Council of Europe, with 47 member states
- **Aim:** criminal sanctions, preventative measures and protection of victims
- **Who:** open to all countries throughout the world
- **Time line:**
  - the convention was opened for signature on 28 October 2011 in Moscow
  - Belgium signed the convention on 24 July 2014
  - the ratification process is under way.

What role is the famhp playing in combating Ebola?

March 2014. There has been an outbreak of the lethal Ebola virus in West Africa. The situation is rapidly deteriorating. The entire world is focusing its attention on containing the spread of the disease. The famhp is also playing its part here.

The Ebola outbreak in 2014 was the largest and most complex ever. Unfortunately there are not always authorised medicines to protect people against this or to treat the disease. Does medicine offer hope? There are a number of medicines at an advanced stage of development.

The famhp is working actively on Ebola medicines

In 2014, the famhp also made extra efforts to stimulate the development and authorisation of Ebola medicines.

- We worked actively on the evaluation of the data available from various experimental Ebola medicines at the level of the European Medicines Agency (EMA). In doing this, the famhp played a part in the worldwide response to the epidemic. This data was shared with health authorities in the countries involved to enable them to take properly considered decisions about the issue of whether and how they wanted to use the vaccines and medicines in the current Ebola outbreak, taking into account their specific situation.
- Action was taken to simplify the development and authorisation of Ebola medicines by the following means:
  - an accelerated scientific advice procedure;
  - an accelerated procedure for the validation, evaluation and granting of authorisations for clinical trials.

The famhp takes care of Ebola patients in Belgium

Healthcare bodies across the world are taking national measures (also see http://www.info-ebola.be/en/how-does-the-government-contribute/) to take care of Ebola patients. In Belgium, the famhp was involved with the Ebola coordination team under the leadership of the Ebola coordinator, Dr Erika Vlieghe.

- Any Ebola patients would be given the chance to be treated in Belgium using an experimental medicine. This was the result of a consultation between the experts from the famhp, FPS Public Health and pharmacists and infectologists from Belgian hospitals.

  The Minister of Public Health, Maggie De Block, issued a ministerial decree for this on 7 November 2014:
  "the decision regarding the permission for the distribution and use of non-authorised medicines in the event of the spread of the Ebola disease based on article 6c, section 1, paragraph 1, item 5 of the law of 25 March 1964 on medicines".

- The famhp took part in an ad-hoc working group with experts on vaccines, infectious diseases and the design of clinical trials. They pooled their expertise and stood ready to support doctors who were treating potential Ebola patients in Belgium and communicated directly with parties including other European member states, Médecins Sans Frontières and the World Health Organisation (WHO).

Fewer Ebola cases were reported for the first time across the entire Ebola region in West Africa during the week of 5 April 2015 than in the third week of May 2014. In the meantime, the famhp continues to be vigilant.

> *"The famhp played a part in the worldwide response to Ebola"*

European Union streamlines regulations on clinical trials

On 27 May 2014, a new directive was issued on clinical trials in the Official Journal of the European Union. The European Parliament and the Council of the European Union want to use this to tackle the falling number of clinical trials. The regulator has cast the new provisions into a regulation. This is a decision that is immediately binding for the entire European Union. However, this does not mean that the new regulation is already in force. The member states first need to validate the European portal site for applications for clinical trials and elaborate national procedures. In anticipation of this, the famhp is already preparing meetings at Belgian level.

WHY ARE THERE NEW REGULATIONS?

The current regulations on clinical trials has been in force since May 2004. These have been criticised for years. Criticisms include the lack of flexibility in the requirements imposed on the pharmaceutical companies. As a result, there are fewer and fewer applications submitted for clinical trials. Europe is tackling the legal restrictions on clinical trials with the new regulations.

EU regulation brings clarity

What measures are included in the new European regulation?

- **Simpler approval process** – The European Medicines Agency (EMA) and the European member states have developed an online European portal for this.
- **One approval per member state** – Until now, the system involved dual approval - approval by the Ethics Committees and the authorised medicines authorities.
- **Joint evaluation of multinational trials** – One member state will evaluate the scientific aspects of a trial. The other parties involved will provide comments. What about the ethical and national aspects? These will be separately assessed by each member state.
- **Simple timelines** – The authorities and Ethical Committees will each have sixty calendar days to evaluate an application. What happens if they exceed this time limit? Then the trial can automatically start.
- **Harmony on informed permission** - The rules on permission (and knowledge of risks and benefits) of the participants in clinical trials will be better harmonised. These include participants who are minors or incapacitated persons.
- **Greater transparency** – Each clinical trial must be registered. Furthermore, researchers will publish their results no later than one year after the trial. The regulation also goes into greater depth on the confidentiality of data from clinical trials.

> *"A key task for the famhp is the performance of checks on clinical trials, in particular to ensure the safety of participants"*

The famhp is ready for the new regulations

The famhp is getting prepared. We are working on procedures, operational plans, sector consultations and where possible, policy suggestions.

A steering group comprising representatives from the various parties involved met during the week following the publication of the directive. During 2014, it established the following points:

- the further elaboration of the **participation model** for the Ethical Committees and the famhp;
- designation of **a unique Belgian point of contact**;
- determination of **future fees** for applications;
- organisation of the **monitoring on safety reporting** of clinical trials;
- clarification of **provisions around the data confidentiality**;
- formulation of several **national positions**;
- adaptation of the **national legislation** where necessary;
- study of the **creation of a national insurance system**;
- **set requirements during the inspections** of Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP);
- creation of a **quality system for a correct implementation** of the directive, in line with the planned audits by the European Commission.

Patients depend on protection by the famhp

A key task for the famhp is the performance of checks on clinical trials, in particular to ensure the safety of participants. The Human R&D Division of the DG PRE authorisation evaluates applications for all Belgian trials and approves or rejects these. As an authorised body, the famhp now ensures that the national medicines sector will be able to apply the new legislation shortly.

LIMITED CHANGES TO EUROPEAN RULES GOVERNING MEDICAL PRESCRIPTIONS

The Royal Decree of 10 June 2014 transposed the European Directive on the minimal information contained medical prescription, as part of cross-border care into Belgian law. This caused changes for Belgian medical prescriptions that are prepared in other European member state countries. The provisions from the previous Royal Decree of 10 August 2005 remain largely intact.

"The new regulations impose additional information on medical prescriptions for greater transparency"

Three areas of the Belgian law have been harmonised with the European rules:

1. New required information on medical prescriptions

The minimum information required on medical prescriptions intended for another European member state has not changed with respect to the situation in 2005. The new requirements are as follows:

- mention of the professional qualification of the healthcare practitioner who prepared the prescription (prescriber) and his or her direct contact information;
- mention of the date of birth of the patient;
- prescription based on the substance name or generic name of the medicine;
  - the brand name will also be mentioned where:
    - o a biological medicine is involved;
    - o the prescriber considers this necessary for medical reasons, which will be described in brief.

