Your medicines
Your medicines and health products, are our concern!
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Dear Reader,

As a year, 2013 was characterised by the wide array of events and issues related to medicines and health products, which can be explained in part by the ever increasing importance that patients are placing on their health. 2013 has also become synonymous with the major issues, such as the safe use of:

- combined oral contraceptives (COCs),
- combination preparations with cyproterone and ethinylestradiol (in Belgium: Diane 35 and generic medicines),
- medicines with domperidone (in Belgium: Motilium and generic medicines), for nausea and vomiting,
- medicines with tetrazepam (in Belgium: Epsipam, Myolastan, Tetrazepam EG) for painful muscle spasms and cramps,
- medicines against cough and cold (antitussives, expectorants and topical nasal decongestants),
- electronic cigarettes.

These issues, the ensuing discussions and the potential impact on patients once again demonstrate the importance of continuous oversight for medicines and health products. One example here would be the scandal of the fraudulent PIP breast implants in 2012, which resulted in a forced overhaul and tightening of regulations on inspection and oversight for implantable medical devices. These kinds of big cases show the importance of proper use of medicinal products, and thus also the need for correct and up-to-date information and raising awareness amongst patients. In this light, I am delighted with the success of our third media campaign, «Medicines and children. Careful! Medicines are not sweets!” with special attention to the use of medicines amongst children.

It is with great pleasure that I invite you read the 2013 Annual Report of the famhp. You will find that 2013 was a year of projects and changes for our agency. After celebrating our 5th anniversary in 2012 and preparing the balance sheet from our first five years, we took a moment to reflect not only internally, but also together with our partners, by means of satisfaction surveys and special discussions. All of this enables us to chart our course for the coming years.

In 2013, we implemented several strategic improvements. We particularly invested in the quality of our services, our management model, our organisation, our knowledge and expertise, our regulations and our spearheads. We started a number of promising projects such as the medical device plan (PMH-PDM) launched in late 2012, the new awareness campaign, and the further reinforcement of our competencies, knowledge and partnership agreements, such as in the areas of clinical trials on medicines for human and veterinary use and drug monitoring or pharmacovigilance.

Several other initiatives also deserve to share the spotlight, which is why I invite you to learn about them in the coming pages.

The 2013 annual report of the famhp features two parts. On top of the information on a number of “2013” topics that the famhp would like to highlight, we wanted to give a transparent overview of our activities. Here you will find text and explanations on the functioning of and results from the various famhp divisions/entities/units and co-ordinations. You may already be familiar with the charts and tables of figures, which we hope will provide a clear picture of the evolution of our duties and the results achieved by our agency.

I can go ahead and say that in 2014 our agency will continue to improve the quality of our services with measures like the reinforcement of the support services, and especially also by maintaining the central role of the patient and protection of public health, all while never losing sight of our motto: «Your medicines and health products, are our concern.»

Finally, we would like to thank not only the entire agency staff for all of their hard work over the course...
of the year, but also our partners with whom we collaborate and above all with whom we work towards a common goal: to watch over the quality, safety and efficacy of medicines and health products, in clinical development and on the market.

Xavier De Cuyper
Chief Executive Officer
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 homeopathic medicines and herbal medicines, pharmacy made and officinal preparations;
· of health products, including medical devices and accessories, and raw materials (active pharmaceutical ingredients) 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
· Cohesion

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

Your medicines and health products, are our concern!
The famhp in 2013
THE NEW 2014-2018 MANAGEMENT PLAN

Before getting started on the next phase of our agency’s lifecycle and on drafting a new management plan, to succeed the previous 2008-2012 business plan, we drew up a balance sheet for our initial years in 2013. This look back allowed us to take stock of the truly extraordinary changes that our organisation has undergone since its founding.

Since 2008, the agency has clearly prioritised clearing up the backlogs in the processing of almost all key processes. In addition, in this same period, an impressive number of projects were launched, including some innovative ones, such as the spearheads. Other initiatives, at both the federal and European levels, left their mark on the first management plan, such as the changes in the areas of drug monitoring, conducting clinical trials, the fight against counterfeit medicines and other illegal medicinal products and the traceability and inspection of medical devices.

The famhp also exhibited the necessary adaptability to navigate the many external factors at play in recent years, such as the financial and economic crisis and the international scandals in the world of medicines and health products, not to mention the flu pandemic.

The analysis of this initial period has also enabled us to identify the key ideas for the future development of our agency. Two key objectives are to:

- consolidate the central place of the patient by means of greater transparency, more targeted listening, reinforced risk management and better communication;
- significantly reinforce the support services needed to fulfil our responsibilities/mission by means of, for instance, greater investments in a real HR policy and in an adapted IT strategy.

Over these first five years, various initiatives were implemented in the interests of continuous improvement, such as customer satisfaction surveys and special discussions to enable the agency to optimise its working methodology.

Based on the findings and on prior implementations, the management of the agency has charted a course for the famhp for the next five years and concluded 2013 with the 2014-2018 famhp management plan.

IMPLEMENTATION OF A MANAGEMENT CYCLE BY THE PROGRAMME MANAGEMENT OFFICE CO-ORDINATION OR PMO

In 2013, the famhp introduced the concept of the management cycle. The management cycle is intended to link the planning of the activities and the decision-taking up with the budget calendar.

In practice, this results in implementation of the key reports and taking major decisions at two critical times: the end of the second quarter and the end of the year. These two times correspond, respectively, to the submission of the estimated budget or the finalisation of the budget and with its approval for the upcoming year. These times are essential to the entire organisation for access to and optimal allocation of the necessary resources, both human and financial.

The gradual introduction of this concept required a great deal of detailed reflection in advance and as its introduction progresses, it will require the necessary logical approach and attention to detail, but at the same time will also bring greater consistency and coherence.
TASKFORCE ON NON-AVAILABILITY OF MEDICINES

In 2013, at the request of the Belgian Minister of Public Health, Mrs Laurette Onkelinx, the Taskforce on non-availability of medicines was created within the famhp, with representatives from the Belgian National Institute of Health and Disability Insurance (RIZIV-INAMI) and the relevant industry.

This taskforce initially focused on getting a proper overview of the situation. After all, marketing authorisation holders (MAH) are legally required to report a variety of data on the availability (or lack thereof) of medicines, both to the famhp and the RIZIV-INAMI. It is required to provide information on the commercialisation, temporary unavailability and reasons for unavailability, the expected return-to-market date or the definitive end of commercialisation. As a result of the various legal requirements for obligatory reporting to the famhp and the RIZIV-INAMI, the information is not always uniform or identical. On the contrary, information on effective commercialisation or temporary unavailability is sometimes conflicting. As a result, there is confusion and loss of time for all involved, to the detriment of the patient, who cannot obtain the necessary medicine on time.

Harmonisation of the various regulations for the two institutions and creation of a central reporting point for collecting information from authorisation holders were identified as priority actions in order to arrive at better oversight on effective reporting of data and monitoring for this. These data will be available to all relevant partners: hospital and retail pharmacists, medical doctors, distributors, insurance offices and patients. The increased transparency should also promote the empowerment of all stakeholders.

1 January 2014 was proposed as a target date and two years after entry into force of the system, the famhp will conduct an evaluation of its impact on medicine provisioning.

On 23 December 2013, the famhp and the RIZIV-INAMI were pleased to announce the new procedure, which took effect on 1 January 2014. On this occasion, the membership of the taskforce was further expanded with representation from the pharmacists’ professional association.

The taskforce continues to seek out sustainable solutions. How it can be arranged in the regulations, in consultation with the pharmaceutical sector, so that authorisation holders, for instance, always have an alternative producer available? In the case of a definitive end to commercialisation of a medicine, how can the market still maintain supplies, at least for a reasonable period, for medicines deemed essential? Another option is to further empower the relevant operators in the distribution chain by introducing stronger penalties for failure to provision the Belgian market for reasons other than stock shortages resulting from production, distribution or commercialisation issues known to the public services.

SOME CASES WITH SPECIAL MEDIA ATTENTION

These days, patients are showing increasing interest in anything related to their health. They want to be more involved in their treatment and find their own information over the internet or pick it up from the media. Thus, it is no wonder that the press regularly contacts us with questions about medicines and health products. Reasons for this may include a new regulation, a case with media attention abroad, a court case after a claim or a case of fraud, a publication in a scientific journal, the dissemination of a press release from one of our partners or day-to-day journalism work.

Aside from the one-off occurrences that give rise to several articles or reports, we give a few examples below of cases that garnered a great deal of media attention in 2013.

Combined Oral Contraceptives (COCs)

In early January of 2013, the French authority competent for medicines or l’Agence nationale de sécurité du médicament et des produits de santé (ANSM) – following a lawsuit filed by several patients against manufacturers of what are known as third and fourth-generation COCs, and against the ANSM itself – requested a re-evaluation from the European Medicines Agency (EMA), resulting in an immediate media storm in all European countries. The claim had to do with the risk of venous and arterial thrombosis associated with the use of COCs.
In November of 2013, this re-evaluation was completed. The two European committees involved, the Pharmacovigilance Risk Assessment Committee (PRAC) and the Committee for Medicinal Products for Human Use (CHMP), came to the conclusion that the known risk of blood clot formation is a serious but very rare adverse reaction and that the risk/benefit analysis for this medicine remained positive as long as the contraindications and precautions for use are observed.

During the re-evaluation, a great deal of information on the risks of using COCs was circulating in the media, at both the national and European levels. The famhp communicated regularly through its website, news articles, press releases or responses to press questions on the state of affairs and the recommendations of the EMA, such as the finding that there was no reason to recommend suspending treatment with a COC. Every communication did in fact iterate that it is always crucial to examine the potential risk factors when a COC is prescribed and conduct regular clinical follow-ups on the patient. Gynaecologists and medical doctors received special letters with information for them and their patients. In these letters, the famhp reminded the reader of the importance of assessing the individual risk/benefit analysis for each patient and to examine the risk factors for thrombosis – such as personal or family history, tobacco use, high blood pressure and obesity – and recommended a clinical follow-up, especially during the first year of treatment.

**Medicines containing cyproterone and ethinylestradiol**

(in Belgium: Diane-35 and generic medicines)

In 2013, the ANSM announced its intention to suspend the marketing authorisations (MA) for medicines containing cyproterone and ethinylestradiol as a result of the risk of venous or arterial thrombosis. In France, these medicines were only authorised for treatment of acne, but the ANSM has determined that they are widely used as a contraceptive outside of the indication approved in France. The indications also appeared to differ widely from country to country: from treating acne, to serious forms of treatment-resistant acne and excessive hair growth and as a hormonal contraceptive. At the request of the French competent authority, the EMA also initiated a re-evaluation.

In May of 2013, the PRAC confirmed the positive risk/benefit analysis of Diane 35 and generic medicines for a specific patient group. It was decided to limit the indications and clearly state not to combine this treatment with any other hormonal contraceptive. Measures were also taken to limit the risk of venous or arterial thrombosis. In June of 2013, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) confirmed the findings of the PRAC. With regard to Belgium in particular, the situation hardly changed at all. After all, the amended formulation of the indications for all of Europe did not differ greatly from the original Belgian formulation.

During the re-evaluation, a great deal of information on the risks of using Diane 35 and generic medicines was circulating in the media, at both the national and European levels. The famhp communicated regularly through its website, news articles, press releases or responses to press questions on the state of affairs and the recommendations of the EMA. The affected pharmaceutical firms sent out a special letter with the recommendations for patients and healthcare professionals from the famhp, in the form of a Direct Healthcare Professional Communication (DHPC).

**Medicines that contain domperidone**

(in Belgium: Motilium and generic medicines)

Due to the potential negative cardiac effects of using medicines that contain domperidone, the famhp launched a procedure in early 2013 to require a medical prescription for these medicines.

Why make them prescription medicines? Medicines based on domperidone may pose a direct or indirect danger, even in cases of normal use, if not used under the supervision of a medical doctor. Some epidemiological studies have demonstrated that domperidone may be linked to a higher risk of serious ventricular arrhythmia or sudden cardiac death. The risk may be higher in patients over 60 years of age or those taking daily doses of over 30 mg. In addition, nausea and vomiting may be symptoms of certain afflictions such as gastroesophageal reflux. The use of domperidone may mask these underlying diseases, which in turn may delay proper diagnosis. In addition, a risk
of interactions with other commonly used medicines exists, especially those that also lengthen the QT interval (phase of heart rhythm).

After this re-evaluation, the Evaluation commission for medicines products for human use established by the famhp decided that in Belgium, just as in most other European countries, medicines containing domperidone would henceforth only be available with a medical prescription. This measure came into force on 30 November 2013. At the same time as its reclassification as a prescription medicine, a re-evaluation was conducted, at the European level and at the initiative of the famhp, on the risk/benefit analysis for these medicines. This procedure was not yet completed at the end 2013.

In order to keep healthcare professionals up-to-date, the famhp used the available communication channels, such as its website, news articles, press releases or information to special famhp partners. Medicines that contain domperidone are well known to the general public. The announcement of the re-evaluation and intention to make these drugs prescription medicines raised a great deal of questions, amongst both patients and the media. The famhp regularly updated the media, the general public and healthcare professionals on the current state of affairs.

Medicines used for cough and cold

In 2012, the famhp Evaluation commission for medicines products for human use re-evaluated the risk/benefit analysis for children’s medicines for cough and cold. These are antitussives, expectorants and topical nasal decongestants. Following this re-evaluation, the provisional advice of the commission was relayed to the relevant MAHs. They were given the opportunity to submit a response or a request for a hearing.

Taking into account the elements supplied by the relevant MAHs, the commission issued a final recommendation. Based on this the following decisions, among others, were taken and have been in force since 1 May 2013:

- the use of antitussives and expectorants is contraindicated for children under six years of age;
- antitussives containing codeine or one of its derivatives (ethymorphine, dihydrocodeine and thebacon), including those intended for adults, are subject to medical prescription;
- a number of topical nasal decongestants are contraindicated for children under seven years of age;
- medicines containing tetrazepam are contraindicated for children under six years of age.

In April 2013, based on the recommendations, the European Commission decided to suspend MAs for these medicines and recall all lots distributed in Belgium. As soon as the advice of the European Commission was announced, the famhp took the necessary measures to implement the decision, relayed the information to the relevant companies and exercised oversight on the recall of the affected lots. Healthcare professionals also received a special letter notifying them that it is no longer permitted to prescribe medicines with tetrazepam and that patients who show up at pharmacies with medical prescriptions must be referred to their attending medical doctor.

As a precondition for lifting the suspension, the PRAC requested data from MAH to identify a specific group of patients for whom the benefits of medicines containing tetrazepam outweigh the risks.

The information on the suspension of MAs for these medicines elicited a great deal of questions from journalists.

For this reason, the famhp has communicated regularly with patients and healthcare professionals through its website, news articles and a DHPC to medical doctors and pharmacists. The various professional associations were also systematically requested to provide their members with the information from the famhp.

Medicines that contain tetrazepam

(en Belgique : Epsipam, Myolastan et Tetrazepam EG)

At the initiative of the ANSM, the EMA re-evaluated the data available on tetrazepam. Tetrazepam is used to treat painful muscle spasms or cramps, primarily in patients with rheumatologic afflictions characterised by inflammation, swelling and pain in the joints and muscles. The review came as a result of rare but serious skin reactions associated with the use of tetrazepam. The risk/benefit analysis for tetrazepam is deemed to be unfavourable, which is why both the PRAC and the CMDh have recommended suspension of MAs for these medicines.

In April 2013, based on the recommendations, the European Commission decided to suspend MAs for these medicines and recall all lots distributed in Belgium. As soon as the advice of the European Commission was announced, the famhp took the necessary measures to implement the decision, relayed the information to the relevant companies and exercised oversight on the recall of the affected lots. Healthcare professionals also received a special letter notifying them that it is no longer permitted to prescribe medicines with tetrazepam and that patients who show up at pharmacies with medical prescriptions must be referred to their attending medical doctor.

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• for all topical nasal decongestants, the following general recommendations apply:
  - it is crucial to use saline solutions initially;
  - only use for a short period of time or a maximum of five days.
MAHs must submit a special file by January of 2015 for the use of a safety cap on all liquid forms and development of a new formula for compound preparations.

Due to the impact of these measures on proper use of medicines amongst children, a communication plan was prepared. The famhp communicated these recommendations through the various communication channels: website, news articles, letters to healthcare professionals and a request to famhp partners, such as professional associations, to disseminate information to their members.

During the launch of the media campaign: “Medicines and children. Careful! Medicines are not sweets!” the recommendations were repeated. A special brochure: “Does your child have a cough or cold?” was distributed through the Children and Family service centres and Office of Birth and Childhood (ONE), paediatricians’ and medical doctors’ practices and retail pharmacies.

The recommendations, and especially the contraindications for children, were also highlighted in responses to questions from journalists.

Electronic cigarettes

In 2013 as well, electronic cigarettes continued to receive a striking amount of media attention. Many questions were raised with regard to safety, efficacy and the regulation applicable to electronic smoking materials.

We distinguish between three main categories: products with nicotine, products with tobacco extract and product containing neither nicotine nor tobacco extracts. The famhp is the authority competent for the category with nicotine: products which are currently only permitted after obtaining a MA as medicine in Belgium. The other categories falls under the authority of the Belgian Federal Public Services for Public Health and for Economy.

Due to the ever increasing success of electronic smoking materials, their diversity and the ban on their commercialisation, talks have been initiated with the three competent authorities. An action plan has been drawn up for the controls on the market and warnings regarding the lack of guarantees and potential risks published on the website.

Many products are sold through illegal websites or end up in shops without the required authorisations. They come from many different parts of the world and vary widely in terms of quality. Smoking materials with nicotine may be hazardous due to the real risk of overdose. An oral dose of 10 mg of nicotine in children or 30-50 mg in adults can be lethal. Nevertheless, 20 mg refills are quite common.

With the warnings, we hope to draw attention to the potential danger due to the lack of guarantees. Regulations on medicines are applicable specifically to products with nicotine and products that feature therapeutic indications. In order to bring the product onto the market, its quality, safety and efficacy must be demonstrated. The sale and marketing of devices of this kind are prohibited in Belgium.
The Bioplatform is an initiative of the Belgian government that brings together representatives of the innovative industry and the government.

A working group with representatives from the strategic entities of the various Deputy Prime Ministers and the Budget Minister, the relevant sector and the famhp worked on measures to support clinical trials and to further expand the effectiveness of the famhp.

Priority was given to various projects approved in order to at least maintain and preferably further reinforce Belgium’s position in conducting clinical trials, with measures such as:

- Meeting the statutory deadlines (as short as possible), which in turn has a positive impact on the expansion of the EARLY PHASE DEVELOPMENT spearhead.
- Reinforce the specific expertise within the famhp.
- Redefine the Evaluation commission for medicines for human use, which will also play a role in the evaluation of clinical trials.
- Optimise the collaboration between the famhp and the Ethics Committees (ECs).

Another priority is to set up a national platform to facilitate recruitment of patients for participation in clinical trials.

The regulation on hospital exemptions for Advanced Therapy Medicinal Products (ATMPs) is currently in the preparation phase so that talks with the relevant sectors can start as soon as possible.

The regulation was also revised for faster access to innovation for Unmet Medical Needs (UMN). This new concept, which requires closer co-operation between the agency and the RIZIV-INAMI, must enable faster provision, to patients, of medicines for which alternative medicines do not currently exist. The famhp and the new Evaluation commission for medicines for human use will release a statement on the risk/benefit analysis in consultation with a recognised EC. If the outcome is positive, then an early reimbursement of the RIZIV-INAMI can be submitted by the applicant.

In 2013, the first cycle of the Global Training Plan (GTP) for the famhp was completed. For each of the five entities, a GTP was implemented, including follow-up on both the budgetary aspects and harmonisation in the development circles within the entity. A cross-disciplinary GTP was also developed with the external and internal training courses available to famhp employees. These are training courses on technical/regulatory and scientific topics, and on more general topics, including management and personal development. The internal cross-disciplinary training courses offer more added value because employees from various entities can share their core competencies with one another, which can only benefit circulation of information within the organisation.

Every quarter, the Executive Council receives an updated summary of the number of training courses taken and the budget expended. Based on this, the budgetary allocation key was optimised for the 2014 GTP and a set of cross-disciplinary training courses were approved. All training courses are maintained in a centralised database. This provides an accurate picture, at all times, of the current state of affairs with regard to their completion progress and budget expended.

The second cycle of the GTP reinforces the link between the development circles and GTP. The training courses are associated with performance or development targets for each employee, enabling systematic evaluation, by means of evaluation interviews, of the Return On Investment (ROI) from the training courses taken.
A NEW STRUCTURE FOR THE MEDICINAL PRODUCTS FOR VETERINARY USE DIVISION

In early 2013, a new custom-tailored structure was applied to the Medicinal Products for Veterinary Use Division. This should result in:

- coherent monitoring of files for products with the same active ingredients;
- addressing the sharp increase in the number of applications;
- evolution along with the increasing shift in files to the European level, such as through work-sharing procedures and transfers to Mutual Recognition Procedures (MRPs) after a referral;
- further reinforcement of the international representation of the famhp;
- better anticipation of new European developments.