2. Standard prescription format will be retained

Belgian prescriptions will not undergo any format changes when they need to be presented in another European country. Prescribers are already required to note several additional details (see above). Furthermore, the format will retain the following traditional elements:

- stamp (with the professional address, contact details and professional qualification) and the email address of the prescriber;
- Belgian national registration number of the patient, a code that also contains the patient's date of birth;
- the brand name or generic name of the medicine to be prescribed.

WHY IS ADDITIONAL INFORMATION REQUIRED ABOUT DOCTORS AND PATIENTS?

Dispensing chemists from other European member state countries are unable to access and verify this information using the secure Belgian online platform MyCareNet, which allows healthcare providers and institutions to rapidly exchange information. Furthermore, the qualification code contained in the National Institute for Sickness and Disability Insurance (RIZIV-INAMI) number of the healthcare practitioner does not provide them with any information. The new regulations impose a requirement for additional information on medical prescriptions to promote transparency.

3. Repayment of medical expenses in other European countries

What happens when a Belgian patient (affiliated with a healthcare insurance body) presents a prescription to a chemist in another European member state? In this case, the patient should be fully reimbursed. Once the patient has returned to Belgium, he or she can apply for repayment from their health insurance company or insurer.

European source

The changes to Belgian legislation are based on two European directives.

A. 2011/24/EU establishes rules for:

- promoting access to safe and high-quality cross-border healthcare;
- guaranteeing the mobility of patients within the European Union.

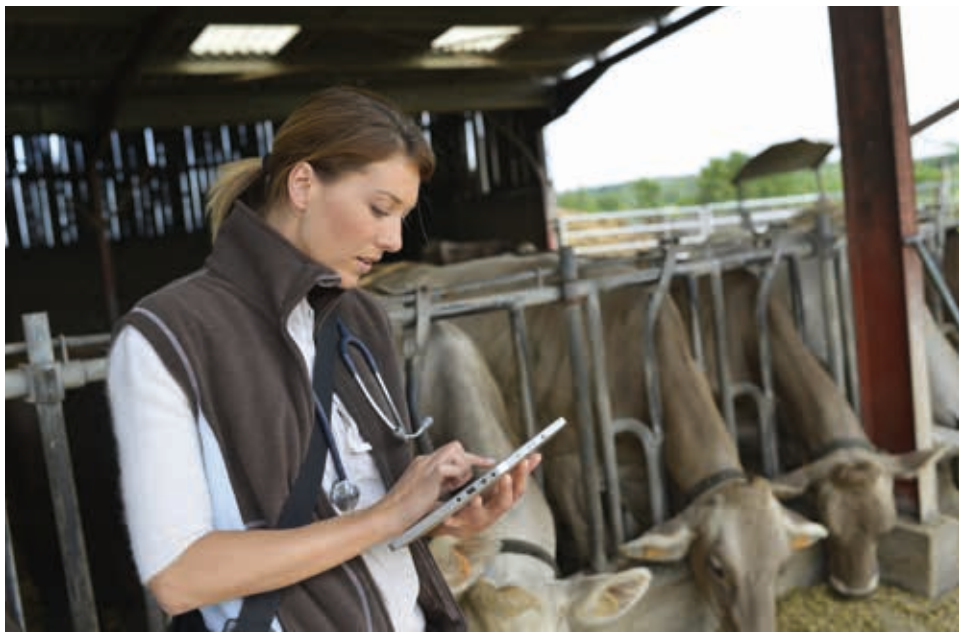
Each European member state must build and offer healthcare and social security systems to its citizens. However, Europe lays down a number of general principles for healthcare practitioners who prescribe, dispense and supply medicines.

B. Implementing directive 2012/52/EU was introduced to:

- simplify the supply of medicines in other European member states;
- limit the risk of errors (such as dosages that do not conform to the age of the patient).

This directive describes the minimum information required for medical prescriptions (see above).

Does this mean that patients will be able to collect their medicines in another European country without any problems? In principle, yes. However, member states are not obliged to accept medical prescriptions for medicines that contain narcotic or psychotropic substances.



Europe harmonises veterinary medicine regulations to requirements of the sector

In September 2014, the European Commission published two new legislative proposals. One of these legislative proposals dealt with medicines for veterinary use and the other dealt with medicated animal feeds. What is the focus of the Commission? To further harmonise the regulations to the requirements of the veterinary medicine sector.

The new legislative proposal takes the form of a regulation. After discussions with the European working groups involved and approval by all member states, they will replace the 2001/82/EC and 90/167/EEG directives respectively.

LEGISLATIVE PROPOSAL ON MEDICINAL PRODUCTS FOR VETERINARY USE

Simplification as an incentive for development

The regulation for medicines for veterinary use brings simplifications to administration, particularly in the following areas:

- the various procedures before and after the granting of an authorisation for marketing (MA) of a veterinary medicine;
- pharmacovigilance.

By doing this, the Commission wants to incentivise the development and availability of new veterinary medicines in the European Union. This also includes the development of new veterinary medicines for animal species where less specific research is carried out, such as bees, goats, turkeys and horses. Furthermore, the rules for the so-called waterfall or cascade system by vets are being relaxed.

LEGISLATIVE PROPOSAL FOR MEDICATED ANIMAL FEEDS

Only recognised manufacturers and authorised medicines

The legislative proposal for medicated animal feeds focuses on the manufacture, marketing and use of animal feeds in which veterinary medicines have been incorporated. The rule that stands out most is that only recognised manufacturers will be able to produce medicated animal feeds and they will only be able to do this using authorised veterinary medicines.

Will these be available soon for pets?

The proposed regulation also comprises:

- measures for the **prevention and development of antimicrobial resistance**, such as a ban on the preventative use of antibiotics in medicated feeds;
- thresholds for residues of veterinary medicines in standard animal feeds;
- a legal basis for the development of innovative medicated feeds for **animals that are not part of the food production chain**, such as cats and dogs with a chronic disease.

Aiming for the end of 2017

Years of preparation and public consultations have preceded the legislative proposals. The discussions about the introduction of the new regulation have been in full swing since the autumn of 2014. The famhp has also taken an active role in these discussions. The two regulations will probably enter effect at the end of 2017.

"The European Commission wants to further harmonise the regulations to the requirements of the veterinary medicine sector"

5 OBJECTIVES OF THE NEW REGULATION FOR VETERINARY MEDICINES:

1. increase the availability of medicinal products for veterinary use;
2. reduce administrative load;
3. stimulate competitiveness and innovation in veterinary medicine;
4. create a more effective internal market;
5. limit the risks to public health by taking measures against the development and spread of antimicrobial resistance.

Europe joins the fight against counterfeit and illegal medicines

In 2014, further work was done at both the European and national levels on the introduction on the Falsified Medicines Directive (2011/62/EU). This directive should inhibit falsified medicines and other illegal medicines from entering the legal distribution chains.

"The European Commission is monitoring the safety and authenticity of our medicines"

View to the future

Didn't the European Commission primarily take regulatory measures in 2013? Yes, so in 2014 they are mainly focusing on the practical implementation of these measures. They are also creating a foundation for further implementation measures at European level. Here is an overview:

- **Brokers register**
  The working group of the network of the European medicines agencies, Heads of Medicines Agencies (HMA) has created a public European register of medical brokers, namely, the persons who act as brokers between the purchasers and sellers of medicines. This register can be accessed by the public.
- **Shared vision**
  This working group is also working on a single vision around falsified medicines and other illegal medicines. The key issue is which criteria and checks prevent suspected falsified medicines and other illegal medicines that are not intended for the European market from finding their way into our legal distribution chains.
- **Compliance with European standards**
  The evaluation of non-European manufacturers of active ingredients has been further elaborated. The foremost criteria is whether these manufacturers meet the standards for European manufacture.
- **Recognisable logo for distance selling**
  A common logo for persons and organisations that offer medicines for sale at a distance (without a prescription) has been developed. This enables the population to recognise the medicines immediately. This logo was established by the European Commission under implementing regulation 699/2014, together with criteria for verifying that providers have not copied the symbol.
  The logo will appear in Belgium from 2015 at dispensing pharmacies that offer medicines online without a medical prescription.
- **Safety features for medicines**
  The European directive on falsified medicines also deals with the technical details of safety features that medicines should carry. Which medicines (with and without a medical prescription) should carry these features and which should not? How is the control procedure and the centralised data management proceeding? These are set out in an implementing regulation that will probably be adopted in 2015.

Read more about the role of the famhp in the worldwide fight against pharmaceutical criminality in the article "The famhp takes up arms against international falsified medicines and illegal medicines".

Presidency of the Council of Europe

The Council of Europe was formed shortly after the Second World War in response to the horrors of the war. The rights of humans, democracy and the rule of law lie at its heart. Even today, the protection of these values is essential. This can be clearly seen from recent events such as the attack in Paris on the editorial board of satirical weekly publication Charlie Hebdo.
The Council of Europe has 46 member states, including all of the member states of the European Union. Belgium is one of the founding members of the Council of Europe and assumed the presidency for six months from November 2014.

The protection of health is one of the rights of humans. In 1964, specific initiatives were taken to guarantee the quality of medicines with the agreement on European Pharmacopoeia.

Since the European Union also became party to this agreement, the European Pharmacopoeia has a direct effect and plays an important role in the legislation of the European Union. This also applies to all of the other activities that are looked after by the European Directorate for the Quality of Medicines & Healthcare (EDQM).

The famhp organised a workshop for journalists together with EDQM on 18 November 2014 to present the activities of both organisations. This discussed the role that the media can play in informing patients and the wider public on matters such as combating falsified medicines or the use, perception and quality of generic medicines.
The theme of informing patients about the non-availability of certain medicines was explored during the discussions with journalists.

Keeping the consequences of supply problems to a minimum

Sometimes a medicine is not in stock. When this happens, pharmacists are unable to supply the medicine when it is prescribed by doctors, dentists, vets or midwives. This is inconvenient for all parties and for the patient. To avoid this, organisations including the famhp, the National Institute of Health and Disability Insurance (RIZIV-INAMI) and the pharmaceutical companies put their heads together and at the end of 2013 the Non-availability Platform saw the light of day.

"Will there be supply problems in the future? This will bring further self-regulation and possibly also sanctions"

The platform began as a consultation body with representatives from the famhp, RIZIV-INAMI and the professional associations for the pharmaceutical industry, pharma.be, FeBelGen and BACHI. During 2014, the following professional associations for pharmacists also joined: the co-ordinating federation of the Belgian professional associations of independent retail pharmacies (APB) and the Belgian professional association of cooperative retail pharmacies (Ophaco) and the association for hospital pharmacies, BVZA, insurance companies and the National Association of Wholesaler-distributors (NVGV).
Their common goal was to identify which medicines were temporarily unavailable and to reduce the impact for patients.

Three achievements: from notification to publication

The Non-availability Platform gathers, pools and publishes information about the availability of medicines. This has led to three achievements:

1. **Unique contact point for pharmaceutical companies**
   What is the situation with the availability of medicines on the Belgian market? It is only possible to answer that question with up-to-date information from the pharmaceutical companies.
   Is a new medicine with a Belgian authorisation for marketing or MA coming onto the market? Will it be temporarily unavailable, for over 2 weeks? Or is it being withdrawn from sale? Then the central contact point will be notified. Furthermore, this simplifies administration.

2. **Database clear-up campaign**
   It is important that the information held on authorised medicines is correct. That is why the famhp mounted a large-scale automated campaign to validate the data held in its database, with the help of the famhp's IT Division.
   The companies that are responsible for marketing medicines were invited to verify their information in 2014. This resulted in 94% of all data in the database being validated by the end of 2014. The famhp would like to further increase this percentage.

3. **Online publication**
   The information we collect should also be made public. That is why on the famhp's website there is a list of medicines that are temporarily unavailable medicines that have an MA for the Belgian market. The overview is updated every working day, based on the data from the medicine dispensers.

How do supply problems arise?

Waarom zijn sommige geneesmiddelen onbeschikbaar?
Why do some medicines become unavailable?
Some of the reasons for this include:

- **a temporary supply problem**, such as:
  - a delay in production, for instance because an ingredient was not delivered on time;
  - a malfunction in the packaging phase;
  - a hitch in the local distribution chains.
- The **definitive removal from sale** of a medicine, such as:
  - due to commercial considerations by the manufacturer responsible;
  - due to a new risk to safety that was revealed by research;
  - due to a decision by the appropriate authorities for reasons of public health, such as new risks to safety that were revealed by research.

Everyone plays a part

Pharmaceutical companies naturally do everything they can to ensure that their medicines remain available. The famhp and the Non-availability Platform try in turn to keep the effects of supply problems to a minimum. There will probably be further improvements in the future, with more self-regulation for medical products and wholesalers. Or specific sanctions for anyone who does not sound the alarm bell on time. In this way, everyone in the pharmaceutical industry plays a part.