Whereas in the past, the linguistic register of the MAH and the procedure type were determining factors in the allocation of the case file to a file manager, the new structure puts all files for all products with the same active ingredients under the responsibility of the same co-ordinator.

In addition to this, two entities have also been created within the division: the first one processes all case files on vaccines or antiparasitic medicines and the second one all case files on pharmaceuticals, with the exception of antiparasitics. Together, the two groups handle roughly 50% of the files submitted on an annual basis.

An employee has also been appointed as a staff assistant to the division head. This staff assistant is responsible for:

- Representing the famhp in the international working groups falling under the Medicinal Products for Veterinary Use Division, such as:
  - the Co-ordination Group for Mutual Recognition and Decentralised Procedures, veterinary (CMDv),
  - the Notice to Applicants (NtA) that helps the European Commission maximise harmonisation of the approaches in the various member States in the drafting of directives to support legislation on medicines,
  - the Standing Committee which is a permanent committee that assists the European Commission in adjusting directives to technology advances, for removal of technical barriers to trade in the sector for medicinal products for veterinary use,
- Co-ordination of some key projects, such as implementation of a quality system.
A NEW STRUCTURE FOR THE HOMEOPATHIC & HERBAL MEDICINES UNIT

In 2013, the Homeopathic & Herbal Medicines Unit underwent a thorough analysis of its functioning to improve performance of core processes, resulting in the introduction of a new structure. For this, the acting head of the unit drew up an inventory of the existing processes, pending case files and procedures used. After this, a thorough analysis was conducted, first on the files for homeopathic medicines and then on those for herbal medicines.

At the same time, a foundation was laid to start reporting on compliance with statutory deadlines and time allocated to both file-related and non-file-related tasks in 2014. An analysis of the costs of each process was prepared and compared to the sums of the fees in order to evaluate the cost effectiveness of the functioning of the unit.

Homeopathy

Timely processing of applications for registration and marketing authorisation for homeopathic medicines was indicated as the ultimate goal for which the following improvement projects were launched:

- discussion with the sector to arrive at a phased prioritisation of case file management by means of the HoMP DB project, followed by a system of bilateral meetings;
- the HoMP DB project, which was completed back in 2013 and cleared up 41% of the case file processing backlog;
- the revised Gentlemen’s Agreement project, focusing on topics such as the conditions for publication of registered medicines and a modified structure for product information;
- a project on the application at the national level of current European projects such as First Safe Dilution and Justification of Homeopathic Use;
- examination of the efficiency of the functioning of a partnership with the Evaluation commission for homeopathic medicines for human and veterinary use (HCG-HCM);
- revision of the database for registered homeopathic medicines, which should be operational in 2014.

Herbal medicines

A study was conducted on optimising the processing of files for herbal medicines, taking into account the fact that the majority of the applications was submitted using the national procedure. In this case, the improvement projects for this application type will also be harmonised with the general approach selected by the famhp for the national procedures. Options were also examined for taking on a more active role in European marketing authorisation and registration procedures. Moreover, an examination was also initiated on the efficiency of the functioning of the partnership with the Evaluation commission for traditional herbal medicines for human use (CKG-CMP).

RECOGNITION OF THE ETHICS COMMITTEES RELATED TO EXPERIMENTS

The Belgian Act of 7 May 2004 on experiments on human persons, or the Belgian Experiments Act, has served as the regulatory framework for conducting experiments in Belgium since 2004. An experiment is defined as any study on humans that is conducted to expand medical knowledge. Within the regulatory framework, the ECs play a major role because they must issue a favourable opinion for all experiments. An additional application to the famhp is only required in cases of clinical trials (experiments with medicines), or certain types of research on medical devices.

In 2013, based on experience with Belgian Experiments Act, several amendments were made which have an impact on the functioning of the ECs, especially those issuing the final opinion for an experiment:

- the recognition conditions for fully recognised ECs were refined;
- in order to ensure better concordance with internationally developed principles and guidelines, ECs must use a quality system;
- stricter requirements were imposed to guarantee the independent and transparent functioning of the ECs. Thus, for instance, the ECs must provide closer oversight for potential conflicts of interests and must also examine whether the competences and expertise of the members are adequate to assess particular experiments.
Because experience is the basis for quality in functioning, the minimum number of case files processed by a leading EC was increased. The recognition procedure was further formalised, introducing a requirement to conduct an audit at least once every four years.

General requirements also apply, such as:
- minimum formal justification requirement for the opinions This will be further elaborated in a Belgian Royal Decree (RD);
- participation in the discussion organised by the famhp for fully recognised ECs on topics within the framework of this law;
- required use of the interactive website of this agency for interventional clinical trials.

All of these changes are geared towards ensuring that approval of clinical trials is handled in a high-quality, independent and scientifically rigorous manner and also towards making optimal use of the available expertise to continue to guarantee the safety of participants and the correctness and reliability of the findings produced by these clinical trials.

**LEAN ACADEMY, THE FAMHP TOOK PART AS WELL**

The lean philosophy focuses on the customer and identification of waste in a process. As soon as waste is detected, it can be analysed and solutions can be proposed, which must result in a streamlined and simplified process. The process analysis is based on mapping out process costs and lead times, thus providing quantitative and objective starting data on which the process analysis can be based.

Within the framework of the Lean Academy, the Federal Public Service (FPS) Personnel & Organisation (P&O) started a training programme to improve performance in the areas of productivity, quality, lead times and costs. The famhp took active part in this:
- DG PRE authorisation in the Optimad project;
- DG POST authorisation in the Optimedi project.

**The Optimad project**

The objective of the Optimad project is to use lean philosophy to rationalise and optimise the decision-taking chain for the application process for an initial MA. The first MA application within the framework of the National Procedure (NP), the Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP) for medicines for human use was analysed.

This exercise consisted of actions such as:
- perform an activity-based costing exercise for calculation of the indirect costs of products and services;
- streamline the activities across the various MA procedures. NP, MRP and DCP;
- simplify the process validating the advice of the Evaluation commission for medicines for human use. The future redefinition of this commission was taken into account here.

In the interests of optimal compliance with the statutory timeframes, a pilot project was launched in the Marketing Authorisation (human) Division intended to facilitate close information exchange between the file manager and the manager responsible for the conclusion process, thus optimising lead times for conclusion.

The initial findings within the framework of this project will be submitted to the Executive Council in early 2014, along with an action plan.

**The Optimedi project**

The objective of Optimedi is to optimise management of incidents with medical devices. This is essential, given the increase in the number of reports to the Materiovigilance Entity. Project goals:
- systematically provide quality-related feedback to submitting parties and implement a system that enables tracing of high-risk incidents and adaptation of the processing to the risk;
- boost effectiveness of efforts in the area of quantity by avoiding time losses and simplification of procedures.
The exercise primarily focused on:
- analysis of the process by identification of the various stakeholders, the data exchanged between the stakeholders and the famhp, the available instruments such as turtle diagrams;
- evaluation of the necessary means, both in terms of time and money, throughout the entire process or application of activity-based costing;
- an analysis of the movements within the locations of the Materiovigilance Entity based on a spaghetti diagram and of work methodology based on a movement diagram;
- measurement of the activities containing added value based on a value stream analysis.

At the end of this exercise, various improvement projects were identified and their costs and benefits (qualitative and quantitative) evaluated. A number of projects are already underway. The exercise also enabled us to draft the necessary procedures and allocate each task to the right employee.

**DG PRE AUTHORIZATION ACTIVELY JOINS IN THE CESP PROJECT OF THE HMA**

On 29 October 2012, the improved Common European Submission Platform (CESP) came into force. The CESP is an electronic platform under the direction of the network of the European Heads of Medicines Agencies (HMA), which was developed by several European member States and industry representatives. This platform enables electronic submission of MA applications for medicinal products for human use and variations via NP, MRP and DCP. After a basic implementation or Proof of Concept (POC) and an extended POC, CESP went into a pre-production phase on 29 October 2012. In the initial phase, the famhp only accepted new MA applications for medicinal products for human use. The experience garnered in the meantime has taught us that submission of files in the CESP is faster, more secure and easier.

In 2013, the famhp began a pilot phase in direct consultation with the relevant partners. The area of application for the CESP in Belgium was expanded, and since 1 July 2013, in addition to MA applications for medicinal products for human use, the famhp has also been accepting applications for medicinal products for veterinary use, and more types of variations.

The famhp has set up the following internally:
- automatic distribution or dispatching of the applications submitted via CESP to the competent authority;
- a system for detecting incorrect submissions and duplicates;
- automated reporting.

The results of the first pilot phase were discussed in the special working group with famhp staff and representatives from the industry. It is clear that the industry wants to continue working with CESP but at the same time does not want to close other submission channels. For this reason, the famhp decided to continue the pilot phase into 2014 as well.

In the meantime, the famhp is also working in close collaboration with its colleagues at the Irish authority competent for medicines involved in the CESP application.

Thanks to continuous discussions, the famhp has succeeded in actively monitoring the changes to the CESP platform to avoid delays in automatic internal dispatch of CESP e-mails. This way, the famhp continues to be able to dispatch the case files submitted via CESP in a professional and efficient manner across the various internal divisions and units.

Proactive action has been taken to address a new version of the CESP application, by allocating the dedicated internal IT team.

In 2014, the famhp hopes to continue to efficiently process CESP submissions and looks forward to remaining in direct contact with the industry to further discuss technical matters in an open dialogue through the working group.
JOINT CVMP/CHMP AD-HOC EXPERT GROUP IN APPLICATION OF THE 3RS

In line with European Directive 2010/63/EU, the EMA wants to commit to Replacement, Reduction and Refinement (the 3Rs) of animal trials for the development of medicines, with initiatives such as the creation of the ad-hoc expert working group affiliated with the CVMP and the CHMP or the Joint Committee for Medicinal Products for Veterinary Use (CVMP)/Committee for Medicinal Products for Human use (CHMP) Ad-hoc Expert Group (the JEG 3Rs).

This group is responsible for:

• improvement and promotion of the use of the 3Rs in regulated trials throughout the entire life cycle of a medicinal product;
• provision of advice and recommendations to the EMA committees on the use of animals in regulated trials with medicinal products.

The JEG 3Rs serves both the CVMP and the CHMP, given that the 3Rs issue applies to both the development of medicinal products for human and the development of medicinal products for veterinary use.

The JEG 3Rs is comprised of one or two experts from each of the relevant CVMP and CHMP working groups, one representative of the CVMP, independent 3Rs experts and observers from the European Centre for the Validation of Alternative Methods (ECVAM) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) (Council of Europe).

The co-ordinator of the Non-Clinical Evaluator Entity of the famhp and member of the SWP of the EMA, Sonja Beken, was appointed chair of the JEG 3Rs. Sonja has many years of experience in the area of the 3Rs, first in academia within the framework of her doctorate in pharmaceutical sciences, later as part of the scientific staff of the Belgian Platform for Alternative Methods for Animal Testing and finally as a non-clinical evaluator at the famhp. As an expert, she sits on various relevant committees such as the Scientific Advisory Committee (ESAC) of the ECVAM (2003-2009), the Ethics Committee of the Belgian FPS Public Health and the European Partnership for Alternative Approaches to Animal Testing (EPAA) and she regularly gives talks at international working groups and conferences.

Although a great deal of progress has been made in the implementation of the 3Rs in regulated animal trials for medicinal products, it is currently still the case that some data can only be obtained by means of animal testing. These trials must be selected and conducted in strict compliance with the principles of the 3Rs.

The duties of the JEG 3Rs encompass four main areas:

• identify the options for implementation of the 3Rs in regulated trials with medicinal products for human and veterinary use by revising current European and international directives and by developing a directive for approval of 3R test methods or test strategies;
• implement the 3Rs in batch release tests of vaccines and biologic medicines;
• contribute to the implementation of Directive 2010/63/EU via the EMA co-ordinating body of the Preliminary Assessment of Regulatory Relevance of new alternative methods (PARERE) network;
• communicate with the EMA partners and external partners.

The mandate of the JEG 3Rs will last for a period of 24 months. Based on the results achieved over the first two years, the Management Board of the EMA decided during its meeting in March of 2013 to renew the mandate of the JEG 3Rs.
JOINT SCIENTIFIC/HTA ADVICE

Recent developments in the pharmaceutical sector in the EU clearly demonstrate the increasing importance of the Health Technology Assessment (HTA) or multidisciplinary research, which evaluates various aspects of a healthcare intervention. HTA is applied in the clinical development and in the approval and commercialisation of new and innovative medicines and therapies. This development is due in part to increased pressure on healthcare budgets and the rising interest in personalised medicines, which are associated with high development costs, especially in therapeutic domains with a high medical need.

In Belgium, the RIZIV-INAMI determines the conditions and evaluates the applications for reimbursement for medicines and other interventions in the Belgian healthcare system. The RIZIV-INAMI is also the authority competent for HTA. The famhp recently began collaborating with the RIZIV-INAMI to issue common scientific/technical advice (STA) and HTA advice.

While the competent authorities for medicines of the European member States evaluate the risk/benefit analysis of new medicines, the authorities competent for HTA compare the relative efficacy of the medicine after granting of the MA in order to evaluate the benefits and generally also the cost for the national healthcare system. Proper and timely interaction between the competent authorities for medicines and the authorities competent for HTA is therefore crucial in order to stimulate innovation and facilitate access to new medicines to the greatest extent possible, in the interests of the patient and the healthcare system. After all, it has occurred all too often in the past that after years of clinical development, and despite the STA and the required MA, new medicines still failed to meet additional requirements from the authorities competent for HTA.

The famhp acknowledges this issue and is convinced of the importance of early dialogue with medicine developers, along with the RIZIV-INAMI. In addition to faster access to new medicines, co-operation of this kind can also provide a considerable reduction in development costs for sponsors.

Analogously to the pilot project that the EMA started in 2010 in collaboration with various authorities competent for HTA in the EU, the famhp, along with the RIZIV-INAMI, took the initiative to offer developers of medicines the option to apply for joint WTA/HTA advice. Both competent authorities provide, in line with their competencies, concurrent advice to the applicant on various facets of their research and development such as, clinical endpoints, study design, selection of comparator, therapeutic value of the product and UMN. In a pilot phase, two joint WTA/HTA advice documents were issued at the national level, both for oncological indications. At the European level, the Belgian SAWP members have already co-ordinated several concurrent SAWP/HTA advice cases.

In 2014, the famhp plans to further build its expertise on joint WTA/HTA at the European and national levels and further expand this service at the national level.

REQUIRED ELECTRONIC SUBMISSION OF FILES FOR MEDICINAL PRODUCTS FOR VETERINARY USE AND IMPLEMENTATION OF AN ELECTRONIC SYSTEM FOR DOCUMENT MANAGEMENT IN THE MEDICINES FOR VETERINARY USE DIVISION

On 1 January 2013, electronic file submission became required for medicinal products for veterinary use. This made Belgium one of the first European member States to impose electronic file submission for procedures before and after granting of a MA for medicinal products for veterinary use.

Electronic submission offers numerous benefits, both for the famhp and for applicants. It is easy to verify conformity of the file with the set requirements for electronic submission using a publicly available software program: the VNeEs Checker. This saves the famhp on physical storage space and also enables quicker and easier retrieval and viewing of archived files. Applicants save on shipping costs and can use the CESP to submit multiple files to different member States at the same time.

In early 2013, in order to facilitate the switch to electronic submission, the famhp organised a workshop with the industry on the electronic file submission.
On a regular basis, discussions were held with representatives of the pharmaceutical industry to monitor the quality of electronic files, discuss problems and gradually increase quality requirements. In late 2013, over 98% of the files submitted electronically met the required format.

The Medicines for Veterinary Use Division started MeSeA Vet in Filenet on 1 January 2013. This documentation management system enables efficient management of files submitted electronically for procedures before and after granting of a MA for veterinary use. The implementation of the new document management system was coupled with a modification of the existing procedures. The transition from DOS-based software to MeSeA Vet in Filenet had a negative impact on division performance in the first quarter of 2013.

The successful implementation of the new document management system and the required electronic submission of files have prepared the Medicines for Veterinary Use Division for the electronic age.

**REVISION OF THE REGULATION ON VARIATIONS**

On 4 August 2013, EC Regulation 1234/2008, concerning the examination of variations to the terms of MAs for medicinal products for human and veterinary use, also became applicable to medicinal products approved by means of the pure NP or pure national MA. The impact of this on the Belgian purely national MA did in fact remain limited because the famhp started applying the provisions of this Regulation to these procedures back in 2010.

In early August 2013 however, the work-sharing procedure also became accessible for the pure NP, and it became possible to submit identical variations for different pure NPs together in a single grouped file.

**NEW PHARMACOVIGILANCE REGULATION**

In July 2012, the introduction of Directive 2010/84/EU and Regulation (EU) 1235/2010 marked a major change in the European regulatory framework for pharmacovigilance.

The transposition of the aforementioned Directive into Belgian regulation began in 2012 with the Belgian Act of 3 August 2012 amending the Belgian Act of 25 March 1964 on medicinal products. This transposition was completed in 2013 with the implementing decree or the Belgian RD of 28 May 2013 amending the Belgian RD of 14 December 2006 on medicinal products for human and veterinary use.

These new regulations are bringing numerous changes, such as in the areas of:

- the requirements for individual reporting of adverse reactions, or Individual Case Safety Reports (ICSRs);
- the contents and the submission cycle for the Periodic Safety Update Reports (PSURs);
- the five-yearly renewal;
- the Post-Authorisation Safety Studies (PASS) and the Post-Authorisation Efficacy Studies (PAES), for which a regulatory framework now exists as well;
- the revisions of the risk management plan.

The famhp published a circular with all amendments as well as the transitional provisions on website in July of 2013.
The new regulations also stipulate that some medicinal products will henceforth be subject to additional oversight at the European level. These medicines are identified by an upside-down black triangle ▼, for which they are known as Black triangle drugs on the package information leaflet and SPC, and in the Annotated Directory of Medicines of the Belgian Centre for Pharmacotherapeutic Information (BCFI, a non-profit organisation). The medicines subject to this additional oversight are:

- medicines containing a new active ingredient that was not authorised for use in the EU until 1 January 2011 or later;
- biologic medicines for which only a limited amount of experience is available since their commercialisation;
- medicines under a conditional MA or for which additional trials were requested of the MAH.

Other medicines may also be designated with an upside-down black triangle after a decision of the PRAC of the EMA. The list of affected medicines is available on the famhp website.

The famhp has also published two circulars with information on the main changes for local authorities in the area of pharmacovigilance, for medicinal products for both human and veterinary use.

**INTRODUCTION OF A QUALITY SYSTEM FOR PHARMACOVIGILANCE AND AUDITING OF PHARMACOVIGILANCE ACTIVITIES**

For the Vigilance Division (pharmaco, materio, haemo, bio), 2013 was an amply busy year with regard to the quality care system or Total Quality Management (TQM), including:

- subdivision of tasks into core processes and drafting of process cards;
- identification, drafting and approval of the necessary written standard procedures or Standard Operating Procedures (SOPs) and Working Instructions (WIs);
- organisation of the cycle for internal audits for 2013 by the famhp Quality Division;
- monitoring and implementation of the Corrective Actions & Preventive Actions (CAPA) plan of the second European Benchmark audit (BEMA) and of the internal audits;
- the first internal audit of the quality system for pharmacovigilance.

Article 101 of Directive 2001/83/EC requires European member States to conduct an audit of their quality systems for pharmacovigilance once every two years and to report to the European Commission on this before 21 September 2013. For this reason, the Vigilance Division has pulled out all the stops to expand its pharmacovigilance system for medicinal products for human use, with processes and activities implemented in accordance with statutory requirements and based on the EMA’s Good pharmacovigilance practices (GVPs). Procedures were also drafted to describe the various processes of the quality system for pharmacovigilance for medicinal products for human use with a view to:

- evaluation of the quality and completeness of the data submitted on pharmacovigilance;
- evaluation of the data on pharmacovigilance and their processing within the statutory timeframes;
- ensuring the necessary degree of independence in the performance of pharmacovigilance activities;
- effective communication with MAH, healthcare professionals, patients and the general public.

In order to meet the requirements imposed by the EMA and the member States themselves with regard to auditing competency, scientific knowledge and independence/impartiality, the famhp and the Belgian Scientific Institute for the Public Health (WIV-ISP) agreed to conduct the audit within the Human PhV/File Management/ADR Entity of the Vigilance Division. Given that this was the first audit for this entity and a new domain for the auditors, it was decided, for the performance of the audit itself, to conduct a general evaluation of the quality system for pharmacovigilance, go over all of its components and then conduct more targeted audits on specific components of the system in the form of follow-up audits according to the findings of the first audit. Specifically, a pre-audit was scheduled for 26 March 2013, followed by a full audit on 11 and 12 June 2013. The objective of this audit was to go over all
domains of the quality system for pharmacovigilance for medicines for human use and evaluate the conformity of all documents and activities of the Human PhV/File Management/ADR Entity with the GVPs.