WHAT IS THE IMPACT OF MEDICINES BEING UNAVAILABLE?

What are the determining factors? The **duration** of the non-availability and the **nature** of the medicine.
Sometimes when medicines are unavailable this endangers an **individual treatment** or even **public health**. This mainly concerns essential medicines for which there is no alternative.
A brief supply problem causes fewer problems. Often there are also **therapeutic alternatives** for the unavailable medicines. Patients or animal owners count on the advice from their doctor, vet or pharmacist about this.

Extension of the moratorium on pharmacies. Is this a good thing or just out-of-date?

Are you thinking of opening a new pharmacy? Over the coming years this will still not be a straightforward matter. During the 1990s a moratorium entered effect in order to better distribute pharmacies across the population. This has now been extended for five years. However, it comes with new features and clarifications.

> *The excessive concentration in urban areas has fallen. However, the moratorium will remain in force until 2019*

Regulation taken to task

The previous moratorium was in force until the end of 2014. This provided a good opportunity to take a closer look at the regulation again. A number of the older articles that no longer apply have been removed. Furthermore, experiences from the previous years have inspired amendments and clarifications, including:

- new rules on the right to be heard during the procedure;
- clarification of the temporary relocation of a pharmacy when the original premises become unavailable due to force majeure;
- more realistic provisions on the definitive closure of pharmacies;
- a limited review of the registration procedure that obliges pharmacies to notify important changes (such as a new holder or proprietor) to the famhp. A legal basis has now been incorporated into the registration procedure to simplify administration, by working together with other databases.

Historic growth

Our country had one of the highest concentrations of pharmacies per head of the population, even back in the 1960s. The illuminated green crosses are an ubiquitous sight, especially in cities. However, these are few and far between in the countryside. So the regulator took action and determined that pharmacies should be distributed proportionately, in accordance with the local population density. It created directives to regulate the opening, relocation and closure of pharmacies.

The regulations restored balance...

The measures did have an effect. Slowly but surely, the excessive concentration of pharmacies in urban areas fell and the number of pharmacies in outlying municipalities increased. In 1999, the regulator finally imposed the moratorium. No more new pharmacies could be opened, with several exceptions.

...but also created annoyance

However, these have caused detrimental side-effects which have been bone of contention among pharmacists. For instance, when a profitable business suddenly sees a competitor appear. Some people consider the reduction in pharmacy numbers as a threat to their sales and take their disputes to the courts. However, the current regulations ignore this phenomenon. They have only one goal, namely to make medicines as easily available as possible to the population.

Keeping pace with the actual situation

The new moratorium will remain in force until 2019 and will undoubtedly continue to provoke discussions about the regulations. Modern pharmacies, in Belgium and in other European countries are also constantly evolving and the regulations must keep pace.

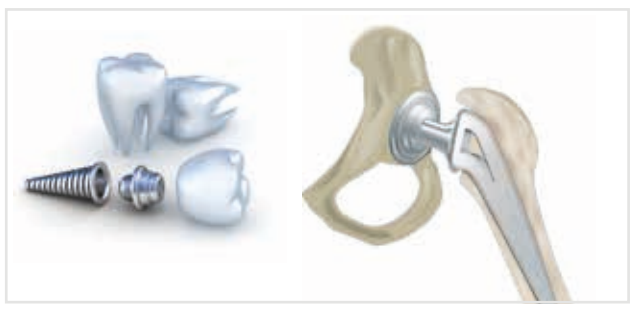
BELGIAN PHARMACIES IN FIGURES

At the end of 2014, Belgium had:

- 4,998 pharmacies
- 11 million inhabitants
- approximately 1 pharmacy for every 2,200 inhabitants

Source: the famhp.

GUIDE TO MEDICAL DEVICES



Would you like to learn about the other work done by the famhp on the Plan for Medical Devices? Then read the article "Where are we now with the Plan for Medical Devices?".

Patients are entitled to clear and complete information about the medical devices that they use or have implanted. That is why the Transparency Working Group of the famhp has published the Guide to Medical Devices. The same team was also behind the three thematic information files about specific devices.

The Transparency Working Group is made up of representatives from patients' associations, the industries concerned and the competent authorities. In the Guide to Medical Devices they provide answers to questions such as:

- What is a medical device?
- What checks do they go through before they are brought onto the market?

Clarity about specific devices

In the information section on the famhp website there are three thematic information files for patients on:

1. breast implants;
2. prosthetic hips;
3. dental fillings using amalgam, which is an alloy of mercury and other metals.

These files are also produced by the Transparency Working Group.

CONTINUING PROFESSIONAL DEVELOPMENT OF PHARMACISTS GUARANTEES OPTIMUM ADVICE ON TREATMENTS

Medical science develops at a rapid pace. But how about retail pharmacists? They cannot be left behind. Since 1 January 2015, retail pharmacists have been required to undertake continuing professional development. Pioneering medicines are constantly appearing and new recommendations are produced for existing medicines. New areas such as healthcare products containing blood and blood derivatives and human body material, medical devices and food supplements are expanding rapidly.

At the same time, the advice from pharmacists must be based on the most correct and up-to-date information in order to guarantee that every patient receives optimum treatment. That is why the Minister of Public Health has also made it a compulsory requirement for retail pharmacists to undertake continuing professional development.

Training courses are no longer voluntary

Until recently, retail pharmacists took the initiative themselves to stay up to date. This is no longer voluntary. After long and fruitful discussions, the compulsory continuing professional development of retail pharmacists was cast into the Royal Decree of 8 July 2014. This has been law since 1 January 2015.

20 training points per year

Continuing professional development applies to pharmacists who work as holders of pharmacist positions, assistants or substitute pharmacists in dispensing pharmacies. They can choose from a list of permitted courses, lectures and conferences for pharmacists. They are awarded training points for these, depending on the nature and duration of the activity. A retail pharmacist needs to accrue twenty training points each year, which should be spread across three areas:

1. knowledge of medicines and healthcare products;
2. care and monitoring of pharmaceutical care;
3. other subjects that are relevant to the exercise of the profession.

Training courses and pharmacists: an autonomous system

The famhp is aiming to create greater autonomy in the pharmaceutical sector. The co-ordinating federation of the Belgian professional associations of independent retail pharmacies (APB) and the Belgian professional association of cooperative retail pharmacies (OPHACO) which are the professional associations for retail pharmacists, assess each training activity. They are responsible for approving these activities. They also link each training activity to an appropriate number of points. From 1 January 2016, pharmacists will be required to send their training certificates to their professional association each year. The association will check whether each pharmacist has achieved twenty points.