The conclusions of the audit of June 2013 brought to light some strong points and some points for improvement:

**Strong points:**
- the Human PhV/File Management/ADR Entity introduced a quality system based on the GVP guidelines and on the existing procedures within the famhp;
- most processes required by the GVP guidelines are being performed and the regulations on these are being followed properly;
- the general development of the quality system within the famhp is an asset that has had a positive impact on all divisions in the famhp;
- the manager of the Vigilance Division is very concerned about the development of the quality system and is making great efforts in this area;
- a schedule has been prepared for drafting the procedures required under the GVP guidelines;
- a CAPA plan was already drawn up due to the minor non-conformities.

**For improvement:**
- SOPs do not yet exist for all processes required by the GVP guidelines;
- some processes outside of the framework of the GVP guidelines have not yet been developed and still need to be incorporated into the quality system.

The CAPA plan of the audit of June 2013 was co-ordinated by the Vigilance Division. The Vigilance, ICT, P&O and Quality Divisions were involved in the corrective actions. The plan is managed by the Quality Division to guarantee follow-up and proper execution of the corrective actions.

**NEW PROCEDURE FOR APPROVAL OF ADDITIONAL RISK MITIGATION ACTIVITIES**

Some medicines receive a MA on the condition that the companies in question introduce Risk Minimisation Activities (RMAs). These may involve development of educational and information materials and programmes and services for healthcare professionals and patients on proper use of these medicines.

Before they are introduced, these RMAs must be approved by the Minister or the delegate, in this case the CEO of the famhp.

The Belgian RD of 28 May 2013, which inserted a new Article 65 quarter into the Belgian RD of 14 December 2006 on medicinal products for human and veterinary use, details a new approval procedure that specifies the contents of the RMA files and strict timeframes.

Circular 603, published on the famhp website in September of 2013, clarifies some practical aspects of the new approval procedure and repeats some guidelines on the presentation and contents of the RMA files.

The list of medicines for which RMAs have been approved is published on the famhp site.

An RMA logo has been developed and must be indicated on all RMA materials so healthcare professionals can easily distinguish these from other information and the required attention can be given to guarantee proper use of the medicine and patient safety.

**PATIENT REPORTS: 1 YEAR OF EXPERIENCE**

Since the launch of the patient reporting point in September 2012, the famhp has received 142 reports of suspected adverse reactions from patients.

Patients can report an adverse reaction by submitting the standard form by post or e-mail to the Vigilance Division (pharmaco, materio, haemo, bio). A paper version can be requested from this division or downloaded from the famhp website. After submitting their report, patients receive a brochure explaining how their report will be processed.
If we compare the direct reports to the famhp in 2013, we see that 17% are reports from patients and 83% are reports from healthcare professionals. The report types differ amongst these two groups. Patients report relatively less serious adverse reactions and with a different medicine profile. They report on older, commonly used medicines, whereas healthcare professionals focus more on new medicines. Thus, reports from patients offer an interesting complement to reports from healthcare professionals.

There was a clear increase in the number of patient reports during and after a period in which several files for particular medicines received a great deal of media attention, such as Combined Oral Contraceptives (COCs) and domperidone. Often, these pertained to adverse reactions that had occurred several months or even years in the past.

Almost 80% of patient reports used the standard form, which produced a detectable improvement in quality.
INFORMATION CAMPAIGN ON MEDICINES AND CHILDREN: “MEDICINES AND CHILDREN. CAREFUL! MEDICINES ARE NOT SWEETS!”

Along the same lines as the 2011 campaign “Medicines are not sweets!”, on 29 April 2013, with the support of the Deputy Prime Minister and Minister of Public Health, Mrs Laurette Onkelinx, the famhp launched a new awareness campaign for the general public on the proper use of medicines amongst children: “Medicines and children. Careful! Medicines are not sweets.”

Children often experience harmless complaints which may come in combination with symptoms like fever, cough, nasal congestion or indigestion. Unless the symptoms are cause for concern, medicines are generally not necessary.

With this new campaign, the famhp reminded the public that medicines are not sweets. A medicine may be ineffective, unsuitable or even dangerous —especially to children— if used incorrectly, without consulting a medical doctor or retail pharmacist, or contrary to the instructions in the package information leaflet. After all, compared to adults, children react differently medicines, and also excrete them differently. The risk of overdose or intoxication is real. Therefore, it is crucial to be cautious and mindful in the administration of medicines to children, for both medical prescription and OTC medicines.

Three brochures on these topics have been made available for viewing and download at: www.geneesmiddelenenkinderen.be www.medicamentsetenfants.be.

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Brochures as well as a poster refer to the mini-site www.geneesmiddelenenkinderen.be - www.medicamentsetenfants.be, which the public can visit for recommendations and practical tips for proper use of medicines for children.

The famhp plays as essential role in the protection of Public Health by overseeing the quality, safety and efficacy of medicines and health products in clinical development and on the market. To fulfil this mission, the famhp strives to bring information on medicines and health products to patients as completely and accessibly as possible to ensure rational and safe use. It is within this framework that the famhp launched the campaign: “Medicines and children. Careful! Medicines are not sweets!”.

Het fagg geeft je enkele tips om je te helpen bij een goed gebruik van geneesmiddelen bij kinderen. Raadpleeg de website www.geneesmiddelenenkinderen.be of de brochures beschikbaar bij je arts of apotheker.
EXTRA PLUS REVISED DATABASE

Extra Plus Revised, abbreviated E+R, is the new medicine database of the famhp which went live in late 2013. This database contains all medicinal products for human and veterinary use that have been approved in Belgium, as well as all medicinal products approved in the past whose MAs have been cancelled.

The database contains both the officially approved data for each medicine and additional relevant information. European or other standard terms are used to the greatest extent possible. E+R offers an additional asset: it can keep track of the packaging sizes of a medicinal product. Each packaging size is assigned a unique ID number which does not change over the life cycle of the medicine. This makes it possible to maintain the history of every packaging size, which offers benefits such as better insight into commercialisation and any temporary supply problems for the medicinal product.

E+R is a web application developed with Java Technology. The data are used for various internal and external applications, such as publication on the website of the database for the approved medicinal products, the waiting times for medicinal products for veterinary use, the list of medicinal products for which a temporary supply problem has been reported and the package leaflets and Summaries of Product Characteristics (SPCs) of medicinal products commercialised in Belgium. The database also makes it possible to exchange data with other public services or institutions. At the same time, attention was given to new, future projects based on the data from E+R.

MEDICAL DEVICES PLAN

General information

In the interests of public health, the famhp launched several improvement projects in late 2012 within the area of medical devices. Following the international scandal of the fraudulent PIP breast implants, the Medical Devices Plan (PMH-PDM) was drawn up. This plan was built around eight main lines.

The plan had a dual objective:
• improve the quality, safety and efficacy of medical devices;
• remove products from the market that do not meet the minimum requirements for commercialisation.

The PMH-PDM was launched in September 2012, and the first major steps were taken over the course of 2013.

PMH-PDM: the first phase of the implementation

2013 was clearly the year of the PMH-PDM. Numerous discussions were organised at set times with a variety of players in the field, the relevant business community, the competent authorities, patients’ associations and healthcare professionals. These discussions made it possible to identify the different parts of the PMH-PDM. This involved, for instance, the implementation of a system for traceability of implantable medical devices, the improvement of procedures for management of incidents and the reinforcement of control activities. This latter aspect translates into an increased presence in the field, as well as new procedures.

Topic cards and other information

Another key part of the PMH-PDM is the transparency, which is primarily provided by means of communication activities on particular medical devices specifically targeted to patients. Topic cards were drawn up with general information on medical devices and more specifically on certain types of medical devices such as hip replacements, dental prostheses and breast implants, to provide patients with better guidance through the broad field of medical devices.

Further development of the rules on medical devices at the European and national levels

2013 was also very much about the intention to revise the regulation on medical devices at the European level. The famhp experts were asked to work out a proposal along with their colleagues from the other European member States. The revision at the European level is perfectly in line
with the Belgian objectives of improving the quality, safety and efficacy of medical devices, as well as oversight in this field. The proposal for the new European regulation states that devices without an immediate medical purpose, such as cosmetic implants, are still required to meet the same requirements as medical devices.

At the national level, and as a foundation for implementation of the PMH-PDM, the new regulation came into force in December 2013. The Medical Devices law provides for harsher penalties for offenders, a more effective follow-up system for contributions and the legal basis for introduction of a traceability system for implants.

Transfer of the competences for medical devices from the FPS Economy to the famhp

In the past, the various medical devices were divided up into three categories under the competences of three different authorities:

- the famhp for the class-I medical devices;
- the Directorates-General for Energy, Quality & Safety and Inspection & Arbitration under the FPS Economy for class-II medical devices;
- the Belgian Federal Agency for Nuclear Control for class-III medical devices.

Based on the new Belgian RDs of 12 July 2013 amending the Belgian RD of 18 March 1999 on medical devices and the Belgian RD of 14 November 2001 on medical devices for in-vitro diagnostics, the famhp was also granted competence over medical devices formerly regarded as class II, but now grouped under class I. These are:

- the active medical devices, electrically, mechanically and magnetically;
- the equipment with a measurement function;
- non-invasive devices for collection of bodily fluids, without return flow, for immobilisation or for exertion of pressure/force on the body or parts thereof, such as traction equipment, elastic support stockings, neck braces; for supporting patients, such as hospital beds, wheelchairs and patient lifting equipment;
- devices for all manner of purposes, such as lenses for eyeglasses, stethoscopes and non-invasive electrodes;
- invasive medical devices, such as contact lenses and hand mirrors;
- reusable surgically invasive devices;
- optical, orthopaedic and auditory devices, and corresponding custom-tailored devices;
- contact lens solutions.

Given the potential impact of these products on patients, it was vital to transfer these competencies to the famhp in order to provide distributors with maximum support in meeting their responsibilities in the protection of Public Health. Transitional measures have been provided for registration, contributions, certifications, inspections and materiovigilance for the players and companies who now fall under the new regulation, up until 1 August 2014.

Training for the internal staff

The medical devices sector is very broad, due to their use in numerous subfields of medicine. Moreover, they can also be examined from several perspectives, such as technical, medical or legal. In light of all of these special factors, it is necessary to train new employees and retain the existing level of knowledge in the agency. In 2013, the relevant employees took special training courses, both internally and externally.

In connection with the internal training, seven information sessions were organised. For 2013, first and foremost, the general training courses were scheduled, with attention to the role of notified bodies, clinical trials before medical devices enter the market and materiovigilance. Later, four technical training sessions were given by a professor of biomedical science, focusing primarily on topics such as biocompatibility, polymers, and the mechanical properties of medical devices. A number of colleagues also took external training courses organised by professional associations or by the European Commission.

The medical device sector is constantly developing and numerous legal changes are in the works, at both the Belgian and European levels. We are also seeing an ever increasing number of products that combine medical devices and medicines or human body tissues. Because ongoing education is required for the staff, a medical devices training plan has been developed for 2014 to meet the educational needs of the agency staff.
Testimonials from employees for the management of scientific files and for distribution inspectors at their recruitment to reinforce the DG for INSPECTION in the implementation of the PMH-PDM

Next steps

After the unavoidable consultation phase and implementation of the initial parts of the PMH-PDM, it is abundantly clear that the famhp intends to move forward with this project. The agenda for 2014 includes the pilot project for the system for traceability of implants in co-operation with a number of hospitals, creation and dissemination of topic-specific cards, and further implementation of new inspection methods.

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<th>What would you like to accomplish professionally in 2014?</th>
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</thead>
<tbody>
<tr>
<td>Everything is based on the regulation on medical devices.</td>
<td>Stay well informed to build expertise.</td>
</tr>
<tr>
<td>It’s an interesting domain, with a lot of variety, so I still have a lot left to learn. Given that the famhp has only existed in its current form for six years and is developing new domains, especially in the area of medical devices, there is plenty of room for initiative.</td>
<td>Immerse myself and build expertise in the area of inspection of the medical devices assigned to me.</td>
</tr>
<tr>
<td>Many inspections in different areas with a variety of players in the field.</td>
<td>Inspections in the field, varied and with a variety of target groups, from distributors to hospitals.</td>
</tr>
<tr>
<td>Varied and interesting; Every company is different. It is not routine work. In the area of GMPs, the companies in the medical devices sector vary widely, such as from small to large companies, truss makers, distributors and hospitals.</td>
<td>Continue to inspect the distributors; along with the MEDDEV team, handle the recurring legal issues in the area of distribution, such as the sale of medical devices in parapharmacies and warehouses; training new employees.</td>
</tr>
<tr>
<td>Practical experience has already been gained by conducting various inspections provided for in the training plan. It is very enriching in both the human and professional sphere, which is something I personally appreciate a great deal.</td>
<td>Putting my professional experience into service for the famhp by taking part in the prevailing dynamic, with respect for the precautionary principle and protection of the Public Health in the supply of medical devices.</td>
</tr>
<tr>
<td>Very enriching and varied; from very small to very large distributors, with a wide variation in degree of complexity.</td>
<td>Finalise new types of inspection activities in the areas for inspection, such as for contributions and clinical studies.</td>
</tr>
<tr>
<td>Inspections in highly varied fields.</td>
<td>Topic-specific inspections in the field with verification of different aspects, such as the contributions, the production of class-I medical devices and publicity.</td>
</tr>
</tbody>
</table>
INDIVIDUAL MEDICATION PREPARATION AT THE NATIONAL LEVEL

In 2012, Individual Medication Preparation (IMP) was regulated as a new form of supplying medicines.

In the basic regulation (Art. 12bis, §3 of the Belgian Act of 25.03.1964 on medicinal products), IMPs are defined as the pharmaceutical activity: “in which one or more medicines are removed from their original packaging and then, if necessary, combined into a single closed package for individual administration, intended for an individual patient at a particular time and performed exclusively by persons authorised to dispense medicine to the public”.

The Belgian RD of 24.09.2012 establishing a scheme for individual medicine preparation, describes the conditions under which IMP is permitted.

IMP can take two forms: manual IMP and automated IMP. Both are only permitted under the responsibility of a pharmacist in a retail pharmacy or a hospital pharmacy. Automated IMP is performed by a robot controlled by a software program. For each patient and ingestion time, the medicines are divided up into closed packets fitted with the required indications as per the implementing decree.

IMP, both manual and automated, is currently mainly used to administer medicines in healthcare centres, especially rest-homes.

Pharmacists who want to use automated IMP must register with the famhp in advance.

You can find the following information on the famhp website:

- the forms for registration for the use of automated IMP;
- guidelines on medicines permitted in IMP packets;
- Frequently Asked Questions (FAQ) on this new regulation;
- a list of retail pharmacies and hospital pharmacies registered with the famhp who can perform automated IMP.

A NEW STRUCTURE FOR THE DG INSPECTION

The DG INSPECTION has undergone two reorganisations over the past four years. An initial reorganisation took place in 2012 with the founding of the Authorisations Division in addition to the Industry Division, Dispensing Division and the Special Investigation Unit Division (SOE-USE).

The Industry and Dispensing Divisions are responsible for planning, performance of control and inspection activities and enforcement in the field of standards for production, distribution and supply of medicines and health products. The Authorisations Division processes applications for performance of activities in the legal circuit for medicines and health products and issues authorisations and certificates for this after favourable results on controls and inspections. This new arrangement provided not only better definition of competencies, but also a structure based on the key processes of inspection: input, inspection, output and a more even distribution of employees from the DG INSPECTION across the different divisions.

After being confronted with several fraudulent case files, such as the PIP breast implants, in 2012 the Belgian Minister of Public Health requested substantial reinforcement of the famhp’s capacity to guarantee the quality, safety and efficacy of medical devices. Aside from reinforcement of expertise in evaluation and materiovigilance, the refinement
and reinforcement of controls on medical devices was a very strong signal in the minister’s implementation plan. Whereas in the past, only the distribution of medical devices was controlled, this has been expanded with checks on notified bodies, manufacturing, clinical trials, publicity, hospitals, private clinics and illegal practices. The range of medical devices falling under the competency of the famhp was expanded. Whereas the famhp previously was only competent to oversee sterile and implantable medical devices, this now includes medical devices formerly under the supervisory authority of the FPS Economy, including devices with a measurement function, (mechanically, electrically and/or magnetically) active medical devices and equipment for medical devices for in-vitro diagnostics. Thus, for instance, a unique portal for medical devices was created at the federal level. The DG INSPECTION received the necessary reinforcement to implement the refined and expanded oversight.

Expansion of inspection capacity also required a significant number of additional employees. A thorough examination of the structure of the DG INSPECTION, with support from external consultants, resulted in a complete restructuring. For the number of new employees, it was decided to run the integration phase within the existing divisions, based on process logic for key processes in the domain of the DG INSPECTION, not based on product logic. Given that the majority of the inspection activities in the field of medical devices are co-ordinated from the Industry Division, which has historically grown in this way, this division should undergo extreme growth. For this reason, a decision was taken to set up a Dispensing Division. In order to maintain process logic, as opposed to product logic, this division will not only have competency over the distribution of medical devices, but also medicines.

At the same time, the role of the SOE-USE was highlighted. Especially in light of the main cross-disciplinary activities, the SOE-USE is not simply positioned between the other divisions, but rather in cross-disciplinary manner with respect to other divisions of the DG INSPECTION.

The new structure of the DG INSPECTION will take effect in 2014, with four divisions: Industry Division, Dispensing Division, Authorisations Division, plus the SOE-USE, specialising in combating illegal pharmaceutical practices with medicines and health products.

The role, mission and strategic plan of the DG INSPECTION were developed by the Director-General, who also handles operational management of the DG. The staff of the DG INSPECTION, with the Director-General and the managers of the four divisions and the SOE-USE, a legal expert with special legal expertise in the area of inspection and control activities, the Management Support staff and experts invited to handle specific cases or provide special expertise. Operational management includes implementation of the strategy, performance management, knowledge and quality management, legal support, training, development and networking.

**ACTION PLAN TO ENHANCE THE QUALITY OF PHARMACY MADE AND OFFICINAL PREPARATIONS**

The Pharmacopoeia/API unit of the DG PRE authorisation and the DG INSPECTION laid the foundation in 2012 for an action plan intended to enhance the quality of pharmacy made and officinal preparations.

This action plan includes four parts:
- measures to enhance the quality of raw materials;
- measures to enhance the quality of formulations;
- measures for making preparations;
- analysis of the preparations.

A phased implementation of this action plan was launched in 2013 by means of:
- revision of the regulatory framework. Revision of the Belgian RD of 19 December 1997 on the inspection and analysis of raw materials used by retail pharmacists will be applied in phases. A new decree, phase I, has been drawn up. Its publication is slated for 2014;
- an effective control policy. This policy is necessary in order to ensure the quality of the raw materials used in pharmacy made and officinal preparations as well as the preparations themselves. The standardisation of the content specifications for the preparations included in the Therapeutic Magistral Formulary (TMF-FTM), launched in 2013, will enable uniform analysis and assessment of TMF-FTM preparations;
• online publication of the TMF-FTM. This project was launched in 2013. Online publication is planned for 2014 and should enable fast and effective revision of the formulations and dynamic provision to medical doctors and pharmacists;
• a list of raw materials for restricted use. A scheme for the raw materials for restricted use was incorporated into the new Belgian RD for raw materials, phase I. For a number of raw materials recognised as raw materials for restricted use by the Belgian Pharmacopoeia Commission, a monograph was developed by the competent experts at the Pharmacopoeia Commission.

PHARMACEUTICAL CARE MONITORING

In 2013, the inspectors of the Dispensing Division of the DG INSPECTION conducted a variety of inspections/controls on retail pharmacies, to verify proper provision of pharmaceutical care.

Pharmaceutical care is one of the many requirements imposed on pharmacies in the Belgian RD of 21 January 2009, in the area of Good Officinal Pharmaceutical Practices. All aspects of this decree took effect in 2012.

The handling of the distribution of medicines and health products by the pharmacist was clarified by the expansion with intellectual added value primarily by means of pharmaceutical analysis of the medical prescription or of a patient’s questions or by providing the patient with the information and advice needed to a proper use of medicines, with the aim of providing the patient with efficacy and safety.

Pharmaceutical care encompasses all activities of the pharmacist, as well as all services provided by the pharmacist to the patient, with the aim of enhancing the patient’s quality of life by achieving pharmacotherapeutic goals in the preventative, curative or palliative spheres.

For retail pharmacies, pharmaceutical care consists of two related care levels within an ongoing process: basic pharmaceutical care and continuing pharmaceutical care.

In both cases, the available information is included in a special file: the pharmaceutical file and the file for continuing pharmaceutical care. For both case files, the consent of the patient is required for entry of personal data and/or transfer of data.

The inspections performed found proper monitoring of the case files for basic pharmaceutical care by pharmacists and a promising outlook in the area of monitoring case files for continuing pharmaceutical care.

In 2013, the various pharmacists’ associations also started up an initiative to share these data. Data exchange should provide every individual pharmacist with insight into the overall treatment of a patient, regardless of whether medicines or other products are being purchased at the pharmacy. This helps the pharmacist identify problems related to the treatment of the patient more quickly, such as interactions with other medicines or products, and thus also provide better advice based on relevant and complete information.

REVISION OF THE REGULATORY FRAMEWORK FOR HOSPITAL PHARMACISTS

In 2013, the famhp finalised a bill for a Belgian RD revising the regulation on tasks and responsibilities for hospital pharmacists, in consultation with the relevant professional associations and other relevant public services, including the DG Healthcare Facilities Organisation under the FPS for Public Health and the RIZIV-INAMI.

Due to the evolution of the healthcare system, the availability of new technologies, the customary quality standards and the emphasis on patient safety, it was necessary to amend the regulation on the manner in which medicines, medical devices and food supplements end up with patients, as well as on the monitoring and evaluation of their rational use, for both inpatients and outpatients. This entailed a thorough revision of the regulation on the functioning of hospital pharmacies and the practice of the profession of hospital pharmacist. Up until now, all of this was governed by the Belgian RD of 31 May 1885 giving instructions for pharmacists and by special provisions included in the Belgian RD of 19 October
1978 giving regulation for retail pharmacies and medicinal stocks in healthcare institutions.

The main amendments intended to guarantee optimal care and maximum rationality in the use of medicines, medical devices and food supplements, taking into account cost-effectiveness of the proposed measures, are:

- cultivate clinical pharmacy as a component of pharmaceutical care. This entails that the hospital pharmacist, along with the medical doctor and other healthcare professionals, contributes to the optimisation of therapy and prevention of medicine incidents;
- sterilisation of reusable medical materials was explicitly included as a part of a hospital pharmacy, which allows the hospital pharmacist to take full responsibility over the sterilisation process and quality of the product supplied;
- provision of food supplements is also included amongst the duties of the hospital pharmacist. This ensures that the overall treatment is examined in terms of interactions and risks of adverse reactions;
- increase traceability by:
  - obligatory use of identifiable unit dose packages to enable tracing of the lot or series number all the way to the patient;
  - the same medicine traceability rules also apply to implants, sterile invasive medical devices and food supplements.
This obligatory traceability also makes it possible to organise the purchase, storage and distribution of medicines in a high quality manner within an association of hospital pharmacies. The economies of scale this offers will help reduce investments in guaranteeing traceability. Quality of treatment will continue to be guaranteed by validation of the medical prescription and provision of pharmaceutical care in the hospital pharmacy. The enhanced traceability and required validation of the treatment by the hospital pharmacist will also result in more efficient distribution of medicines, medical devices and food supplements. It is now possible to work with decentralised stocks as part of the hospital pharmacy for regular use in recurring orders, not just for emergency medicines, as is currently the case;
- the supply of medicines and medical devices to patients for administration outside of the hospital has been revised. To guarantee continuity of care, this will be expanded with:
  - medicines for clinical trials;
  - medicines for CU and MNPs;
  - medicines for persons in community living situations;
  - medicines for home care, such as parenteral nutrition and home dialysis.
- the change with the biggest impact came in the area of pharmacy made preparations. Internationally, the international partnership for conducting pharmaceutical inspections or the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme - PIC/s 010-03 has been put forth as the standard. These guidelines detail the method for making pharmacy made preparations in hospital pharmacies, adapted to the working environment, comparable to the Eudralex GMP (the collection of documents with European regulation on medicines, here for GMPs) which are applied by the pharmaceutical industry. This standard is being incorporated into national regulation and further fleshed out, as certain choices must be made in terms of investment. Incorporation of these standards requires major investments, but will considerably improve quality and result in fewer medicine errors thanks to standardisation, use of preparation protocols and quality control within a quality system. The majority of the serious medicine errors in the hospital pharmacy occur during ad-hoc preparations.

In order to make all of this feasible, the manner in which hospital pharmacies can collaborate will be significantly expanded. Thus, for instance, certain hospital pharmacies could dedicate themselves to specialising in a particular type of preparation, or small hospitals could opt not to invest in preparations and instead rely on another hospital. The hospital pharmacists/holders can also set up a special branch outside of their hospitals, known as a compounding centre, where together they can dedicate themselves to special activities for the various hospitals involved. These may be inventory management, unit dose packages and certain
preparations such as radiopharmaceuticals. Of course, every hospital pharmacy must continue to provide validation of prescribed treatments and pharmaceutical care. In smaller hospitals, because a full-time hospital pharmacist who can guarantee these services is not available, it is recommended to rely on the nearest hospital pharmacy for this.

In addition, the draft also takes into account the option of outsourcing pharmacy made preparations, as well as reconstitution of authorised medicines, to a pharmaceutical industry facility that holds a manufacturing licence. This may be an industrial facility that already holds a manufacturing licence, or also specialised compounding centres that would like to dedicate themselves to these activities. This option was provided for in the Belgian Programme Act at the end of 2013. This also set out quality standards adapted to the activity types which are comparable to the Eudralex GMPs applied by the pharmaceutical industry;

- the pharmaceutical case file has become part of the medical file and its storage period has been set to thirty years, the same as for the medical file. Most hospitals are implementing an electronic file system, which means storage and retrievability are no longer issues. The task reform stipulates that the hospital pharmacist can have certain tasks performed by a suitable staff member, other than a pharmaceutical technical assistant. The hospital pharmacist must be able to demonstrate that s/he maintains high-quality supervision over all employees to whom tasks have been entrusted.

This draft entails certain amendments in the regulation on the standards for hospitals, such as transfer of personnel from sterilisation to the hospital pharmacy and the partnerships. These changes were included in the Belgian RD of 4 March 1991 adopting the standards which hospital pharmacies must met in order to be recognised. At the same time, work is also being performed with the relevant working group at the Belgian National Council for Hospital Facilities. The advice of the National Council has been requested.

**ELECTRONIC CIGARETTES**

Electronic smoking materials and especially electronic cigarettes are a rapidly growing phenomenon which regularly took the spotlight in 2013, not only due to their growing popularity but also due to the regulatory framework that was under discussion at the EU level.

Electronic cigarettes are devices that looked like traditional cigarettes a few years ago, but now come in all shapes, sizes and colours. The basic principle is that the device contains a liquid that is vaporised by a heating element and inhaled by the user. The whole unit is supplied with power from a battery and controlled by an electronic circuit. The liquid in question primarily consists of propylene glycol, to which flavourings are added, and often nicotine as well.

Nicotine is one of the addictive chemicals in traditional smoking materials and is also a highly toxic substance. In its pure form, one drop can be enough to produce lethal effects on intake. The electronic cigarette often contains a high dosage of nicotine which is released in smaller doses. This feature has prompted the necessary concern from the competent authorities. Then we also have the question of whether or not the vapour in itself, even if it does not contain nicotine, is harmful over the long term.

Based on the existing regulation in Belgium, electronic cigarettes can be divided up into three categories:
• electronic cigarettes which do not contain nicotine and do not make any therapeutic claims in this case, it is a normal consumer product that falls under the authority of the FPS Economy;
• electronic cigarettes that contain nicotine due to the presence of tobacco extracts and are considered tobacco products in this case, the electronic cigarettes must meet the requirements of tobacco regulations and fall under the authority of the FPS Public Health;
• electronic cigarettes that contain pure nicotine, possibly also augmented with flavourings, or which make therapeutic claims. This category is regarded as medicine because nicotine has a pharmacological effect and must therefore meet pharmaceutical regulation:
  • MA is required before the electronic cigarette can be brought onto the market;
  • distribution is restricted to pharmaceutical wholesalers;
  • supply is only possible through an authorised pharmacy.

In our neighbouring countries as well, electronic smoking materials are a growing phenomenon and the supply has increased sharply in recent years. The internet is home to numerous suppliers, and more and more specialised shops are popping up on Belgian soil. For this reason, in 2013, the famhp took various actions to curb the sale of electronic cigarettes with nicotine. In the area of imports, we are collaborating with customs to intercept shipments that infringe on regulation. In the field, various locations were inspected and thousands of electronic cigarettes and refills were confiscated.

Electronic cigarettes have a large following. Many regard them as a way to smoke less and limit the negative effects of tobacco use, without having to kick their nicotine addiction. The degree to which this is correct is not yet clear, but the safety of electronic cigarettes continues to raise major questions, due to:
  • the acute toxicity of nicotine; The refills typically contain more than enough nicotine to kill an adult. In a child, as little as a millilitre can be enough to result in death;
  • the potential negative effects over the long term;
  • electronic cigarettes serving as a gateway to traditional cigarettes. It is not yet clear whether electronic cigarettes may serve as a gateway device for young people before they move on to traditional cigarettes, or if they are instead a way to avoid the use of traditional cigarettes.

The Belgian Minister of Public Health has requested advice from the Superior Health Council (HGR-CSS) on these products. This advice will be used to frame the future regulation of electronic cigarettes.

Future regulation has been the topic of extensive discussion at the EU level. During the reform of the tobacco directive, it was decided to include electronic cigarettes here as well. 2013 saw intense debate on this topic: should electronic cigarettes be freely available? Should they be regarded exclusively as a medicine? What precautions are needed to guarantee consumer safety? Can advertisements be made for them? Should access be restricted for young people? and so on.

After numerous discussions between the European Parliament, the European Council and the European Commission, a compromise text for the new tobacco directive has been proposed. This directive still needs to be approved and published. The bill gives member States the option to either regard electronic cigarettes with nicotine as medicines or to allow them onto the market as consumer products. In the former case, strict regulation of medicines guarantees protection of the user. In the latter case, some measures have been imposed to ensure consumer safety, such as maximum nicotine content, protection against accidental contact with the liquid, restrictions on advertising, compliance with other regulations, including content of heavy metals and battery safety. If this legislation is passed, then it must be transposed into Belgian law, with special provisions for Belgian jurisdiction. Until this new regulation is ready, the current provisions of the law will remain in force.
MEDICRIME, THE CONVENTION OF THE COUNCIL OF EUROPE ON COUNTERFEITING OF MEDICINAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO THE PUBLIC HEALTH

Counterfeiting of medicinal products and associated illegal practices are an international phenomenon. Illegal practices of this kind sometimes have serious and large-scale consequences due to the use of the internet to supply counterfeit medicines and other illegal medicinal products through a black market that imports and sells these products that evade all forms of oversight, in various (third) countries with porous borders. In practice, these criminal activities keep patients from getting the medical treatment they need. The illegal products are often hazardous to the user’s health and may even result in death.

In addition to the potential risk for the health of the users, this phenomenon may also undermine public trust in the competent authorities for healthcare and in healthcare systems. It is necessary to use the legal circuit to combat the risk of counterfeit medicines and other illegal medicinal products popping up, and to minimise the potentially pernicious effects on the Public Health.

Despite the measures taken at the national and international levels, we are seeing an upwards trend in counterfeit medicines and other illegal medicinal products. This proliferation can be explained by the relatively low risk of legal prosecution compared to the potential profits. The use of the internet to distribute these potentially harmful counterfeit products to patients and consumers from all over the world has made the problem global.

To address this issue, the Council of Europe, an international organisation bringing together 47 European countries, drafted an international convention on the counterfeiting of medicinal products and similar crimes involving a threat to the Public Health: the Medicrime Convention. This convention should be regarded as a general agreement on all aspects of the fight against criminal activities with counterfeit medicines and other illegal medicinal products.

The Medicrime Convention is the first international instrument of criminal law to introduce criminal penalties, aside from preventative measures and measures to protect the victims. The convention is open to countries all over the world. It also offers a regulatory framework for international co-operation and provides for measures to enhance co-ordination at the national level. In addition to this, the convention is a perfect supplement to national and international regulation, such as Directive 2011/62 of the European Union as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

The Medicrime Convention was presented to Moscow for signing on 28 October 2011. Countries that are not members of the Council of Europe but who collaborated in the development of the convention, Israel and Japan, countries with the status of observers in the Council of Europe and all countries throughout the world who want to join this convention are also invited to sign on.

The convention comes into force on the first day of the month following expiry of a period of three months after the date of signature by five countries, at least three of which are members of the Council of Europe, which will expressly endorse adherence to the Convention by ratifying it. Belgium signed the Medicrime Convention on 24 July 2012. The ratification procedure is underway.

The famhp firmly believes in the need for an international instrument of this kind in the fight against counterfeit medicines and other illegal medicinal products. The agency actually played a key role in the work activities related to the Medicrime Convention and is currently working to promote it in other countries. In 2013, the famhp took part in conferences of the Council of Europe to promote the convention, those of 16 to 17 October 2013 in Strasbourg, and of 21 and 22 November 2013 in Madrid. Currently, the famhp is collaborating with the other relevant national bodies in the ratification case file for the convention.

In light of the massive needs in third countries, and within the framework of the government partnership in Public Health of 3 February 2010 with the Democratic Republic of Congo (DRC), the famhp – along with the Council of Europe and the DRC Ministry of Public Health and with assistance from...
the Belgian Technical Cooperative (BTC) organised a training course within the framework of the Medicrime Convention. This training course was held in Kinshasa from 4 to 7 November 2013. The training course was intended to make the various relevant competent authorities aware of the partnership and co-ordination of their activities in the fight against counterfeiting and other illegal pharmaceutical practices, and was inspired by the system of Single Points Of Contact (SPOCs) developed by the Council of Europe. Its objective was to provide officials with the basic knowledge, tools and skills needed to set up a national and international network between the SPOCs of the competent authorities, the healthcare authorities competent to regulate medicines and health products, customs, police and the justice division. Fast and structured sharing of information on counterfeiting and other illegal pharmaceutical practices between the relevant competent authorities should result in targeted and co-ordinated actions. Angola and Zambia also took part in the training in the DRC, which was provided by a group of famhp employees.
THE FALSIFIED MEDICINES DIRECTIVE

This directive, intended to prevent falsified medicines (the term falsified is used to distinguish the infringement to intellectual property rights, so-called counterfeits) and other illegal medicinal products entering the legal distribution channels, or the Falsified Medicines Directive (2011/62/EU), was transposed into national regulation in 2013 by means of the Belgian Act of 20 June 2013 amending the Act of 25 March 1964 on medicinal products.

This directive seeks to offer better protection to consumers against falsified medicines and other illegal medicinal products in the legal distribution chain and also added a number of measures to pharmaceutical regulation, such as:

• stricter controls over pharmaceutical raw materials, also imposing requirements on producers and distributors/importers who import products from outside the EU;
• rules for what are known as medicine brokers, i.e. middle-men between medicine buyers and sellers;
• a regulatory framework for authorised internet pharmacies;
• a system for providing medicines, especially prescription medicines, with a unique code for rapid detection of falsification;
• requirements on the pharmaceutical sector to implement stricter controls over the purchase and sale of medicines;
• a reporting obligation in cases of suspected counterfeiting;

• rules for medicines not intended for the European market but which are in fact traded through Europe.

Just as with any other illegal practice, there is no silver bullet to fix all of the problems in the fight against falsified medicines and other illegal medicinal products. The measures are intended not only as a response to illegal pharmaceutical practices, but also as a proactive measure to get a handle on the ever increasing problem.

The provisions of the directive called for transposition into national regulation in 2013. For Belgium, this was handled by means of an amendment to an act and two amendments to Belgian RDs:

• the Belgian RD of 19 September 2013 amending the Belgian RD of 14 December 2006 on medicinal products for human and veterinary use;
• the Belgian RD of 19 September 2013 amending the Belgian RD of 21 January 2009 giving instructions for pharmacists;
• the Belgian Act of 20 June 2013 amending the Act of 25 March 1964 on medicinal products.

These decrees will be further supplemented over the coming years with, for instance, the delegated and implemented actions to be elaborated by the European Commission. This involves practical details, such as the form of the unique code, with bar code and number, and the method for consumer identification of legal internet pharmacies.

One of the most striking measures that came into force on 2 July 2013 in the EU is the stricter standards for pharmaceutical raw materials. Henceforth, raw materials of this kind must meet the European GMPD standards for pharmaceutical raw materials. The standards must be met for products manufactured or traded in the EU, as well as for raw materials that are imported. This entails that foreign producers must meet the European standards and must also be able to demonstrate this. This can be done in various ways, most notably:

• written confirmations from foreign competent authorities affirming that an inspection has found that the producer is working in accordance with European standards on its territory;
• inclusion of a country on a list of countries whose inspection and standards frameworks for pharmaceutical raw materials have been deemed equivalent to European standards. This evaluation is conducted by the European Commission. As soon as a country is listed, all authorised producers in that country will be permitted to supply the EU, and it will no longer be necessary to issue a written confirmation for each producer.

Notwithstanding the concern that these measures would cause shortages in medicine supplies, on 2 July 2013 it appeared that most of the major producers exporting to the EU were in possession of a written confirmation. A number of countries had also already obtained the equivalence and were listed as such. The list of equivalent countries has now grown longer.
There remains plenty of work to be done in the future. One of the main items for attention is the unique code for medicines. The practical details of this requirement were the topic of various discussions and work meetings during the second half of 2013. The famhp took part in a number of these events and of course also in the meetings of the European working group tasked with fleshing out this regulation.

The famhp also actively collaborated in the special task force of the HMA. The directive on falsified medicines and other illegal medicinal products leaves several aspects of the transposition to the discretion of the member States. For this reason, this task force wants to launch several proposals to harmonise the work surrounding these topics. Although this is not a European requirement, it is a way to work more efficiently, reduce costs for the industry and citizens and provide better service. The famhp has taken on leadership of two tasks: harmonisation of the registration or notification of brokers and elaboration of a harmonised vision on the unique code for medicines.
2013 results for each of the five entities
Directorate-General PRE authorisation

competent for all activities prior to approval of the first marketing authorisation for a medicine or health product
R&D Division (human)

**KEY TASKS**

The most important basic task of the R&D Division (human) is handling files relating to authorisations for clinical trials, Clinical Trial Applications (CTAs) and amendments to such files. The files are submitted by the sponsors of clinical trials: commercial or academic sponsors. After validation, the files are verified and if necessary passed to the Assessors Division to evaluate the results of the quality aspects and/or non-clinical data for the Investigational Medicinal Product (IMP). After this process has come to an end, the agency’s decision is communicated to the company/sponsor and the file is closed and archived.

The R&D Division (human) also participates in the European Voluntary Harmonisation Procedure (VHP). This is a procedure in which a harmonised evaluation of multinational clinical trials takes place in collaboration with the various authorities involved. Belgium is quite heavily involved in this procedure, both in its role as Reference Member State (RMS) and as Concerned Member State (CMS).

Since December 2012 there have been new modes of application for submitting an Annual Safety Report (ASR) in the form of a Development Safety Update Report (DSUR). The R&D Division (human) follows these reports closely, in order to protect participants of clinical trials.

Another important task is the handling of questions concerning clinical trials or research and development.

The division handles application files for medicines without MA for Compassionate Use (CU) or for medicines in Medical Need Programs (MNPs).

The division also participates in discussions around an important project in the context of Unmet Medical Need (UNM) and discussions about application of the law in the case of experiments on human people since 7 May 2004 as well as in the revision of the European Directive 2001/20.
### Applications and substantial amendments

<table>
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<th>9</th>
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<th>11</th>
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<th>Total 2012</th>
<th>Total 2011</th>
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<td>56</td>
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<td>1,776</td>
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<tr>
<td>Applications (original + substantial amendments) closed within the statutory timeframes</td>
<td>98 %</td>
<td>99,5 %</td>
<td>99,5 %</td>
<td>97,3 %</td>
<td>96,6 %</td>
<td>99,1 %</td>
<td>99,4 %</td>
<td>99,6 %</td>
<td>96,6 %</td>
<td>96,9 %</td>
<td>99,2 %</td>
<td>98,2 %</td>
<td>98,8 %</td>
<td>96 %</td>
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</tr>
</tbody>
</table>

### Questions regarding clinical trials or research and development

| | | | | | | | | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Answers to known questions within two days | 100 % | 100 % | 100 % | 100 % | 96 % | 100 % | 100 % | 97 % | 100 % | 84 % | 88 % | 65 % | 94 % | 97,9 % | 100 % |
| Answers to new questions within five days | 71,1 % | 70,7 % | 78 % | 79 % | 65 % | 73 % | 80 % | 73 % | 56 % | 55 % | 41 % | 28 % | 64 % | 79,9 % | 76 % |

### ASR in the form of a DSUR

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</tr>
<tr>
<td>Total number of applications</td>
<td>82</td>
<td>117</td>
<td>143</td>
<td></td>
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<tr>
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<td>63</td>
<td>78</td>
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<tr>
<td>Belgium as RMS</td>
<td>1</td>
<td>9</td>
<td>5</td>
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</tr>
<tr>
<td><strong>Medicines without MA in CU and medicines in MNPs</strong></td>
<td></td>
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<tr>
<td>General CUs</td>
<td>11</td>
<td>7</td>
<td>4</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Amended CUs</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Exceptional CUs</td>
<td>3</td>
<td>7</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>General MNPs</td>
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<td>19</td>
<td>34</td>
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<tr>
<td>Amended MNPs</td>
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<td>20</td>
<td>12</td>
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</tr>
<tr>
<td>Exceptional MNPs</td>
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<td>10</td>
<td>6</td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
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</tr>
</tbody>
</table>
KEY TASKS

The main responsibility of the Marketing Authorisation Division (human) consists of following up MA applications of medicinal products for human use. This follow-up involves three phases – validation, management and evaluation – in order to reach a final decision and possibly grant a MA.