Certificates should be kept for 10 years

The famhp's inspectors may also directly request to see attendance certificates. Retail pharmacists (and their assistants) should therefore keep their documents for at least ten years in their quality handbook.

> *Pharmacists will be free to supplement their training*

Individual medication preparation gains ground nationally

Do you want to take the right medicine at the right time? This is a tall order for many patients. That is why pharmacists are supporting patients through individual medicine preparation (IMP) where patients receive the medicines they need to take in a user-friendly package for each ingestion time. However, IMP is not just a technical procedure for pharmacists. Pharmacists are also playing a key role in extended pharmaceutical care. Each patient, whether they are outpatients or have been admitted to a hospital or rest home, receives personalised guidance both before and after their treatment.

Pharmacist increases safety and trust in therapy

What are the duties of a pharmacist who offers IMP? The pharmacist:

- sets a dosage schedule, namely a summary of which medicines that should be taken at which times;
- examines whether it is indicated (and therefore safe) or permitted to take certain medicines at the same time and also whether these can be combined with food supplements;
- prepares the individual packages;
- is always available to provide information, advice and guidance.

This method of working extends the care of outpatients in familiar surroundings. It also reduces the chance of medical errors and harmful interactions. In short, IMP plays a part in increasing patient trust in therapy and increasing patient safety.

From manual work to working with a robot

There are three ways that pharmacists can package medicines for IMP, ranging from manual to automated working.

The pharmacist:

1. fills a holder with daily cassettes containing the medicines;
2. prepares a weekly pill box for medicines with set compartments for each medicine to be taken;
3. works with a robot or automated distribution system that packages each medicine to be taken in a plastic bag or wraps them in a roll.

Do you want to use automated IMP?

Manual division methods are suited to small groups of patients and automated methods are more suited to larger groups. However, automated IMP requires a substantial investment. This is why pharmacists may outsource this work to a colleague who already has a robot. If a pharmacist wants to start using automated IMP, then he or she should first notify the famhp and obtain approval. All of the information for doing this is available online at: www.fahmp.be.

Special attention for IMP pharmacists

In July 2014 there were 53 pharmacists, of whom 11 were hospital pharmacists, authorised to carry out automated IMP. The Dispensing Division of DG INSPECTION will concentrate further on these retail pharmacies in 2015.

> *IMP can be done manually or by machine. Pharmacists who do not have a robot can outsource individual packages*

THE LEGAL CONTEXT OF IMP

For the regulator, IMP is a pharmaceutical activity that may be performed by a pharmacist or a hospital pharmacist.
The Royal Decree of 24 September 2012 defines a IMP package as "a closed package with one or more products intended for individual dosage to particular patient at a specific time".
This Royal Decree also contains provisions for high-quality IMP. Furthermore, it outlines the responsibilities of pharmacists who prescribe IMP or who take IMP orders.

THERE IS STILL TOO LITTLE REPORTING OF THE SIDE EFFECTS OF MEDICINES

We use the term pharmacovigilance to refer to the monitoring and evaluation of the side effects of medicines. Every retail pharmacy has an important role to play in this area.

Post-university training focused on pharmacovigilance

An important task of retail pharmacies is to remain vigilant to and report side effects. That is why two experts from the Vigilance Division took a series of evening classes offered by the Institute for Continuous Education for Pharmacists (IPSA) in Spring 2014 on pharmacovigilance. IPSA is an association that organises additional post-university training for pharmacists and pharmaceutical technicians in Belgium. In this way, the famhp was able to raise awareness among no less than 1600 healthcare practitioners. That is an excellent result!

Moving from the theory of pharmacovigilance to practice

The evening classes highlighted the theoretical aspects but primarily focused on the importance of reporting any suspected side effects of medicines. Therefore the classes delved further into practical cases that appealed to everyone's imagination. For instance, subjects that commonly appear in the media, such as the side effects of medicines containing codeine that are used for coughs and the side effects of Domperidone (Motilium and generic variants).

Still a lot to be done

We distributed a questionnaire during the evening classes and the answers confirmed our fears, namely that although people are familiar with pharmacovigilance, it is not a priority issue. 91% of the participants had never reported a suspected side-effect via the famhp website.
Through our active participation in the IPSA lessons, we hope to raise awareness among retail pharmacists so that they will play a more active role in pharmacovigilance in the future.

Preparation licence opens the way for personalised medicines

In contrast to retail pharmacies that are only able to outsource hazardous preparations, hospital pharmacies that do not have the requisite equipment or the necessary staff have recently been able to outsource every pharmacy-made preparation. The manufacturer to which the preparation is outsourced must hold a preparation licence and demonstrate that it is able to supply the quality required.
The regulator wants the preparation licence to better correspond to individual medical prescriptions and written requests from doctors. For instance, when a patient or group of patients wants a treatment and the pharmacist concerned feels that he/she is unable to make the preparation. This will benefit patients, hospitals and also the National Institute of Health and Disability Insurance (RIZIV-INAMI). Pharmaceutical preparations made by an authorised manufacturer must not find their way into the standard medicine retail chain.

Adapted forms and packaging

Many patients have specific needs. Medicines in the standard pharmaceutical form or strength are therefore not always satisfactory. Furthermore, not all pharmacists have the resources to respond to specific requirements. Using manufacturers/specialists with a preparation licence enables doctors, hospitals and pharmacists to focus their medications on an individual treatment. This includes adapting the sizes of packages.

After completing their treatment, patients occasionally have medicines left over, the costs of which are fully or partly reimbursed by the National Institute of Health and Disability Insurance (RIZIV-INAMI). The preparation licence now means that these extra costs will be avoided.

What about small-scale industrial preparations?

The preparation licence was incorporated into Belgian law in 2014 and is based on the Pluriannual Estimates Act of 25 December 2013. The Royal Decree of 17 July 2014 contains further conditions and standards on the quality, safety and traceability of prepared and used medicines, among other matters. For example, the preparation of industrially produced medicines is often not suited to adaptation to a smaller scale. Therefore the Royal Decree contains specific provisions to guarantee good methods of preparation.

Time to define tasks

In summary, the preparation licence opens the way for greater collaboration and for personalised medicine. An indispensable part of this is an agreement that describes the tasks and responsibilities of all of the parties involved. This is on the agenda for 2015!

> *Doctors, hospitals and pharmacists are now tailoring medicines with a greater focus on individual treatments*

FROM PREPARATION TO RECONSTITUTION

Manufacturers that hold a preparation licence are specialised in the following:

- pharmacy-made preparations
- unit packaging of medicines
- mixing components and the reconstitution of medicines.

In contrast to what happened in the past, hospitals are now able to outsource all preparations, not only hazardous preparations.