The main tasks of the Marketing Authorisation Division (human) are:

- receipt and validation of MA applications;
- receipt and administrative monitoring of Active Substance Master Files (ASMFs);
- co-ordination and follow-up of applications in function of the deadlines;
- ensuring the link between the pharmaceutical industry, national and international bodies such as the EMA, internal and external assessors and partner institutions such as the Wetenschappelijk Instituut voor de Volksgezondheid (Scientific Institute for the Public Health, WIV-ISP);
- ensuring the secretariat of the Evaluation commission for medicines for human use;
- active participation in consultations with other competent authorities, such as the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) and the Belgian Regulatory Affairs Society (BRAS) regarding regulatory affairs;
- drafting of Public Assessment Reports (PARs);
- administrative closing of files and delivery of MAs.
SOME FIGURES

National Procedure for obtaining a MA (NP)
26 applications were closed for NP 2013.

<table>
<thead>
<tr>
<th>Applications</th>
<th>Total in 2011</th>
<th>Total in 2012</th>
<th>Total in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>IN</td>
<td>270</td>
<td>262</td>
<td>221</td>
</tr>
<tr>
<td>OUT (without variations)</td>
<td>467</td>
<td>274</td>
<td>222</td>
</tr>
<tr>
<td><strong>Total OUT</strong></td>
<td><strong>538</strong></td>
<td><strong>330</strong></td>
<td><strong>256</strong></td>
</tr>
</tbody>
</table>

Notes:
- The division recorded a small decrease in the number of new applications in 2013.
- The total number of applications closed (total OUT) relates to the number of applications closed without variations (OUT without variations) increased with the number of variations that were closed by the division just after file approval and which therefore had not yet been granted a MA.

Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP)
222 applications were closed for the MRP and DCP.

<table>
<thead>
<tr>
<th>Applications</th>
<th>Total in 2011</th>
<th>Total in 2012</th>
<th>Total in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>IN</td>
<td>376</td>
<td>449</td>
<td>418</td>
</tr>
<tr>
<td>OUT</td>
<td>370</td>
<td>384</td>
<td>377</td>
</tr>
</tbody>
</table>

Centralised Procedure (CP)

<table>
<thead>
<tr>
<th>Applications</th>
<th>Total in 2011</th>
<th>Total in 2012</th>
<th>Total in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>IN</td>
<td>44</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>OUT</td>
<td>32</td>
<td>23</td>
<td>26</td>
</tr>
</tbody>
</table>

Number of submitted applications (IN) and number of applications closed (OUT)
Number of submitted files (IN) by type

<table>
<thead>
<tr>
<th>Type of procedure IN</th>
<th>Total in 2011</th>
<th>Total in 2012</th>
<th>Total in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full application</td>
<td>10</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Line extension</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Renewal</td>
<td>5</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Variation IA</td>
<td>46</td>
<td>44</td>
<td>54</td>
</tr>
<tr>
<td>Variation IB</td>
<td>31</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Notification</td>
<td>21</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Grouped variation</td>
<td>8</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Grouped variation IA</td>
<td>42</td>
<td>51</td>
<td>50</td>
</tr>
<tr>
<td>Grouped variation IB</td>
<td>22</td>
<td>25</td>
<td>30</td>
</tr>
<tr>
<td>Analytical variation (60 days)</td>
<td>24</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>Analytical variation (90 days)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Clinical variation (60 days)</td>
<td>22</td>
<td>32</td>
<td>47</td>
</tr>
<tr>
<td>Clinical variation (90 days)</td>
<td>4</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Post Approval Commitment (PAC)</td>
<td>137</td>
<td>165</td>
<td>120</td>
</tr>
<tr>
<td>Referral</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>376</strong></td>
<td><strong>449</strong></td>
<td><strong>418</strong></td>
</tr>
</tbody>
</table>

Note:
Due to a change in representation within the Committee for Medicinal Products for Human Use (CHMP) and the limited capacity of preclinical and non-clinical assessors, for a number of months in 2013 the division was unable to act as rapporteur/co-rapporteur/peer reviewer. This led to fewer full applications in 2013 than in 2012.
<table>
<thead>
<tr>
<th>Type of procedure OUT</th>
<th>Total in 2011</th>
<th>Total in 2012</th>
<th>Total in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full application</td>
<td>3</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Line extension</td>
<td>4</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Renewal</td>
<td>11</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Variation IA</td>
<td>42</td>
<td>40</td>
<td>51</td>
</tr>
<tr>
<td>Variation IB</td>
<td>30</td>
<td>78</td>
<td>58</td>
</tr>
<tr>
<td>Notification</td>
<td>16</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Grouped variation</td>
<td>9</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Grouped variation IA</td>
<td>43</td>
<td>51</td>
<td>53</td>
</tr>
<tr>
<td>Grouped variation IB</td>
<td>22</td>
<td>23</td>
<td>30</td>
</tr>
<tr>
<td>Analytical variation (60 days)</td>
<td>28</td>
<td>16</td>
<td>26</td>
</tr>
<tr>
<td>Analytical variation (90 days)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Clinical variation (60 days)</td>
<td>38</td>
<td>23</td>
<td>38</td>
</tr>
<tr>
<td>Clinical variation (90 days)</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Post Approval Commitment (PAC)</td>
<td>116</td>
<td>117</td>
<td>99</td>
</tr>
<tr>
<td>Referral</td>
<td>1</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>370</strong></td>
<td><strong>384</strong></td>
<td><strong>377</strong></td>
</tr>
</tbody>
</table>
The main task of the Medicines for Veterinary Use Division is, according to the NP, MRP or DCP, the validation, management and closing of files for:

- applications for MA;
- analytical and clinical variations;
- five-yearly renewals (RQs).

The division also provides administrative support to the Belgian delegates in the Committee for Medicinal Products for Veterinary Use (CVMP). This committee evaluates applications for new veterinary medicines via the CP in Europe.

Furthermore, the division is responsible for authorising clinical trials for medicines intended for veterinary use, medical devices for veterinary use, parallel import, management of the infovet mailbox and participation in working groups at European and national level, as well as ensuring transversality of veterinary issues within the agency. There is close collaboration with the CVMP by means of administrative and logistic support in realising its tasks.

In 2013 the division began the implementation of MeSeA and the electronic submission of files was made obligatory.

The move from the IT system within the division resulted in the number of files being calculated in a different way than was the case with the former system. In the new system, groups of files are calculated as only one file. This calculation method makes a comparison with the figures from the Marketing Authorisation Division (human) and the Marketing Authorisation Division (Variations & Renewals) more relevant.
### SOME FIGURES

#### Number of applications submitted and closed for medicines for veterinary use

<table>
<thead>
<tr>
<th>Procedure</th>
<th>IN 2010</th>
<th>OUT 2010</th>
<th>IN 2011</th>
<th>OUT 2011</th>
<th>IN 2012</th>
<th>OUT 2012</th>
<th>IN 2013 (calculation according to the old system)</th>
<th>OUT 2013 (calculation according to the old system)</th>
<th>IN 2013 (MeSeA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variations IA &amp; IB</td>
<td>640</td>
<td>664</td>
<td>577</td>
<td>540</td>
<td>957</td>
<td>785</td>
<td>763</td>
<td>165</td>
<td>229</td>
</tr>
<tr>
<td>Variations II</td>
<td>64</td>
<td>121</td>
<td>88</td>
<td>67</td>
<td>35</td>
<td>66</td>
<td>64</td>
<td>3</td>
<td>43</td>
</tr>
<tr>
<td>Renewals</td>
<td>35</td>
<td>193</td>
<td>9</td>
<td>75</td>
<td>18</td>
<td>51</td>
<td>11</td>
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<td>MA</td>
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<tr>
<td>Clinical trials</td>
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<td>23</td>
<td>12</td>
<td>10</td>
<td>21</td>
<td>13</td>
<td>12</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Variations IA &amp; IB</td>
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<td>697</td>
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<td>865</td>
<td>1,243</td>
<td>1,027</td>
<td>905</td>
<td>216</td>
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<tr>
<td>Variations II</td>
<td>84</td>
<td>259</td>
<td>113</td>
<td>126</td>
<td>152</td>
<td>82</td>
<td>135</td>
<td>15</td>
<td>69</td>
</tr>
<tr>
<td>Renewals</td>
<td>56</td>
<td>119</td>
<td>44</td>
<td>70</td>
<td>46</td>
<td>43</td>
<td>75</td>
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<td>55</td>
</tr>
<tr>
<td>MA</td>
<td>26</td>
<td>100</td>
<td>41</td>
<td>42</td>
<td>36</td>
<td>34</td>
<td>51</td>
<td>10</td>
<td>46</td>
</tr>
<tr>
<td>DCP</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MA</td>
<td>120</td>
<td>106</td>
<td>92</td>
<td>89</td>
<td>129</td>
<td>118</td>
<td>102</td>
<td>3</td>
<td>67</td>
</tr>
<tr>
<td>Total</td>
<td>1,698</td>
<td>2,297</td>
<td>2,069</td>
<td>1,894</td>
<td>2,654</td>
<td>2,225</td>
<td>2,151</td>
<td>441</td>
<td>951</td>
</tr>
</tbody>
</table>

Note: The introduction of MeSeA and the new way of counting files made a comparison of the figures from 2013 with those from 2012 more complicated. In order to gain a comparison, the figures for the number of files submitted in 2013 had to be shown according to the new calculation method via MeSeA as well as via the former calculation method (former database). In terms of closing files, given that most files from the previous database were closed and the number of files in the former database was difficult to convert into figures according to the new calculation method, the applications closed were only shown according to the former method.
Evolution of the number of open files for medicines for veterinary use in the previous database

Notes:
- After an increase in the number of files received in comparison with previous years (22% in 2011 and 28% in 2012), the number of files received in 2013 decreased in comparison with 2012. This decrease can be explained by the extremely high number of administrative variations in 2012 as a result of a number of mergers and takeovers in the veterinary sector.
- The numeric decrease in the number of simple variations IA was partly compensated by a high increase in the more work intensive files such as variations II, renewals and applications for obtaining a MA.
- As a result of the introduction of MeSeA and of quality control in completing files, in 2013 we saw a slight decrease in the number of files closed.
- In 2013, Belgium acted as the RMS for two new applications for obtaining a MA via DCP, for four renewals, five variations and a PAC.
- In 2013 Belgium was the rapporteur/co-rapporteur for seven new applications for obtaining a MA via CP, six variations and four files about maximum residue limit or MRL in or on foodstuffs.
Assessors Division

KEY TASKS

The Assessors Division assesses scientific data for instances including applications for scientific advice, clinical trials and MAs submitted by external stakeholders.

In order to assess scientific data in a professional and efficient manner, there is ongoing maintenance and strengthening of expertise within the division. Various systems have also been developed in order to check and guarantee the quality of the work. Assessors represent the famhp in most international scientific committees and working groups.

All of these aspects contribute to an increase in the national and international recognition of the famhp.

ORGANISATION

The division consists of:

- the Preclinical & Clinical Veterinary Entity or the groups of assessors who deal with the (pre) clinical aspects of veterinary medicines and in which each assessor follows up a number of specific therapeutic areas;
- the Non-Clinical (human) Entity in which the various assessors have their own areas of expertise such as vaccines, Advanced Therapy Medicinal Products (ATMPs), biosimilar medicines, nanomedicines, early phase clinical trials and paediatrics.
- the Quality Entity or the group of assessors who deal with the quality of medicines (human and veterinary use) with specialists in chemical products, biological products, plant based medicines and ATMP medicines;
- the Clinical Human Entity or the group of assessors in which some employees concentrate on bio-equivalence (BE) and pharmacokinetics (PK), biostatistics or the methodology of clinical trials, while others follow one or more pharmacotherapeutic areas.
THE TABLES BELOW GIVE AN OVERVIEW OF THE NUMBER OF ASSESSMENT REPORTS CLOSED IN 2013, BY TYPE OF PROCEDURE FOR MEDICINES FOR HUMAN AND VETERINARY USE.

### Number of assessment reports for medicines for human use

<table>
<thead>
<tr>
<th></th>
<th>Quality</th>
<th>Non-clinical</th>
<th>Clinical</th>
<th>BE/PK</th>
<th>Total</th>
<th>Total</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First round</td>
<td>From second round</td>
<td>First round</td>
<td>From second round</td>
<td>First round</td>
<td>From second round</td>
<td>2011</td>
</tr>
<tr>
<td>MA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NP new</td>
<td>39</td>
<td>56</td>
<td>26</td>
<td>23</td>
<td>38</td>
<td>30</td>
<td>11</td>
</tr>
<tr>
<td>NP variation &amp; renewal</td>
<td>187</td>
<td>215</td>
<td>107</td>
<td>157</td>
<td>211</td>
<td>172</td>
<td>4</td>
</tr>
<tr>
<td>MRP &amp; DCP</td>
<td>104</td>
<td>84</td>
<td>42</td>
<td>24</td>
<td>390</td>
<td>201</td>
<td>88</td>
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<tr>
<td>CP</td>
<td>43</td>
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<td>48</td>
<td>36</td>
<td>150</td>
<td>88</td>
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<td>0</td>
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<td>0</td>
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<td>Clinical trial</td>
<td>244</td>
<td>39</td>
<td>297</td>
<td>96</td>
<td>36</td>
<td>30</td>
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<tr>
<td>Total</td>
<td>645</td>
<td>419</td>
<td>666</td>
<td>336</td>
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<td>521</td>
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<tr>
<td>Quality</td>
<td>(pre-)Clinical</td>
<td>Total</td>
<td>Total</td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>----------------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>First round</td>
<td>From second round</td>
<td>First round</td>
<td>From second round</td>
<td>2011</td>
<td>2012</td>
<td>2013</td>
</tr>
<tr>
<td><strong>MA</strong></td>
<td></td>
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</tr>
<tr>
<td>NP new</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>24</td>
<td>22</td>
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<tr>
<td>NP variation &amp; renewal</td>
<td>48</td>
<td>33</td>
<td>39</td>
<td>19</td>
<td>265</td>
<td>189</td>
<td>139</td>
</tr>
<tr>
<td>MRP &amp; DCP</td>
<td>10</td>
<td>5</td>
<td>25</td>
<td>32</td>
<td>95</td>
<td>45</td>
<td>72</td>
</tr>
<tr>
<td>CP</td>
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<td>11</td>
<td>6</td>
<td>29</td>
<td>23</td>
<td>39</td>
</tr>
<tr>
<td>Scientific advice</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Clinical trial</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>75</td>
<td>52</td>
<td>76</td>
<td>58</td>
<td>434</td>
<td>286</td>
<td>261</td>
</tr>
</tbody>
</table>
The most important responsibility of the Scientific-Technical Advice & Knowledge Management Unit (STA-KM) consists of ensuring a centralised, performing and transparent service that guarantees the handling of national STA applications within the statutory timeframe. For each STA application, and in close collaboration with the Assessors Division, the most suitable internal and/or external experts are involved in providing direct and high quality advice. In doing so, there must be a guarantee of absolute confidentiality and any potential conflict of interest (COI) for those involved must be avoided. The famhp follows an analogue method for COI management as it does at EMA level.

For STA applications that require multidisciplinary advice, the STA-KM Unit works closely with all divisions within the famhp, with other national public services and institutions such as WIV-ISP, the Federal Agency for Nuclear Control – FANC and the National Institute of Health and Disability Insurance (RIZIV-INAMI), as well as with other national and international authorities for joint STA applications, such as the Medicines Evaluation Board (CBG-MEB), the EMA and the World Health Organization (WHO).

The most important tasks of the STA-KM Unit are:
- validation, management, comprehensive co-ordination and closing of applications for national STA;
- handling general as well as specific file related questions about national STA services;
- consistent follow-up of previously granted national and European advice reports via channels including the Belgian representatives of the Scientific Advice Working Parties (SAWP & SAWP Veterinary), the Committee for Advanced Therapies (CAT), the CHMP and the Paediatric Committee (PDCO) of the EMA;
- within the context of European STA provision, famhp is also active in providing qualification advice, as well as advice about multidisciplinary research into which various aspects of Health Technology Assessment (HTA) are evaluated;
- administrative management of European advice co-ordinated by Belgian SAWP members;
- management of the STA-SAWP database at the famhp;
- management of the internal and external expertise network at national and European level including via management of the expert database and the Knowledge Management project;
- improvements to and expansion of new strategic
partnerships and interaction mechanisms with external experts in line with the further expansion, consolidation and distribution of external expertise;

• co-ordination of and participation in various projects within the famhp that are important for building up expertise and the further expansion of national STA services, such as the UMN projects and the national Medical Devices Plan (PMH-PDM).

MOST IMPORTANT REALISATIONS IN 2013

• creating a draft proposal for the expansion of the scientific STA scope for medical devices and other health products;
• implementation of the communication plan to promote the STA service at a national level;
• implementation of a benchmark study with other national competent authorities for the procedures for national STA;
• optimisation of the STA procedures and of the operational working of the STA-KM Unit;
• update of the STA-SAWP-database for optimised use within famhp;
• update of the expert database for optimised use within famhp;
• implementation of a uniform policy for payment of external experts working with STA and on SAWP consultancy;
• participation in the structuring of a needs analysis and draft regulation for UMN;
• implementation of a document management system (DMS) at famhp level; development of the mission and vision, the basic structure, basic document governance rules and delivery of identified quick wins;
• implementation of policy for knowledge transfer in line with internal mobility.
<table>
<thead>
<tr>
<th>Number of national STA</th>
<th>2011 IN</th>
<th>2011 OUT</th>
<th>2012 IN</th>
<th>2012 OUT</th>
<th>2013 IN</th>
<th>2013 OUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type II/III STA</td>
<td>32</td>
<td>27</td>
<td>26</td>
<td>26</td>
<td>29</td>
<td>30</td>
</tr>
<tr>
<td>Type I STA</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>According to spearheads</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccines</td>
<td>9</td>
<td>7</td>
<td>9</td>
<td>9</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Early Phase Development</td>
<td>15</td>
<td>12</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>Oncology</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>According to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human use</td>
<td>33</td>
<td>27</td>
<td>30</td>
<td>30</td>
<td>34</td>
<td>36</td>
</tr>
<tr>
<td>Veterinary use</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1(*)</td>
</tr>
<tr>
<td>Total number of national WTAs received</td>
<td>36</td>
<td>30</td>
<td>31</td>
<td>31</td>
<td>34</td>
<td>38</td>
</tr>
</tbody>
</table>

Note:
° One STA application was not related to medicines for human or veterinary use.
<table>
<thead>
<tr>
<th>Number of European STA</th>
<th>2011 IN</th>
<th>2011 OUT</th>
<th>2012 IN</th>
<th>2012 OUT</th>
<th>2013 IN</th>
<th>2013 OUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scientific advice</td>
<td>71</td>
<td>71</td>
<td>99</td>
<td>32</td>
<td>81</td>
<td>81</td>
</tr>
<tr>
<td>Qualification procedures and HTA</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>According to spearheads</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccines</td>
<td>3</td>
<td>3</td>
<td>7</td>
<td>9</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Early Phase Development</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Oncology</td>
<td>28</td>
<td>28</td>
<td>23</td>
<td>2</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>According to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human use (SAWP)</td>
<td>74</td>
<td>74</td>
<td>103</td>
<td>33</td>
<td>84</td>
<td>84</td>
</tr>
<tr>
<td>Veterinary use (SAWP-V)</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total number of European SAWP/SAWP-V</td>
<td>75</td>
<td>75</td>
<td>103</td>
<td>36</td>
<td>85</td>
<td>85</td>
</tr>
</tbody>
</table>
The Homeopathic & Herbal Medicines Unit underwent further restructuring in 2013 as well as a thorough analysis of its operations with a view to improve its core processes and achieve the ultimate goal of increasing performance.

**HOMEOPATHY**

Based on dealing with applications for registration and authorisation of homeopathic medicines within set statutory deadlines, consultation was instigated with the sector in order to set priorities. A number of improvement projects were determined, on which further work will be done in the course 2014. The first project was completed and enabled the processing of 41% of the backlog in files.

We also looked at options for optimising dialogue with clients and improving accessibility for employees.

The database with notified homeopathic medicines was thoroughly revised and will be operational in 2014.

**HERBAL MEDICINES**

In 2013, the unit worked on more efficient handling of files for herbal medicines, considering the fact that the largest section of applications is submitted via the NP. This was attuned to the general approach used by other divisions of the famhp for NPs.

We also intend to take a more active role in European registration and authorisation procedures.

**KEY TASKS**

The role of the Homeopathic & Herbal Medicines Unit is to grant and follow up registrations and MA for homeopathic medicines and herbal medicines. This unit is therefore charged with evaluating and managing, in the broadest sense of the word, application files for registration and MA for homeopathic medicines and herbal medicines, as well as with treating applications for variations to existing registrations and MAs.

The unit works with internal and external experts to guarantee the quality, safety and efficacy of this category of medicines, in consideration of the specific regulation.

The unit also plays a role in the granting of WTA.

The Homeopathic & Herbal Medicines Unit co-ordinates the tasks and ensures the secretariat of two independent committees:

- The Evaluation commission for homeopathic medicinal products for human and veterinary use (HCG-HCM);
- The Evaluation commission for traditional herbal medicines for human use (CKG-CMP).
Employees of the unit represent the famhp at European level in committees and working groups, such as the Committee on Herbal Medicinal Products (HMPC), the Homeopathic Medicinal Products Working Group (HMPWG) and the European Directorate for the Quality of Medicines & Healthcare (EDQM).

**BALANCE 2013 – HOMEOPATHIC MEDICINES**

- A new MA was granted for a homeopathic medicine.
- Five publicity files were approved for homeopathic medicines.
- A reference file was approved for a pharmaceutical form.
- In terms of file evaluation, we noted the following evolution:

Most evaluations dealt with files submitted prior to 2013. This means that the degree of new evaluations remains limited in terms of a higher number of responses to questions and a higher number of evaluations in module 4. Prioritisation in these evaluations matches the results of the analysis done within the context of the upcoming improvement project and a phased prioritisation.
BALANCE 2013 – HERBAL MEDICINES

2012 saw an exceptional 144 files closed for herbal medicines, thanks to the implementation of a new follow-up system and an increase in staff. This lead to a large number of files being closed that had been waiting for closing for some time.

The new approach in file management also proved its worth in 2013: 105 files were closed, up from an average of 60 per year in previous years.
Pharmacopeia/API Unit

SOME FIGURES

The main tasks of this unit are:
- contributing to the improvement of the quality of pharmacy made and officinal preparations;
- processing applications for authorisations;
- processing files within the activities of the European Pharmacopoeia Committee.

SOME FIGURES

Results achieved

<table>
<thead>
<tr>
<th>Situation on 31 December 2013</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of applications for authorisation to be processed</td>
<td>1 285</td>
<td>760</td>
<td>568</td>
</tr>
<tr>
<td></td>
<td>100,00 %</td>
<td>100,00 %</td>
<td>100,00 %</td>
</tr>
<tr>
<td>Total number of authorisations granted</td>
<td>663</td>
<td>417</td>
<td>92</td>
</tr>
<tr>
<td></td>
<td>51,60 %</td>
<td>54,87 %</td>
<td>16,20 %</td>
</tr>
<tr>
<td>Total number of licences revoked</td>
<td>622</td>
<td>813</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>48,40 %</td>
<td>52,38 %</td>
<td>2,46 %</td>
</tr>
<tr>
<td>Remaining number of authorisation applications pending on 31 December</td>
<td>622</td>
<td>343</td>
<td>462</td>
</tr>
<tr>
<td></td>
<td>48,40 %</td>
<td>45,13 %</td>
<td>81,34 %</td>
</tr>
<tr>
<td>of which:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pending on company level</td>
<td>303</td>
<td>269</td>
<td>363</td>
</tr>
<tr>
<td></td>
<td>48,71 %</td>
<td>78,43 %</td>
<td>78,57 %</td>
</tr>
<tr>
<td>pending on administration level</td>
<td>115</td>
<td>68</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>18,49 %</td>
<td>19,83 %</td>
<td>21,00 %</td>
</tr>
<tr>
<td>pending on assessors level</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0,32 %</td>
<td>0,00 %</td>
<td>0,00 %</td>
</tr>
<tr>
<td>ready to be granted</td>
<td>204</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>32,80 %</td>
<td>1,46 %</td>
<td>0,43 %</td>
</tr>
</tbody>
</table>
Directorate-General POST authorisation

competent for all activities following approval of the first marketing authorisation for a medicine or health product
The main task of the Marketing Authorisations Division (Variations & Renewals) is dealing with applications for variations and renewals of MA for medicinal products. The files pass through various phases: loading into the database, evaluation of the requested variations and administrative closing.

The division is divided into several entities, with the most important tasks being:

- **Variations without/with Minor impact on MA/EC Decisions, EU Recommends Entity**
  (Marketing Authorisations – MAs, European Commission, European Union)
  This entity deals with all variations IA/IB that have no or little impact on the MA, SPC and the patient information leaflet. The files are loaded into the database, evaluated by our staff and then closed.
  Given the pressing nature of these variations to the SPC and patient information leaflet in terms of safe use of the respective medicines, these files are handled by a separate entity that has to guarantee the information is included in the SPC and patient information leaflet as soon as possible.

- **Change MAH/Batch Releaser Entity**
  (Marketing Authorisation Holder)
  This entity is responsible for the transfer of MAH and variations to batch releasers responsible for batches of medicines.

- **Cluster Entity**
  This entity deals with all other variations that may have a significant impact on the MA, SPC, patient information leaflet and packaging or mock-up (= a flat design, in colour with the final font and final font size, that gives a clear view of the three dimensional presentation of the packaging). As well as uploading the files to the database and evaluating and managing these files during the evaluation phase, these files are administratively closed by a customised MA, along with the approved SPC and patient information leaflet, to be sent to the MAH.

The Marketing Authorisation Division (Variations & Renewals) is also responsible for handling applications for parallel import and applications for withdrawals of MAs.

The Call Centre Entity for MA is also part of this division.
## SOME FIGURES

<table>
<thead>
<tr>
<th>Situation</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity</td>
<td>IN</td>
<td>OUT</td>
<td>IN</td>
</tr>
<tr>
<td>Variations without/with Minor impact on MA</td>
<td>4,055</td>
<td>4,110</td>
<td>4,599</td>
</tr>
<tr>
<td>Change MAH/Batch Releaser</td>
<td>400</td>
<td>633</td>
<td>385</td>
</tr>
<tr>
<td>EC Decisions, EU Recommends</td>
<td>174</td>
<td>123</td>
<td>259</td>
</tr>
<tr>
<td>Cluster</td>
<td>3,970</td>
<td>4,571</td>
<td>3,314</td>
</tr>
</tbody>
</table>

**Notes:**
- 430 files were closed following the scrapping of MA, 65 files were revoked by the MA holder and 32 files were rejected.
- Figures included in IN but not in the OUT figures for this division are included here:
  - 41 files were entered twice,
  - 52 files were dealt with by the Homeopathic & Herbal Medicines Unit,
  - 71 files were closed at the same time as the application for a new authorisation by the Marketing Authorisation Division (human).
KEY TASKS

The Vigilance Division (pharmaco, materio, haemo, bio) monitors the safety in use of medicines for human and veterinary use (pharmacovigilance), of medical devices (materiovigilance), of blood and unstable blood products of human origin (haemovigilance) and of human tissue material (biovigilance). This responsibility includes gathering information, evaluating that information and, if necessary, taking corrective measures.

The main tasks of the division are:
- collection and evaluation of:
  - individual reports of adverse reactions from MAH and healthcare professionals (medicines for human and veterinary use);
  - Periodic Safety Update Reports (PSURs) (medicines for human and veterinary use);
  - Risk Management Plans (RMPs) (medicines for human and veterinary use);
  - Annual Safety Reports (ASRs) on clinical trials conducted on medicines authorised in Belgium (medicines for human and veterinary use);
  - incidents after using medical devices;
  - information about serious adverse events and reactions with blood and blood components;
  - information about serious adverse reactions and events with human tissue material (MLM-MCH);
- participation in the evaluation of applications for five-yearly renewals (RQ) (medicines for human and veterinary use);
- participation in activities relating to vigilance in the European context (medicines for human and veterinary use);
- dissemination of information about vigilance for the attention of healthcare professionals and the public;
- implementation of measures proposed following evaluation of pharmacovigilance data (medicines for human and veterinary use). This is done in collaboration with the Marketing Authorisation Division (Variations & Renewals) of the DG POST authorisation and with the DG PRE authorisation;
- implementation of measures proposed after evaluation of data about materiovigilance, haemovigilance and biovigilance.
### SOME FIGURES

<table>
<thead>
<tr>
<th>Activity (number of applications submitted)</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>Evolution 2012-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacovigilance of medicines for human use</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>PSUR</td>
<td>1,700</td>
<td>1,705</td>
<td>1,154</td>
<td>-32,3 %*</td>
</tr>
<tr>
<td>Individual reports of adverse reactions</td>
<td>4,601</td>
<td>5,279</td>
<td>5,259</td>
<td>-0,4 %</td>
</tr>
<tr>
<td>Pharmacovigilance for medicines for veterinary use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSUR</td>
<td>744</td>
<td>670</td>
<td>840</td>
<td>+25,4 %</td>
</tr>
<tr>
<td>Individual reports of adverse reactions</td>
<td>314</td>
<td>442</td>
<td>272</td>
<td>-38,5 %**</td>
</tr>
<tr>
<td>Materiovigilance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of reports</td>
<td>1,641</td>
<td>1,714</td>
<td>2,001</td>
<td>+16,7 %</td>
</tr>
<tr>
<td>Haemovigilance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of serious adverse events and reactions</td>
<td>943</td>
<td>917</td>
<td>989</td>
<td>+7,9 %</td>
</tr>
<tr>
<td>Biovigilance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of serious adverse events and reactions</td>
<td>33</td>
<td>9</td>
<td>47</td>
<td>+422 %</td>
</tr>
<tr>
<td>Backlog: EudraVigilance*** (January 2005-April 2008): evolution of the % of reports yet to be processed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic forms</td>
<td>0 %</td>
<td>0 %</td>
<td>0 %</td>
<td>/</td>
</tr>
<tr>
<td>Yellow paper forms</td>
<td>34 %</td>
<td>34 %</td>
<td>34 %</td>
<td>/</td>
</tr>
</tbody>
</table>

**Notes:**
- * As a result of a variation to European regulation, the number of PSURs has dropped, but the size of the average PSUR has increased.
- ** This decrease is a result of a change to the calculation method. Previously, reports were sometimes counted twice if more than one medicine was involved.
- *** Central EMA database with reports of adverse reactions with medicines for human and veterinary use authorised in the EU, coming from national competent authorities of EU-countries and from pharmaceutical companies.
Health Products Division

Medical Devices Entity

**KEY TASKS**

In 2013, the Medical Devices Entity worked hard to address the level of backlog in the processing of notifications for marketing class I medical devices.

The entity was actively involved in the implementation of the Belgian PMH-PDM, the most important measures of which will come into effect in 2014.

The entity followed European work in line with the development of European regulation about variations to notified bodies and the European recommendation about audits carried out by notified bodies, as well as the information about future European regulation relating to medical devices.

The entity continued to actively contribute to the development of the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, which is regularly updated.

The Medical Devices Entity deals with applications for distribution notifications, applications for export certificates, notifications of clinical trials for medical devices without a CE mark, notifications for activities of manufacturers of custom medical devices, notification for trading of class I medical devices, applications for accreditation within the context of the care plan for diabetes and applications for exceptional use. On a daily basis, the entity responds to all sorts of questions and follows up processing of fees.
## SOME FIGURES

<table>
<thead>
<tr>
<th>Activity</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IN</td>
<td>OUT</td>
<td>IN</td>
</tr>
<tr>
<td>Declaring taxes</td>
<td>829</td>
<td>829</td>
<td>897</td>
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<tr>
<td>Notifications for distribution</td>
<td>245</td>
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<td>Export certificates</td>
<td>690</td>
<td>791</td>
<td>1,336</td>
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<tr>
<td>Clinical trials</td>
<td>36</td>
<td>22</td>
<td>26</td>
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<tr>
<td>Customised manufacturer notifications</td>
<td>45</td>
<td>45</td>
<td>35</td>
</tr>
<tr>
<td>Notification class I manufacturers</td>
<td>200</td>
<td>582</td>
<td>189</td>
</tr>
<tr>
<td>Approval in the context of the care plan for diabetes</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
**KEY TASKS**

The main tasks of the Proper Use Division are:
- ensuring the application of the Sunset Clause and therefore withdrawal of the respective MAs. If an authorised or registered medicine is not actually traded for a period of three consecutive years, then the MA or registration for that medicine will expire in accordance with the Law on medicines of 25 March 1964 (article 6, § 1ter);
- providing information about medicines and health products;
- in terms of medical advertising: setting standards and, particularly in terms of public advertising, carrying out prior controls on advertisements for medicines and information campaigns on radio or television that refer to medicines;
- assessing and approving Additional Risk Minimisation Activities (RMA) which are compulsory for some medicines in order to be granted a MA.

**SOME FIGURES**

<table>
<thead>
<tr>
<th>MA withdrawn in line with the Sunset Clause</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>(April 2010-2011)</td>
<td>919</td>
<td>217</td>
<td>188</td>
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</table>

<table>
<thead>
<tr>
<th>Notification and visa for advertising to the public at large</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of evaluated advertising notifications</td>
<td>548</td>
<td>580</td>
<td>562</td>
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<tr>
<td>Number of visa applications for radio/tv advertising</td>
<td>68</td>
<td>65</td>
<td>94</td>
</tr>
<tr>
<td>Number of visa application for radio/tv information campaigns</td>
<td>3</td>
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<td>0</td>
</tr>
<tr>
<td>Submitted RMA files</td>
<td>38</td>
<td>42</td>
<td>51</td>
</tr>
</tbody>
</table>
DG INSPECTION
competent for all inspection and control activities
The tasks of the Industry Division are very diverse and extend over different domains.

The various inspections are based on the respective directives or regulations in the domains of:

- Good Clinical Practices (GCP), collection of data from these trials and protection of participating patients.
- Good Manufacturing Practices (GMP)/Good Distribution Practices (GDP), Active Pharmaceutical Ingredients (APIs) and materials for pharmacy made preparations;
- Pharmacovigilance. Pharmacovigilance inspections related to the collection and assessment of pharmacovigilance data (reports of suspected adverse reactions and other safety issues) by MAH.
- Medical devices. The Industry Division monitors the distribution of medical devices in line with the regulation and via a qualitative circuit. The famhp was given new powers to deal with complaints relating to manufacturing of medical devices. Following the fraud case concerning PIP breast implants, an action plan was set up: the PMH-PDM (see part I of the 2013 annual report).
- Blood banks and MLM-MCH banks.
- Checks on advertising and other promotional activities for medicines and health products.

Some figures

See more in the DG INSPECTION overview table.
Inspection of retail pharmacies, hospital pharmacies and medicinal stocks at veterinarians

KEY TASKS

In 2013 a team of sixteen inspector pharmacists/vets carried out inspections into retail pharmacies, hospital pharmacies and medicinal stocks at veterinarians.

As well as standard routine checks, they also conducted more specific theme actions. In order to improve communication around effectiveness of the inspections, these sorts of actions are governed by much closer communication in respect of upcoming checks and any potential sanctions that may result.

Another valuable facet of the impact of the inspection team is the regular collaboration with a variety of legal prosecutors for various files relating to medicines and health products.

As well as actions in this area, the inspectors from the Dispensing Division also took part in countless consultation meetings with the respective sector and worked on transversal projects with a view to the revision, improvement or design of regulation.

The inspectors of hospital pharmacies worked mainly with the consultation groups set up to fully rewrite the regulation relating to instructions for hospital pharmacists. Inspectors for retail pharmacies ensured the basis for the consultation group in relation to the regulation for permanent development of those pharmacists.

SOME FIGURES

See more in the DG INSPECTION overview table.
The Authorisations Division was set up in 2012 in order to consolidate handling of the whole range of authorisations within one division in the DG INSPECTION. Its inspectors provide input for handling authorisation applications. The inspectors’ conclusions and the authorisations granted are essential elements of the control policy that determines inspection planning.

The Authorisations Division’s key tasks are receiving authorisation applications, validating such applications and ultimately delivering authorisations.

This includes:
- manufacturing authorisations (GMP);
- authorisations for manufacturing, import and distribution of APIs;
- notifications of medical brokers;
- wholesale authorisations;
- export declarations;
- certificates of Pharmaceutical Products (PPs);
- accreditations for blood, cells and tissues;
- authorisations of establishments of retail pharmacies;
- registrations of pharmacies;
- authorisations of substances that fall under the 12 April 1974 RD;
- drugs precursors that need to meet the United Nations (VN) Convention of 1988;
- narcotic substances and psychotropic materials that need to meet the UN Convention of 1961 and 1971.

MAs are not handled by this division, rather within DG PRE authorisation and DG POST authorisation.

We brought about a number of important realisations in 2013 in terms of the falsified medicines directive 2011/62/EU. The directive requires the registration of medical brokers and of distributors, importers and manufacturers of pharmaceutical materials. The necessary forms and procedures were set up for this new activity. The division also actively participated in consultancy within the specific work group, the Taskforce on Falsified Medicines of the network of the Heads of Medicines Agencies (HMA).

For the register of pharmacies, the necessary preparations were made within the context of the PMH-PDM to enable accreditation of hospital pharmacies.

We also launched a trial project for administrative streamlining for the so called regulated substances, in which the authorisation applications for import...
and export of narcotic substances and psychotropic materials can be submitted online.

**SOME FIGURES**

See more in the DG INSPECTION overview table.
KEY TASKS

In 2013 the Special Investigation Unit (SOE-USE) was dealing with pharmaceutical crime, both in the fight against the illegal trade in medicines as well as against the trade in falsified medicines and other illegal medicines. There were official investigations, assistance in prosecutions and checks of postal packages from third countries.

Illegal online trading is further complicated due to its cross-border nature. One crucial detail in dealing with illegal trading and other illegal practices is and remains the building of expertise and partnership between the various authorities involved at national, European and international level. Product knowledge and the expertise and experience accrued from the countless interventions in this area have resulted in the SOE-USE becoming a crucial link in the partnership chain between police, customer, justice, the Federal Agency for the Safety of the Food Chain (FASFC), the FPS Economy and other divisions within the famhp and analogue bodies at European and international level. Product knowledge and expertise is slowly being built up for newer areas of regulation, such as medical devices and blood, cells and tissues.

The SOE-USE has a leading role in the application of the complex SALDUZ Act in the events of violations of medicines and health products. This regulation influences the operational approach and demands a more careful approach to infringements, for which the prison term is at least one year.

For strategic, tactical and operational consultation and for an exchange of best practices, the SOE-USE participates at national level in meetings of the Multidisciplinary Hormone Entity and in various platforms aimed at fighting fraud.

At international level, the SOE-USE is an active participant in:

- Pangea actions co-ordinated by Interpol. The Pangea VI in 2013 took place for the first time from 18 June to 28 June, while earlier editions were held in the autumn. Worldwide, 99 countries took part, with 13,700 websites being closed and 9.8 million units of falsified medicines and other illegal medicines (offered for sale via illegal internet trading) being confiscated. This came to a total value of 41 million dollars;
- meetings of the Working Group Enforcement Officers (WGEO) of the HMA;
- meetings of the European Council;
- specific meetings with regard to falsified medicines.

SOME FIGURES

1,989 posted items and 252 files were checked whilst in transit. As a result of this and other information that lead to investigations, 413 files were processed. Of these 413, 285 were fully handled by the SOE-USE and 128 with the aid of prosecutions. 132 of the 285 related to substances regulated by the Royal Decree (RD) of 12 April 1974 with respect to some actions relating to materials with a hormonal, anti-hormonal, anabolic, beta-adrenergic, anti-infectious, anti-parasitic and anti-inflammatory effect (mainly doping) and 153 to other medicines. Broadly speaking, we have seen a strong increase in the number of files; this can mainly be explained by more thorough and regular checks on posted items.