HOW DO WE MINIMISE THE RISKS OF CERTAIN MEDICINES?

For certain medicines, pharmaceutical companies are required to inform healthcare practitioners and patients about any risks they carry. What is the main purpose of this? Safe treatment. How is this done? Using educational materials (informative brochure, patient card, etc.). The famhp now subdivides these on its website to improve publicity and make them easier to access. These materials vary in format, objective and target audience.

Does a pharmaceutical company need to apply for an authorisation to launch a medicine on the market? Yes. Furthermore, the European or Belgian health authorities can sometimes impose requirements on the authorisation holder to create educational material. This requirement is a so-called additional activity to reduce risks. The umbrella term for this is Risk Minimisation Activities (RMA).

The famhp checks the quality of the educational material and that it is being used correctly

The famhp has a leading role in three aspects:

1. **granting approvals** for RMA materials. Then the pharmaceutical companies must distribute the materials.
2. **publishing approved materials** on its website www.fahmp.be.
3. **using a recognised logo** for the correspondence concerning RMA materials, designed together with the pharmaceutical industry. This logo helps healthcare practitioners to quickly distinguish RMA materials from other materials in their letterbox, for instance, promotional materials. The logo can be found on the top-left corner of the envelope and the accompanying letter.

Do you want to download approved RMA materials?

Go to www.famhp.be, see box at Links to useful pages and documents for healthcare practitioners", "RMA materials" section – available in Dutch and French.

Making great efforts for Unmet Medical Needs

There are still no authorised medicines for certain serious medical conditions. We refer to these as Unmet Medical Needs (UMNs). In some cases, a promising medicine is already at an advanced stage of development. Patients can then use this at an early stage, after approval. Initiatives at both national and international levels are now working on a safe and reliable way to access to these medicines.

UMNs at international level

Shared scientific advice

Collaboration in the area of UMNs is essential. That is why we are stimulating the Scientific Advice Working Party (SAWP) and national medicine authorities such as the famhp and the sharing of Technical Scientific Advice (TSA) by bodies authorised for the medicines and by organisations that evaluate healthcare interventions (such as treatments) through multidisciplinary research.

EMA adaptive pathways trial project

The European Medicines Agency launched a trial project in March 2014 on:

- adaptive licensing - a flexible approach to allow the early release of orphan medicines and medicines onto the market;
- adaptive pathways - a staged manner of licensing a pioneering medicine.

What is the purpose of the EMA project? To support the full life cycle of promising medicines, from research to accelerated development, authorisation and repayment and usage and follow-up. The EMA has already received many enquiries about this advanced therapy and will soon be testing its concept using selected projects. What happened to the files that SAWP went through? These were taken over by the famhp.

UMNs at national level

New regulations

The famhp and the National Institute for Sickness and Disability Insurance (RIZIV-INAMI) have issued new regulations concerning UMNs:

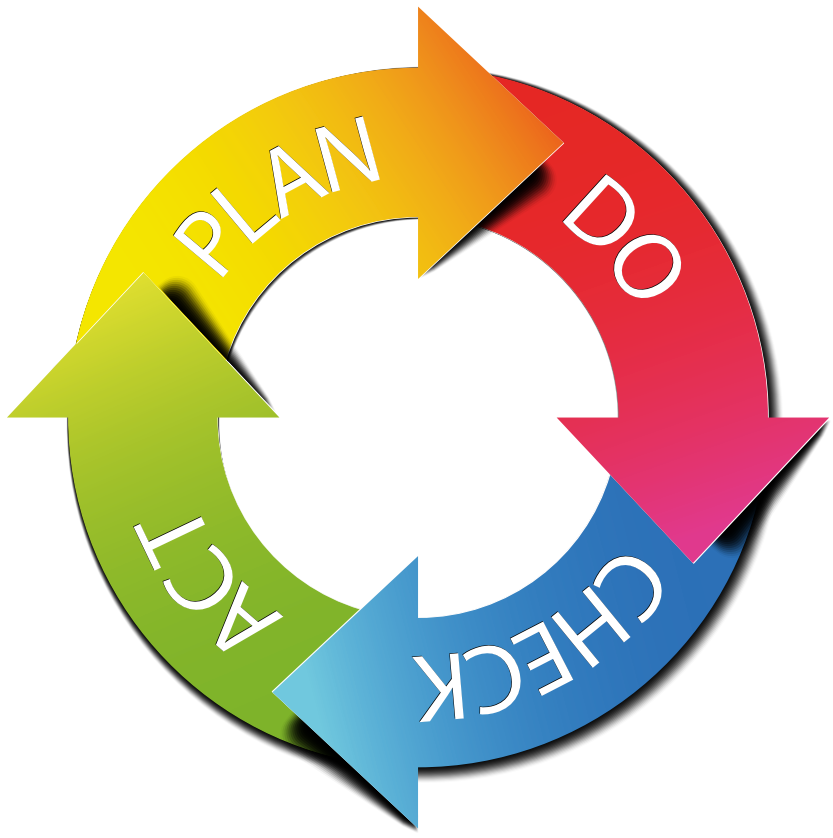
- The famhp and the committee for medicines for human use have are evaluating medicines that may fulfil an UMN.
- Is there a positive balance between the benefits and risks? In this case, the Minister of Public Health and Social Affairs or a pharmaceutical company can submit a cohort application to the Board of Medical Association Directors of the RIZIV-INAMI for:
  - early repayment of the medicine when the need is extremely urgent: the use of medicines without authorisation before these are brought onto the market in harrowing cases or CU (compassionate use);
  - other UMN programmes.

  One essential condition is that the pharmaceutical company concerned must also submit an application to market the medicine within six months of submitting an UMN application.

This project has been launched by the Bioplatform. The Bioplatform is an initiative that brings together representatives from the innovative industry and the government. The Human R&D Division of the DG PRE authorisation will put the updated procedure into practice.

> *"National and international UMN initiatives are creating space for safe and early access to promising medicines"*

Charting the famhp's processes



In 2014, the famhp reached a significant milestone in the development of the quality system. The first catalogue of processes was approved[1] as part of the process-driven approach.

What is a process catalogue?

A process catalogue lists all of the activities and competencies with which an organisation is confronted in line with its mission. A process catalogue is an important instrument in the process-driven approach.

The benefits of a process-driven approach

The most important benefits are as follows:

- lower costs and reduced handling times through the efficient use of resources;
- improved, coherent and predictable results;
- consideration for improvement opportunities and priorities.