See the DG INSPECTION overview table.
### FIGURES FOR THE DG INSPECTION

<table>
<thead>
<tr>
<th>Activity</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
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<tbody>
<tr>
<td><strong>Number of inspections</strong></td>
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<td></td>
<td></td>
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<tr>
<td>retail pharmacies</td>
<td>667</td>
<td>414</td>
<td>319</td>
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<tr>
<td>hospital pharmacies</td>
<td>83</td>
<td>60</td>
<td>51</td>
</tr>
<tr>
<td>medicinal stocks at veterinarians</td>
<td>538</td>
<td>524</td>
<td>476</td>
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<tr>
<td>pharmaceutical companies – GMP</td>
<td>87</td>
<td>264</td>
<td>205</td>
</tr>
<tr>
<td>pharmaceutical companies – GDP</td>
<td>130</td>
<td>-</td>
<td>-</td>
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<tr>
<td><strong>Number of official reports</strong></td>
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<td></td>
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<tr>
<td>inspectors of retail pharmacies</td>
<td>189</td>
<td>144</td>
<td>131</td>
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<tr>
<td>inspectors of hospital pharmacies</td>
<td>2</td>
<td>10</td>
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<tr>
<td>inspectors of pharmaceutical industry</td>
<td>10</td>
<td>43</td>
<td>34</td>
</tr>
<tr>
<td><strong>Narcotics and psychotropic substances, number</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inspections of stock and accounts at manufacturers, wholesalers-distributors, importers and exporters (Fr)</td>
<td>197</td>
<td>242</td>
<td>277</td>
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<tr>
<td>licence reviews – import (Fr)</td>
<td>309</td>
<td>340</td>
<td>399</td>
</tr>
<tr>
<td>licence reviews – export (Fr)</td>
<td>33</td>
<td>64</td>
<td>150</td>
</tr>
<tr>
<td>inspections of stock and accounts at manufacturers, wholesalers-distributors, importers and exporters (Nl)</td>
<td>237</td>
<td>219</td>
<td>231</td>
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<tr>
<td>licence reviews – import (Nl)</td>
<td>620</td>
<td>997</td>
<td>1,073</td>
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<tr>
<td>licence reviews – export (Nl)</td>
<td>86</td>
<td>82</td>
<td>76</td>
</tr>
<tr>
<td><strong>Narcotics and psychotropic substances, import/export licences</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nombre</td>
<td>7,088</td>
<td>7,157</td>
<td>7,499</td>
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<tr>
<td>Délai moyen d’obtention de cette autorisation</td>
<td>8 days</td>
<td>4 days</td>
<td>4 days</td>
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</table>

**Comment:**

- Total number of GMDP inspections, GMP and GDP inspections are no longer differentiated.
<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2020</th>
<th>2019</th>
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<td>Narcotics and psychotropic substances, number of narcotics order forms (per 100 forms)</td>
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<td></td>
<td></td>
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<tr>
<td>number</td>
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<td>5,672</td>
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<td>average period for sending of a narcotics forms</td>
<td>5 days</td>
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<td>Precursors, number</td>
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<td>activity licenses to market participants</td>
<td>94</td>
<td>65</td>
<td>92</td>
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<tr>
<td>import/export licences – export</td>
<td>408</td>
<td>435</td>
<td>454</td>
</tr>
<tr>
<td>import/export licences – import</td>
<td>29</td>
<td>25</td>
<td>29</td>
</tr>
<tr>
<td>import/export licences – Pre Export Notifications (PENs)</td>
<td>376</td>
<td>330</td>
<td>380</td>
</tr>
<tr>
<td>import/export licences – intra-community trade</td>
<td>3,227</td>
<td>2,016</td>
<td>2,489</td>
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<tr>
<td>import/export licences – suspicious orders and transactions</td>
<td>64</td>
<td>64</td>
<td>59</td>
</tr>
<tr>
<td>Hormones and antibiotics, number</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>new licences (NL)</td>
<td>56</td>
<td>62</td>
<td>45</td>
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<tr>
<td>renewals (NL)</td>
<td>139</td>
<td>139</td>
<td>66</td>
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<tr>
<td>extension of certificates (NL)</td>
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<td>167</td>
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<tr>
<td>new licences (Fr)</td>
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<td>36</td>
<td>33</td>
</tr>
<tr>
<td>renewals (Fr)</td>
<td>72</td>
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<tr>
<td>extension of certificates (Fr)</td>
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<td>71</td>
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<td>Export, number</td>
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<td>EUDRA-certificates</td>
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<td>89</td>
<td>94</td>
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<tr>
<td>EUDRA-repeat orders</td>
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<td>608</td>
<td>694</td>
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<tr>
<td>GMP-certificates</td>
<td>888</td>
<td>624</td>
<td>767</td>
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<tr>
<td>certificates of Pharmaceutical Products (PP)</td>
<td>3,382</td>
<td>3,228</td>
<td>3,044</td>
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<tr>
<td>certificate for Medical Device (CMD)</td>
<td>848</td>
<td></td>
<td>See DG Post Authorisation</td>
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<tr>
<td>other certificates (e.g. certified copies, analysis reports)</td>
<td>539</td>
<td>435</td>
<td>856</td>
</tr>
<tr>
<td>export declarations</td>
<td>159</td>
<td>172</td>
<td>227</td>
</tr>
<tr>
<td>declarations of toll manufacturing activity</td>
<td>135</td>
<td>131</td>
<td>145</td>
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</table>
### RAS of quality, of which

<table>
<thead>
<tr>
<th>Category</th>
<th>No. 1</th>
<th>No. 2</th>
<th>Total</th>
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<tbody>
<tr>
<td>of Belgian origin</td>
<td>111</td>
<td>129</td>
<td>142</td>
</tr>
<tr>
<td>of European origin</td>
<td>141</td>
<td>137</td>
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<tr>
<td>of class 1</td>
<td>55</td>
<td>62</td>
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<tr>
<td>of class 2</td>
<td>117</td>
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<td>of class 3</td>
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<tr>
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<tr>
<td>fraud/counterfeit</td>
<td>30</td>
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<tr>
<td>for medicines for human use</td>
<td>219</td>
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<td>for medicines for veterinary use</td>
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<tr>
<td>for raw materials</td>
<td>5</td>
<td>2</td>
<td>2</td>
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<tr>
<td>for medicines for research or Investigational Medicinal Products (IMP)</td>
<td>8</td>
<td>3</td>
<td>7</td>
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<tr>
<td><strong>Total</strong></td>
<td>252</td>
<td>266</td>
<td>324</td>
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### “14.12.2006” and “30.06.2004” licenses, number

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<th>Category</th>
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<tr>
<td>new applications</td>
<td>23</td>
<td>24</td>
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<tr>
<td>applications for amended licences</td>
<td>171</td>
<td>174</td>
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### Number of applications for variations submitted to the Advisory Commission

<table>
<thead>
<tr>
<th>Category</th>
<th>No. 1</th>
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</tr>
</thead>
<tbody>
<tr>
<td>urgent applications</td>
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<td>19</td>
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<tr>
<td>applications processed according to normal procedures</td>
<td>89</td>
<td>73</td>
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### Commission for the establishment of retail pharmacies, French language chamber, number

<table>
<thead>
<tr>
<th>Category</th>
<th>No. 1</th>
<th>No. 2</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>applications</td>
<td>48</td>
<td>85</td>
<td>93</td>
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<tr>
<td>decisions</td>
<td>36</td>
<td>87</td>
<td>78</td>
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### Registry of pharmacies, French language chamber, number

<table>
<thead>
<tr>
<th>Category</th>
<th>No. 1</th>
<th>No. 2</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>application for amendments</td>
<td>441</td>
<td>396</td>
<td>591</td>
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<tr>
<td>current applications (monthly average)</td>
<td>120</td>
<td>152</td>
<td>200</td>
</tr>
<tr>
<td>attestations/authorisations delivered</td>
<td>403</td>
<td>448</td>
<td>452</td>
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</table>
### Commission for the establishment of retail pharmacies, Dutch language chamber, number

<table>
<thead>
<tr>
<th>Category</th>
<th>Number 1</th>
<th>Number 2</th>
<th>Total</th>
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<tr>
<td>new applications</td>
<td>77</td>
<td>90</td>
<td>104</td>
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<tr>
<td>ministerial decisions</td>
<td>78</td>
<td>88</td>
<td>111</td>
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### Registry of pharmacies, Dutch language chamber, number

<table>
<thead>
<tr>
<th>Category</th>
<th>Number 1</th>
<th>Number 2</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>application for amendments</td>
<td>649</td>
<td>611</td>
<td>864</td>
</tr>
<tr>
<td>current applications (monthly average)</td>
<td>176</td>
<td>59</td>
<td>171</td>
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<tr>
<td>attestations/authorisations delivered</td>
<td>567</td>
<td>517</td>
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### SOE-USE

<table>
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<tr>
<td>number of applications: infringements of the RD of 12 April 1974</td>
<td>54</td>
<td>67</td>
<td>132</td>
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<tr>
<td>number of applications: other infringements of medicinal products regulations (other than RD of 12 April 1974)</td>
<td>142</td>
<td>60</td>
<td>153</td>
</tr>
<tr>
<td>warnings</td>
<td>35</td>
<td>41</td>
<td>24</td>
</tr>
<tr>
<td>assistance to public prosecutors number of opened files</td>
<td>53</td>
<td>47</td>
<td>128</td>
</tr>
<tr>
<td>number of postal packages inspected</td>
<td>1,078</td>
<td>1,072</td>
<td>1,989</td>
</tr>
<tr>
<td>number of transit files (Bierset)</td>
<td>222</td>
<td>118</td>
<td>252</td>
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### Recognition of pharmacists-clinical biologists

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<thead>
<tr>
<th>Chamber</th>
<th>New training plans</th>
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<th>Number 2</th>
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<td>8</td>
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<td>Dutch language chamber</td>
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<th>Total</th>
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<tr>
<td>Dutch language chamber</td>
<td>14</td>
<td>10</td>
<td>7</td>
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</tbody>
</table>
The specific objectives in 2013 of the P&O Division (personnel and organisation) were determined by the results of the satisfaction survey conducted in 2012 amongst famhp employees. A variety of large scale actions were set up or established over the course of the year in order to meet the needs of our staff. There was a particular focus on the communication between the P&O Division and staff. The recruitment process still remains an important priority within the famhp. A variety of selections were organised to meet the needs of the various directorate-generals.

Finally, there were three essential points to be finished up in 2013: the changes to regulation for evaluating federal staff, the new career and implementation of Crescendo and the application designed to electronically manage the evaluation cycle.

- The needs of staff
  - Training follow-up
    Training remains one of the most important issues for the federal government. The P&O Division is aware of this and therefore developed a database containing all training opportunities in order to gain an insight into all development activities planned for and taken up by staff. The database also allows us to follow up costs on an annual basis.

- Internal training
  In order to meet staff demand and the needs of the various services, the P&O Division has set up the following training courses:
    - scientific English, for staff dealing with files in English. This course will be held again, given the very positive feedback following the first round of lessons in 2011;
    - courses related to selections organised by Selor, for staff who wish to register for these selections.

At the initiative of the P&O Division a needs analysis was also carried out regarding training of the functional heads. This showed that certain generic competencies need to be developed for these functional heads. The P&O Division, in partnership with the respective internal partners, created a list of providers who would be able to offer these specific courses. This project will be formalised and implemented in 2014.

- Internal market and procedures to be promoted to a higher level.
This year there was also a variety of vacancies offered, in the first instance via the internal market. This meant that seven members of staff found new activities within the various entities of the famhp.

The procedure to be promoted to B-level was completed, with seventeen members of staff moving up to higher levels in 2014.

- MidiMidma and bilateral meetings
  MidiMidma network and the bilateral meetings were intensified. Monthly meetings offer the chance for shared brainstorming for e.g. improvements in communications between the various services and the P&O Division. At every meeting there is a sharing of opinions and a statement drawn up of the state of affairs as regards open files and developments within the famhp, current selections, P&O projects, training courses and amendments to regulation.

- Communication with staff
  Communication and information are two very important themes for the P&O Division. In 2013, 45 messages were published via the internal electronic newsletter, Vit@ express, informing staff of important notifications, reminders and any changes to regulation and procedures.

The second half of the year was largely given over to restructuring and updating the P&O Division information on the intranet. Each theme was revised to provide more clarity and transparency and to answer questions asked by staff. By the end of 2013, 85% of the P&O Division information on the intranet had been rewritten.

- Recruitment of new staff
  The famhp is still an agency undergoing significant expansion. The extension of our competences and providing optimal service also require more people. In 2013, the P&O Division began no fewer than 23 statutory selections. For the purposes of qualitative recruiting, the P&O Division appointed new jury members specifically trained in the recruitment techniques of the federal government.

- Changes to staff careers
  In the final quarter of 2013, a number of additions were made to federal career regulation. The new directives relating to evaluation cycles and new careers were published and Crescendo was systematically used for the administrative management of the evaluation cycle.

  In order to keep all staff up to date on this information exchange with the P&O Division, information sessions were organised about the additions and practical application thereof. Internal newsletters were sent and a detailed intranet page was set up to supplement these sessions. A range of documents regarding Crescendo were made available, such as simplified instructions, tips & tricks and presentations intended for evaluators as well as those evaluated. A specific helpdesk was also set up. The aim was to make sure that everyone properly understood the process and that the systems could be put into action in accordance with regulation as from January 2014.

SOME FIGURES

See the Staffing Data section.
The main tasks of the B&MC Division (budget and management control) are:

- compiling and monitoring the annual budget;
- recording income and expenditure and compiling the annual financial accounts;
- paying invoices;
- logistics or service provision.

Thanks to an increase in staffing in the B&MC Division, solutions were found for a variety of important bottlenecks, including ensuring the continuity of services in the event of staff absence. A first backup line was established within the division, as well as a second line for certain activities of an urgent nature. From now on, there will be a daily follow-up of priority tasks within the division.

In 2013 a variety of working meetings contributed to the development of the transversality of bookkeeping activities. This transversality is notable in the development of interactions between the front and back office. The meetings lead to the development of common financial tables. Using these tables, the full income of the famhp can be safeguarded, securing the financial basis. These meetings also saw amendments to the financial predictions, based on information from the field. This way of working will be further developed during 2014.

Income and expenditure were more systematically and better checked in 2013. In order to optimise these checks, approval of the famhp annual accounts has now been passed on to an external auditor. This auditor has already reported on the 2012 accounts and his recommendations have formed the basis for the 2013 balance sheet.

In line with the evolution of the famhp, a number of more specific purchases have come to light. In order to ensure that all purchases remain in line with regulation, a support unit was set up for government projects. This unit is part of Logistics and has already supported various divisions in setting up specifications and in providing advice for the various stages of approval.

Logistics has also already formed a number of working groups on specific subjects, such as building safety, terrain optimisation and ideas for new saving measures. These working groups are supplementary to the logistics network, which ensures a flow of information about staff needs and expectations at a logistics level.

Finally, staff health was central to logistics activities in 2013. Logistics has also released resources, in a budget-neutral way, for so-called “vitamin breaks”,...
by supplying fruit on a daily basis and is also working on an evaluation of the air conditioning system.

**SOME FIGURES**

See the Some budgetary elements section.

**ICT Division**

**KEY TASKS**

The key tasks of the ICT Division are made up of meeting the IT needs of famhp staff and partners.

The division is divided into:

- **Helpdesk**
  This section insures the installation of computer material such as computers (pc), keyboard/mouse and telephones, registers all intervention requests relating to software and hardware and tries to resolve problems as quickly as possible.

- **Infrastructure**
  This section manages the network, network rights, databases (such as Oracle and Access), working environments (such as Windows XP and Windows 7), manages and maintains servers and maintains supervision of the data-room. Infrastructure and Helpdesk work closely together.

- **Projects and Development**
  This section is responsible for the specific applications of the various sections of famhp and famhp partners.

In 2013 the Helpdesk supported all famhp staff. There were no fewer than 3,520 intervention requests, the majority of which came from teleworkers.
In 2013, the ICT Division, specifically the Infrastructure Team working closely with the ICT network of Single Points of Contact (SPOCs) and respective staff from other famhp divisions, successfully introduced a series of projects, such as:

- **MeSeA**
  - The new MeSeA tender:
    - Successful completion of the modernisation of the full MeSeA hardware environment, the publication of the patient information leaflets and the SPCs and the migration to a faster environment;
    - Installation of our own network connection with Cegeka for hosting MeSeA, independently of other government services;
    - Project allowing easier access rights for all users;
    - Project for improving the response time/response of MeSeA applications in various steps;
    - MeSeA checker or improvement of the checker applications to the most recent specification, in two steps.
  - New functionality for reporting from the application for medicines for veterinary use (two functional versions).
  - New versions of the functionality for publishing SPC and patient information leaflets, resulting in more published documents, improved
publication quality and independent problem solving by staff;
- Given the importance and specification of MeSea, a specific helpdesk was set up in 2013 to deal with 1,200 assistance requests.
- **Declaration of interest (DOI)**
  A small application was developed to inform the internal user if a new DOI needs to be published on the famhp website.
- **Common European Submission Platform (CESP) Connector**
  This is an automatic connector to CESP, the European platform for the electronic submission of MA and registration files for medicines for human and veterinary use, with automatic distribution within the famhp, a system of repeat mails and automatic removal of files upon completion.
- **Sharepoint-platform**
  Set up of a DMS light for things such as team meetings.
- **Extra plus Revised – E+R**
  Extra plus Revised is the new database, as well as the authentic source of medicines authorised in Belgium for human and veterinary use, including packaging size and availability on the Belgian market. The database enables the exchange of information with other agencies or governments, such as the RIZIV-INAMI and the Federal Public Service (FPS) Economy.
- **Traceability system of implantable medical devices**
  2013 saw the final stages of analysis and work began on the programming of the traceability system for implantable medical devices. This system is intended to be able to identify any medical devices implanted in a patient with respect for right to privacy.
- **Description of projects**
  Within the context of the PMH-PDM, a specific information area was identified: the traceability system for implantable medical devices (TIMD). This area is comprised of five different IT projects:
  - expansion of the register of pharmacists with non-public pharmacies (KADINSP);
  - creation of an authentic source of distributors active within the Belgian market (SADN);
  - creation of an authentic source of implantable medical devices (SADMI);
  - construction of a Central Tracing Register (CTR) in order to anonymously collect all information about the location of implantable medical devices in Belgium;
  - integration of the CTR with existing applications such as OrthoPride in order to avoid double entry of information in relation to traceability by involved healthcare professionals.

For the development of these five projects, we went to Smals (a non-profit organisation supporting the social sector and federal government services and helping them with their information management), retaining oversight via a famhp project leader.
- **Technology**
  The various applications will be developed in Java for Oracle databases and will be included into the IT environment of eHealth for better access.
Translation Division

KEY TASKS

The Translation Division of the famhp is responsible for translating and reviewing texts and for providing linguistic advice.

Due to the specific nature of the Belgian federal government, documents primarily need to be translated from French into Dutch and vice versa. To a lesser extent, translations are required to and from English and German.

The Translation Division works for all services of the famhp and mainly translates internal and external messages for electronic newsletters such as Vit@, Vit@ Express, Flash ICT and Flash PMO, press releases, service instructions, circulars and other letters, texts for the intranet and the website, draft regulation, answers to parliamentary questions, contracts and agreements, minutes and reports, presentations and speeches.

This year, within the context of expanding a quality control system, the Translation Division also translated, along with all of the usual items, an entire range of Standard Operating Procedures (SOPs) set up by all divisions, entities, units and other sections of the famhp.
CHIEF EXECUTIVE OFFICER’S SERVICES
Management support

KEY TASKS

In order to better follow up administrative decisions and improve project management, there was active participation of the Co-ordination Project Management Office (PMO) in the management of the famhp. The PMO, now Management Support, also ensured the organisation and follow-up of the Direction Committee, project management, implementation of the management cycle and the development of the strategic and operational plan.

For 2013, Management Support reported an analysis for the implementation of a new project management and priority setting method, as well as the evaluation of IT tools for planning and reporting on project management.
Division Communication

KEY TASKS

The Communication Division is responsible for the internal and external communication policy at the famhp and assumes the role of spokesperson in this capacity.

Internal communication activities
The division is responsible for final editing, co-ordination of translation, publication and archiving of messages distributed via the most important internal communication channels such as:
- the intranet;
- the various internal newsletters, each with their own specific objective;
- LCD screens;
- specific brochures for famhp staff.

External communication activities:
This comprises the realisation of the annual report, information campaigns, brochures and general presentations.

The Division also responds to the many varied questions posed by journalists and about specific projects for which press releases are sent and/or press conferences are held.

The staff of the Communication Division helps editing speeches and presentations for the Chief Executive Officer and for communication activities from all other divisions within the agency, such as:
- use of company branding,
- final editing of internal and external announcements,
- organisation of events.

In 2013 the division worked on a number of larger projects, including:
- The information campaign: “Medicines and Children. Careful! Medicines are not sweets!” in partnership with the Proper Use Division and the Chancellery of the Prime Minister. As well as publications within the general and specialised press, information sheets and brochures are designed for doctor’s waiting rooms, retail pharmacists and child health centres (of Kinder en Gezin and the ONE). The division worked on the final editing of all texts for the campaign material including for the mini site www.ge-neersmiddelenenkinderen.be - www.unmedica-mentnestpasunbonbon.be, for the organisation of the press conference and for the distribution of a press release to journalists and to partners of the agency including the professional associations and other public services.
- The co-ordination of the integration days of the Chief Executive Officer’s services for new staff
and the creation of a question and answers game aimed at testing what people know about the famhp.