The various management aspects that arise from the application of this principle, are as follows:

- the systematic definition of the basic activities needed to fulfil the mission;
- the setting of clear responsibilities for the management of the activities;
- the measurement and analysis of the performance and the potential of these activities;
- the improvement of the activities through the introduction of elements such as the resources, methods and materials to achieve the desired result;
- the assessment of the risks and the impact of these activities on clients and other stakeholders.

An overview of the famhp's processes

Three types of processes have been listed in the famhp process catalogue:

1. The professional processes, also referred to as the basic processes, which are classified in four process areas:
   - provision of expert advice on behalf of an authorised body;
   - granting an authorisation, notification, certificate or approval;
   - monitoring quality, safety and effectiveness;
   - imposition of sanctions.
2. The supporting processes have been classified into six process areas:
   - finance;
   - IT expertise and support;
   - communication;
   - legal expertise and support;
   - organisation;
   - personnel.
3. The control processes and the management have been classified into four process areas:
   - strategy and planning;
   - monitoring and reporting;
   - management of improvements;
   - information security.

The catalogue is schematically organised according to the Plan-Do-Check-Act cycle:

- **PLAN:** the strategy and planning processes;
- **DO:** all professional processes, supporting processes and information security processes;
- **CHECK:** the monitoring and reporting processes;
- **ACT:** the management and improvement processes.

A process catalogue is never finalised. The catalogue may be revisited again during the annual management reviews and/or when new activities and competencies are created or shed. The catalogue currently contains 107 processes. Each process in the catalogue will be identified in the form of a process file. This is planned for 2015.

1. The famhp's quality system is based on a process-driven approach that corresponds to principle four of the ISO 9000 standard for quality management.

Where are we now with the Plan for Medical Devices?

On 14 September 2012, the council of ministers approved the Plan for Medical Devices (PMD). FAMHP and the bodies involved have since achieved many of the points from the improvement project by the Minister of Health. The current state of affairs.

The PMD needs to have two purposes:

1. to increase the quality, safety and effectiveness of medical devices;
2. to remove from sale any products that do not meet the minimum standards of quality.

Action in 5 areas

To accomplish this, obligations in five crucial areas are defined in the PMD:

1. traceability
2. verification
3. evaluation
4. materiovigilance
5. transparency

Learn more about what has changed in each of these areas:

1. TRACEABILITY

Medical devices must be traceable from the point of manufacture to when they reach the patient. They could be used by the patient, or used within the patient, in the case of implants.

- The **Traceability working group** will set out the theoretical concept of "traceability" of medical devices in Belgium between October 2012 and March 2013. The team members come from a cross-section of the medical industry and the competent authorities.
- The **law concerning medical devices** will be published on 15 December 2013. This will lay the foundation for better traceability and more efficient verification of devices.
- The electronic **Central Implant Tracing Registry** will come into being during the final quarter of 2013. The registry will be populated with data from two authentic sources: (1) distributors and (2) implantable medical devices. Furthermore, this forms part of the 2013-2018 roadmap for the computerization of healthcare.
- On 17 April 2014, a trial project will begin on **cross-system data exchange** between the supervisory bodies and the hospitals. A web application for reporting on the fitting of implants will also be developed.

2. VERIFICATION

The internal officers from the famhp will begin using an **electronic notification portal** in May 2014. This will make it easier for distributors to send notifications when they launch medical devices, or alter their files. The platform is not yet available online. It will be available once the regulations for this electronic notification have been published, as a supplement to the Royal Decree of 18 March 1999.

3. EVALUATION

- **DG PRE authorisation** will be contracting two experts to evaluate medical devices for clinical trials and to continue its supervision of the market.
- **DG INSPECTION** will be reinforced by further inspectors.

4. MATERIOVIGILANCE

Materiovigilance comprises the study and follow-up of incidents involving medical devices. These incidents should be reported in order to detect and remove any unsafe products from sale.

- The procedures involving the **handling of incidents** with medical devices are being reviewed. Each new record will now automatically undergo a risk analysis. The famhp publishes a guide for the medical profession on its website about the notification of irregularities:http://www.fagg-afmps.be/nl/binaries/Gebruikershandleiding%20inzake%20materiovigilantie%20ter%20attentie%20van%20de%20gezondheidszorgbeoefenaars_tcm290-260956.pdf.

5. TRANSPARENCY

The Vigilance Division of the famhp sends out a new edition of **VIG NEWS** to healthcare practitioners every three months. This electronic newsletter contains the latest news about pharmacovigilance and a **permanent feature on materiovigilance**.

Greater attention to safety notices for medical devices

The famhp has been publishing Field Safety Notices (FSNs), which are safety notices for medical devices, since June 2013. The agency decided to do this after it conducted a survey among healthcare practitioners. The results showed that the medical devices sector has too little visibility.

What was the context of this publication? The Medical Devices Plan and the objective to communicate clearly about implants, prosthetics, medical equipment, etc.

Intentional focus on the greatest risks

The famhp is intentionally focusing on the FSNs for the category of medical devices with the greatest risk, namely class III, or the medical devices which are used for implants in Belgium. These include stents, heart valves and breast implants. It is estimated that around eighty FSNs appear online every year. Each of these is written in Dutch, French and English. The list is updated every two weeks.

"The medical devices sector has too little visibility according to a survey conducted by the famhp"

INFORMING USERS ABOUT RISKS

A safety notice for medical devices or Field Safety Notice (FSN), explains the risks of a medical device and the corrective actions which are partly the duty of users, namely patients and healthcare practitioners.

Manufacturers prepare these safety notices for their products. These are comparable to the letters sent by pharmaceutical companies to healthcare practitioners to inform them of the potential risks of medicines or Direct Healthcare Professional Communication (DHPC).

Reducing the falling use of antibiotics in veterinary medicine even further

Belgium is on the right path! Between 2011 and 2013, the use of antibiotics in veterinary medicine fell by 12.7%. However, we have ambitious goals. We have set a target of 50% by 2020. This means it is time for an equally ambitious plan.

Not the best pupil in the class

When we look at the Belgian figures (2012), we are the sixth largest user out of the 26 European member states[1]. We took a joined approach and in 2014 the Medicines for Veterinary Use Division worked intensively on the problem of antibiotic resistance. Various risk factors control resistance selection and of these, the number of doses of antibiotics used with animals is of great importance for the maintenance of effective medicines. This implies that sickness prevention and biosafety measures take precedence.

Coordinator for Antimicrobial Resistance (AMR) means business

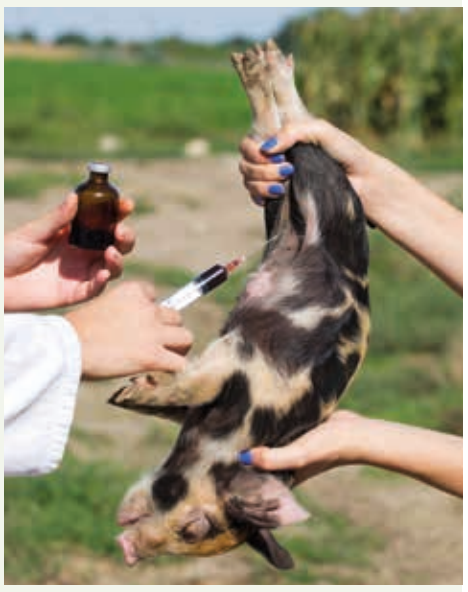
The Medicinal Products for Veterinary Use Division did not watch from the sidelines. It prepared an action plan that was based in part on the European Commission action plan.[2] On 1 April 2014, a coordinator was appointed within the Medicines for Veterinary Use Division to put all of the activities that are part of the AMR action plan on the right track.

Tax op antibiotica

Since 1 June 2014, the famhp has imposed a tax on the licence holders of all veterinary medicines containing antibiotics that are marketed in Belgium. The tax applies to both farm animals and pets. It is calculated according to the percentage of active ingredients. This tax is higher for medicines that contain critically important antibiotics such as third or fourth generation cefalsporins, quinolones or macrolides. It is important to note that the revenue from the tax is reinvested into the financing of actions from the AMR action plan.

Monitoring the use of antibiotics

In order to make cattle farmers and vets aware of their responsibilities, in 2014 the famhp began development of a system to measure the quantities used for each of the cattle farms: the Sanitel-Med module within the Sanitel identification and registration system. This module will enable vets to register the quantities of antibiotics supplied or administered to each cattle farm and for each animal species in a central database. Identifying the activities of the vet/cattle breeder team will give us an idea of the score for each farm/each vet. This awareness-raising monitoring should open the way for preventative measures. The development of this database takes the ESVAC recommendations on data collection into account at the level of individual cattle farms.



Action plan against antimicrobial resistance (AMR)

The famhp gives a substantial financial boost to AMCRA

The non-profit organisation, AMCRA, the Centre for Antibiotic Use and Resistance for Animals in Belgium, has made a substantial contribution in this area by raising awareness. Their guides to the good use of antibiotics, awareness campaigns and proposals for self-regulating measures have had an extremely positive response. That is why the famhp has decided to take a 30% stake in the funding of the AMCRA.

Development of a regulatory framework

The famhp is aware that a well-honed regulatory framework can accelerate the results from the action plan. Together with the other government departments involved, such as the Federal Agency for Safety of the Food Chain and FPS Public Health, the famhp is working on an effective regulation.

1. *4the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report. The quality of antibiotics sold for veterinary use is measured using the annual Belgian Surveillance on Consumption of Antibiotics in veterinary medicine (BelVet-Sac). Wholesalers, distributors and feed manufacturers that produce medicated animal feeds provide this information.*
2. *It is also based on compliance with the recommendations from the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) and the HMA's (Heads of Medicines Agencies) working group for AMR.*

THE NEXT STEP IN COMPUTERISING THE MEDICINES FOR VETERINARY USE DIVISION

Since 1 January 2013, the Medicines for Veterinary Use Division has been using the following electronic system for more efficient management of electronically submitted files: MeSeA Vet (Medicines e-Approval and e-Submission VET).

At the beginning of 2014 the division began to analyse and test the implementation of the MesExtra UI application, which is the next step in computerising the department. This application allows information about a medicine, including its composition, manufacture and packing information to be electronically archived and monitored. The new application was implemented within the division on 1 June 2014.

Advantages of the new application

The implementation of this system ensures for better harmonisation of the internal procedures and the handling of data on medicines for human use and medicines for veterinary use.

Having electronic access to this data opens up possibilities for the inspection departments and enables medicines for veterinary use and the file management for these products to be more efficiently monitored.

The implementation of MesExtra UI enabled the division to move to a simplified version of the Marketing Authorisations (MAs) on 1 September 2014. As a result, the number of amendments that have an impact on the official documents have been considerably reduced and an amended MA only needs to be provided in a limited number of cases. This signifies a simplification of administration for both the pharmaceutical industry and for the famhp.

Protecting humans and animals

The famhp at agricultural fair in Libramont.

In 2014, the 80th agricultural fair was held in Libramont. This was a splendid open-air event that attracted at least 214,000 visitors where 1,500 exhibitors has stands across an area of no less than 300,000 m².

In Libramont, the famhp stressed the importance of veterinary medicine monitoring, the good use of veterinary medicines and the issues around antimicrobial resistance.

The veterinary medicine section of the famhp was not only able to count on the interest of professionals who had connections with veterinary medicine, but the general public also showed a clear interest.

The famhp stand attracted many visitors, including people from both the agricultural and healthcare sectors and non-professionals who were able to approach us with their questions.
Around 400 visitors took part in an educational quiz, with the aim of becoming better acquainted with the famhp.

People appreciated the presence of the famhp. This was encouraging for an organisation that is dedicated to raising the profile of its role as an authorised body for medicines and healthcare products.

Working towards a more efficient framework for homeopathic medicines

In 2014, we thoroughly analysed the operation of the Homeopathic & Herbal Medicines Unit. Our ultimate aim was to guarantee the timely handling of applications for registration and authorisation for marketing homeopathic medicines.

To achieve this aim, we completed a number of improvement projects. For instance, the 2003 list of 18,000 notified homeopathic medicines was slimmed down to 5,654 medicines. We also began a comprehensive reflection on marketing homeopathic medicines with the sector. We looked at the availability of stem products (the basis for preparing homeopathic medicines) and closely examined the advertising of homeopathic medicines. Furthermore, we gave thought to how package inserts can contribute towards better use of these medicines.

We also developed a section in the electronic system for submitting and approving medicine files, Medicines e-Submission and e-Approval (MeSeA), that was specially adapted to the file management needs of homeopathic medicines. This should lead to more efficient monitoring and handling of the files.

Medicinal cannabis and the current scientific position

The Homeopathic & Herbal Medicines Unit played a leading role in the set-up and operation of the Belgian Working Group on the use of medicinal cannabis. This working group received a mandate from both the Commission for Medicines for Human Use and the Commission for Herbal Medicines for Human Use to review the existing recommendations on medicinal cannabis from 17 March 2006 on the basis of the current scientific position.

The proposal for recommendations was submitted on the basis of scientific evaluation reports using data available on the quality of the raw materials, the use of medicinal cannabis and the safety of cannabis and cannabis preparations. Both commissions sanctioned the proposal for recommendations. The Minister will use the recommendations to decide whether the existing regulations should be amended or whether new measures are required.

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