- Launching a new internal communication channel, LCD screens, which we aim to use to pass on our messages to staff in a faster, more attractive and more dynamic way. Additionally, the screens are also a great way to inform visitors to the famhp about planned meetings.

In collaboration with the B&Mc Division, which is charged with the procedures and budget for purchasing LCD screens, and with the internal communication working group, themes were decided upon as regards what should be communicated via these screens and specific designs were developed.

Just as was the case in previous years, journalists were very interested in the famhp. This means that our health plays an ever more important role in all of our lives and that citizens have a particular need for famhp as an authority in medicines and health products. We are pleased to summarise a number of reoccurring press subjects:

- the quality, safety and efficacy of medicines in general and specific questions about the potential adverse reactions of specific medicines, in particular:
  - potential risks of hormone based contraceptives and combinations of cyproterone and ethinylestradiol, particular blood clots;
  - potential risk of sudden heart death in the use of medicines containing domperidone;
  - increased risk of bleeds with new oral anti-coagulants;
  - recommendations for a more correct and safer use of medicines for coughs and colds: antitussives, expectorants and topical nasal decongestants;
  - recommendations for a more correct and safer use of medicines containing codeine;
  - suspension of MAs for medicines containing tetrazepam;
  - unavailability of medicines, in particular flu vaccines during the vaccination period;
  - quality, safety and efficacy of generic medicines versus the original medicines;
  - falsified medicines and other illegal medicines sold/offered via illegal websites;
  - further progression of the fraud file as regards PIP breast implants and the impact of this on the traceability of medical devices in general and the PMH-PDM;
  - occurrence of incidents that sometimes are attributable to quality problems with medical devices, such as prosthetic hips or breast implants;
  - sperm donation and mainly the traceability thereof;
  - electronic cigarettes with nicotine, which are currently without MA and therefore illegally available on the market;
  - illegal advertising for plastic surgery.

In 2013, the Communication Division also represented the famhp in the network of communicators of the Belgian public services, COMMnet, created by the FPS P&O, as well as in the Working Group of Communication Professionals (WGCP) of the HMA.
## SOME FIGURES FOR 2013

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<th>Month in 2013</th>
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<th>03</th>
<th>04</th>
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<th>Total 2012</th>
<th>Average per month (2012)</th>
<th>Total 2011</th>
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<td>138</td>
<td>12</td>
<td>145</td>
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Note:
Figures are based on the preliminary calculation system via board tables and are therefore slightly underestimated.

### Number of brochures sent in 2013 for the campaign “Medicines and Children. Careful! Medicines are not sweets!”, after the first distribution to medical doctors, pharmacists and child health centres (of Kind en Gezin and the ONE)

<table>
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<tr>
<th>Brochure</th>
<th>FR</th>
<th>NL</th>
<th>German (De)</th>
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<tr>
<td>“Does your child have fever?”</td>
<td>5,555</td>
<td>2,356</td>
<td>120</td>
<td>8,031</td>
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<tr>
<td>“Does your child have a cough or a cold?”</td>
<td>5,545</td>
<td>2,306</td>
<td>120</td>
<td>7,971</td>
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<tr>
<td>“Does your baby suffer from burping?”</td>
<td>5,385</td>
<td>2,246</td>
<td>120</td>
<td>7,751</td>
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<tr>
<td>Posters A3</td>
<td>312</td>
<td>169</td>
<td>6</td>
<td>487</td>
</tr>
<tr>
<td>Posters A4</td>
<td>21</td>
<td>2</td>
<td>-</td>
<td>23</td>
</tr>
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</table>
The Quality Division is responsible for the internal checking, co-ordination and follow-up of all actions in relation to Total Quality Management (TQM), or more specifically with the development of the quality system. The division’s activities concern optimisation of how the famhp works, the organisation of external audits, the co-ordination of internal audits and the management of external complaints.

The division offers advice and support in all aspects of quality within the famhp.

Realisations in 2013
Given that information is essential for achieving our goals and due to the permanent evolution of our content, our agency takes pride in identifying the current changes, opportunities and risks. The famhp decided to also conduct satisfaction surveys with our partners.

• Self-evaluation of the client-focused approach
  In the first instance, the famhp conducted a self-evaluation of the client-focused approach, using the DG Organisation & Staff Development (OSD) of the FPS P&O. A list of 50 questions was put to the 22 representatives of the units and divisions. The survey was drawn up around five themes: strategy, relationship, culture, structure and results. For each of these themes there were 10 questions, including a synthesis question. The results of the self-evaluation demonstrated eight points for improvement. Consensus between the units and divisions highlighted three elements for improvement. These were essential indicators for the formulation of objectives for the famhp’s new strategic plan for 2014-2018. The three areas are:
  • Within our organisation, customer information is collated, stored, processed and used in a structured way.
  • We regularly assess the effectiveness of our various communication channels.
  • We constantly safeguard the quality delivered to the customer.

• External Inquiries
  Afin d’avoir une idée des attentes et besoins actuels de ses partenaires, l’amps a interrogé ses principaux partenaires. En préparation du lancement de la première enquête de satisfaction externe, le Comité de Direction, avec l’aide de la DG DOP, a réalisé une analyse typologique de ses partenaires. Cette analyse a permis d’identifier l’industrie et les professionnels de la santé comme groupes cibles prioritaires de ces enquêtes.

Based on the catalogue of products and services,
the Executive Council decided to focus the survey on the aspects of authorisation, controls, scientific aspects, regulation and information relating to the proper use of all medicines and health products, or therefore raw materials, medicines for human and veterinary use, medical devices, blood and human tissue material.

Two surveys were compiled.

1. External satisfaction survey, industry
In May 2013 the external satisfaction survey, industry sector, was held amongst 2,633 representatives of this sector. 427 representatives (16%) completed the survey fully. The famhp also bore in mind the 130 suggestions submitted by the industry.

Results:
• General overview of the agency
  Broadly speaking, 42% of famhp partners in the industry are happy with the services provided. They consider famhp to be a highly useful organisation, in which the client focused approach scored 40%. The famhp is considered to be a sustainable and reliable partner that meets its responsibilities, but is not flexible or innovative.
• Values of the agency
  Of the four values that were carefully selected within the famhp and which form the basis

### Profile of participants
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Companies</td>
<td>227</td>
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<tr>
<td>Company branches</td>
<td>122</td>
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<tr>
<td>Consultants</td>
<td>78</td>
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### Areas of use and processes in which participating firms and branches are involved

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<th>Areas of use and processes in which participating firms and branches are involved</th>
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</thead>
<tbody>
<tr>
<td>Medicines for human use</td>
<td>187</td>
</tr>
<tr>
<td>First application for MA for Over The Counter medicines (OTC)</td>
<td>92</td>
</tr>
<tr>
<td>First application for MA or ATMP</td>
<td>75</td>
</tr>
<tr>
<td>First application for MA for generic medicines</td>
<td>71</td>
</tr>
<tr>
<td>Application for variation to existing MA</td>
<td>134</td>
</tr>
<tr>
<td>Application for clinical trials in Belgium</td>
<td>45</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
</tr>
<tr>
<td>Medicines for veterinary use</td>
<td></td>
</tr>
<tr>
<td>First MA application</td>
<td>25</td>
</tr>
<tr>
<td>First application for MA for generic medicines</td>
<td>13</td>
</tr>
<tr>
<td>Application for variation to existing MA</td>
<td>29</td>
</tr>
<tr>
<td>Application for clinical trials in Belgium</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
</tr>
<tr>
<td>Medical devices</td>
<td></td>
</tr>
<tr>
<td>Medical devices for veterinary use</td>
<td>19</td>
</tr>
<tr>
<td>Medical devices for human use</td>
<td>187</td>
</tr>
<tr>
<td>Total</td>
<td>190</td>
</tr>
<tr>
<td>Raw materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>31</td>
</tr>
<tr>
<td>Total (excluding consultants)</td>
<td>349</td>
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</table>
of daily activities, integrity and engagement were valued most highly, with a score of 63% and 58% respectively. Adaptability scored lowest.

- Knowledge of the agency
  Results of the survey show that 72% of participants knew our mission, knew how to contact the agency via the general e-mail addresses (86%) and that they were easily able to find us online (88%). The industry representatives questioned did not seem to be aware of the fact that they had the option to submit a complaint, or of the procedure for doing so.

- Authorisation
  In terms of authorisation applications in the broad sense of the words, participants stated that they were happy with our professionalism (73%), the relevance of the information supplied (73%) and the adequate content of our legislative texts (60%).
  Our availability to them, as well as the speed of our response to their questions, could have been better.

- Moreover, they wanted to be informed in a more effective way about the progress of files, mainly in terms of minimising the handling period.

- Inspection and control activities
  The industry considered inspection and control activities to be important (75%) and was of the opinion that these were carried out in a correct and professional manner (90%). The speed with which the reports were sent could have been better.

Based on these results, the Extensive Executive Council has selected two areas for improvement in terms of our client focused approach:
- information about our products and services;
- information about open files.

2. External satisfaction survey, healthcare professionals
The second satisfaction survey was conducted amongst the famhp’s most important healthcare professionals: pharmacists, medical doctors (including specialists), veterinarians and dentists. The survey was sent out to 43,351 healthcare professionals in October 2013.

The results will be put to the Extensive Executive Council in January 2014. As with the self-evaluation and the external survey for industry, improvement issues will be identified in order to work on the continued improvement of the famhp’s services and products. The results will be used as points of inspiration for future improvement projects for the famhp’s quality system.

SOME FIGURES FOR 2013

- Improvement points follow-up
  In previous years the famhp’s operations have been regularly evaluated, such as was done by Kompas in following up quality indicators, internal research, the self-evaluation Common Assessment Framework (CAF) and the European Benchmark exercise BEMA III. Each of these evaluations lead to a series of improvement actions being implemented by the services directly involved. All of these actions, as well as the actions based on the Corrective Actions and Preventive Actions plans (CAPA) after the audits, were collated into a single scoreboard managed by the Quality Division, which ensures the follow-up of the correct implementation of these points.

At the end of 2013 the scoreboard showed 253 actions with a deadline of 2013 or later. 66 actions were completed, in line with 40% of planned activities for 2013.

The follow-up plan for the improvement actions following the BEMA III included 60 actions; thirteen of these were completed.

In terms of improvement actions following the CAF in 2012, fourteen undertakings that had been entered into and were in line with the
perception of four new famhp values, were completed.

• **The DMS for famhp quality documents**
  The documents in the DMS for quality documents or DMS Quality are regularly revised and amended, based on comments and recommendations formulated during evaluations of the quality system.

At the end of 2013, DMS Quality showed 219 SOPs, 105 of which were already approved and implemented, as well as 42 Work Instructions (WITs), of which 33 were approved and implemented.

• **Audit**
  Four new members of staff were accepted as internal auditors, increasing the initial two-man team following internal training. The internal audit plan for 2013 was followed in full. Eleven services were checked. For each of these, auditors assessed two different procedures.

As well as carrying out audits, the initial intention was to form a full and valuable team of experienced auditors and to safeguard the various services within the famhp, based on the use and follow-up of audits.

**Evolution of quality documents in 2013**

<table>
<thead>
<tr>
<th>Month in 2013</th>
<th>01</th>
<th>06</th>
<th>09</th>
<th>12</th>
<th>Total 2013</th>
<th>Total 2012</th>
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<tbody>
<tr>
<td>Planned</td>
<td>108</td>
<td>113</td>
<td>107</td>
<td>118</td>
<td>446</td>
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<tr>
<td>Ready for approval</td>
<td>11</td>
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<td>12</td>
<td>5</td>
<td>38</td>
<td>8</td>
</tr>
<tr>
<td>Approved and implemented</td>
<td>120</td>
<td>123</td>
<td>134</td>
<td>138</td>
<td>515</td>
<td>118</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>239</td>
<td>246</td>
<td>253</td>
<td>261</td>
<td><strong>999</strong></td>
<td><strong>246</strong></td>
</tr>
</tbody>
</table>
Two external audits were carried out within the B&Mc and Dispensing Divisions. The first audit related to insurance policies and the second, carried out by the FASFC, focused on the organisation and implementation of checks by the famhp on nutritional supplements and infant food, within the context of the partnership protocol between both agencies.

For each of the audits, the auditors wrote an audit report. Depending on the comments and recommendations made, the services checked submitted a CAPA-plan in which the actions on the scoreboard were included.

- External Complaints Management
  The expectations of partners and in particular patients are key to the famhp, which is why further work was carried out on the implementation of effective policy for external complaint management. The procedure for the management of external complaints was revised and now contains a full section about the management of complaints submitted to the federal ombudsman.

Famhp staff was told about the importance of this procedure via the traditional internal communication channels and via a specific folder explaining the complaints procedure.

Federal complaints logo:

Each complaint can be submitted to the famhp by post, by e-mail or via the website.

In 2013, 43 complaints were received: 6 by post, 7 by mail and 30 via the online complaints form. The average complaint handling time was 34 days.

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average time to deal with a complaint (in calendar days)</td>
<td>30</td>
<td>34 calendar days</td>
</tr>
<tr>
<td>Percentage of complaints dealt with within the set complaints handling time</td>
<td>66 %</td>
<td>55 %</td>
</tr>
<tr>
<td>Number of founded and therefore correct complaints</td>
<td>53</td>
<td>39</td>
</tr>
<tr>
<td>Number of ongoing complaints (received in 2013, but not yet processed)</td>
<td>18</td>
<td>12</td>
</tr>
</tbody>
</table>

- Number of complaints
  - about the behaviour of the acting official | 0    | 0    |
  - about the quality of the product or service | 27   | 34   |
  - about the handling (procedure) of the product or service | 8    | 4    |
  - about the way in which the complaint was handled | 1    | 1    |

- Number of complaints
  - from first to second line (Federal Ombudsman/Ombuds Service for Pensions/Comité P) | 0    | 0    |
  - that were also the subject of a case with the Council of State | 0    | 0    |
  - that were also the subject of a case with another court | 0    | 1    |

For 2014, two new projects have been introduced to improve the quality system:
- the installation of an audit committee within the agency;
- the revision of the catalogue with famhp processes and the cartography of the key processes.
In 2013 the Legal Affairs Division of the famhp was charged with various tasks, including the following:

- legal advice and information, to both internal and external parties;
- drawing up regulation;
- requests for clemency;
- litigation; follow-up and co-ordination of the defence elements;
- proposals for amicable settlements;
- requests relating to the public nature of administration.

SOME FIGURES FOR 2013

- Regulation published in 2013:
  - 21 RDs and MDs;
  - working on 4 laws and 2 decrees;
  - various nomination decisions for Committees set of the famhp.
- Circular letters: 10 letters went into circulation in 2013.
- Proposals for amicable settlements: 75
  - a proposal was made for amicable settlement of 72 files;
  - 3 files were sent directly for prosecution.
- Requests for clemency: 24.
- Requests relating to the public nature of administration: 33.
International Relations Unit

KEY TASKS

The International Relations Unit is charged with the co-ordination of internal and external information streams within a national and international context, with a view to harmonisation of Belgian perspectives at an international level.

This year, two important new legislative texts were discussed within the Council and European Parliament, both of which were of strategic importance to farnhp:

• the revision of the regulation relating to clinical trials;
• the revision of the regulation relating to medical devices.

In relation to the proposal for a regulation relating to clinical trials, the most important amendments are:

• the partnership procedure between member states if a clinical trial is to be carried out in various member states;
• the explanation of the data to be handled in terms of ethics and quality;
• the European portal for submitting applications;
• the Clinical Trial Master File (CTMF);
• the transparency of information about clinical trials.

At the end of this year an agreement was reached between three European organisations (the Council, Parliament and Commission) about the content of the text. The International Relations Unit was active in the discussions within the Council work group.

The European plan regarding medical devices focuses on checks of how notified bodies work and on the partnership between member states for inspections and aspects of vigilance. The regulation proposal relating to medical devices and in-vitro medical devices is aiming for an earlier revision or recast of the current regulation and includes:

• increase in evaluation activities for conformity and quality of medical devices prior to and during trading, including establishing criteria that includes efficacy and the cost-benefit risk balance;
• improvement measures regarding how notified bodies work, including a European system for inspection of these;
• vigilance and traceability with unique identification of each medical device;
• certain aesthetic devices being subject to control systems for medical devices;
• transparent working of notified bodies;
• increase in checks on manufacturers, representatives and importers;
• optimisation of information in the European database for medical devices, EUDAMED,
including access for the public and use of medical devices and categorisation of medical devices for any new form of use.

The International Relations Unit is active in discussion at the Council work group level. In order to make this file as effective as possible at Belgian level, an information platform was set up with other involved governments, such as RIZIV-INAMI, WIV-ISP, the Federal Centre for Health Care (CHC), FPS Economy, including BELAC, DG Living Environment of the FPS Public Health and the Permanent Representative. During this information sharing, the Belgian perspective was established, proposals to text amendment were put forward and feedback was given from the Council meetings.

The International Relations Unit is also active within two European work groups:

- the Taskforce on Falsified Medicines of the HMA, that directs the further implementation of directives relating to the fight against fraudulent medicines;
- the EMA work group that deals with the problems of unavailable medicines: Working Group on Medicinal Products Shortages.

**MLM-MCH AND BLOOD**

**MCH et Sang**

Activities relating to these two categories of health products are co-ordinated within the Chief Executive Officer’s services.

**Key tasks**

Activities relating to MLM-MCH and blood are handled by various divisions within the famhp:

- the Vigilance Division (pharmaco, materio, haemo, bio) of DG POST authorisation,
- the Industry and Authorisations Divisions of DG INSPECTION,
- the Legal Affairs Division of the Chief Executive Officer’s services.

The Industry Division of DG INSPECTION operates inspections of all MLM-MCH organisations: MLM-MCH banks including fertilisation centres, production organisations and intermediary structures for MLM-MCH and the BI. Inspectors are authorised to carry out all necessary checks, to formulate comments and, where necessary, draw up minutes. Their advice is important for the delivery, extension, suspension or revocation of a recognition.

The Authorisations Division of DG INSPECTION works to prepare accreditation decisions for the BI for the minister in charge. In order for an accreditation to be...
granted, the following things must be born in mind:
- principal investigation into the accreditation application or request to extend the accreditation with documentary management, and if necessary any request for additional information;
- follow-up of an inspection (the inspector’s conclusion);
- publication of an accreditation outcome in the BS-MB;
- provision of information via the website as well as specific to European organisations.

As well as supplying accreditation, this division is charged with tasks such as:
- management of the MCH-MLM mailbox in which various questions arise from the public and sector;
- creation of statistics about activities of MLM-MCH organisation and the Bi:
  - amendments to overview tables with MLM-MCH and blood activities that are published on the website;
  - analysis of annual activity reports and financial reports of MLM-MCH organisations and BB (principal investigation);
- handling external questions, including from the European Commission, or questions from other famhp divisions;
- participating in the work group on cells and tissue for the Superior Health Council (HGR-CSS);
- working on the Eurocet 128 project for the coding of cells and tissues at European level;
- working on the approval procedure of an application file for a new accreditation or for granting accreditation;
- automating document management for each MLM-MCH organisation or BB;
- revision of the activity report for fertility centres or MLM-MCH banks working with reproductive MLM-MCH, with a view to the simplification and increased readability/comprehension.

The Vigilance Division (pharmaco, materio, haemo, bio) of DG POST authorisation works to safeguard the quality and safety of blood and blood components of human origin and of MLM-MCH. Serious adverse reactions in donors and recipients and serious undesirable lapses in safety or quality of blood components and MLM-MCH or which may influence the safety of donors, are registered and evaluated. Recommendations will be formulated based on this information. In 2013 information sessions were organised to explain the information gathered and the recommendations made. A brief overview of the haemovigilance data was passed to the European Commission, as is done every year, as well at the European Council, for comparison with haemovigilance data from other member states.

Informative memos were written and sent to BB and MLM-MCH organisations about precautionary measures in the selection of donors in the event of outbreaks including transmissible infectious complaints, such as the West Nile Virus.

The Legal Affairs Division works to draw up legislative and regulatory texts about MLM-MCH and to provide legal advice about the correct use thereof.

The following legislative projects are almost completed:
- the RD relating to bio-banks;
- various refinements to the act of 19 December 2008 relating to the acquisition and use of MLM-MCH with a view to the medical use on humans or scientific research, via the preliminary draft relating to various health stipulations;
- amendment to the act of 6 July 2007 concerning medically assisted procreation and the use of excess embryo and gametes;
- the RD that production organisations must permit the acquired MLM-MCH be tested by them from now on;
- the RD to overturn Directive 2012/39/EU of the
Committee of 26 November 2012 to amend Directive 2006/17/EG in respect of certain technical conditions for testing human cells and tissue;
• the draft ministerial decree (MD) to amend the MD of 14 October 2009 to set the price of MLM-MCH.

The RD to amend the RD of 28 June 2009, to amend the RD of 4 April 1996 concerning the taking, preparation, storage and use of blood and blood derivatives of human origin, was published on 17 June 2013 and has since come into effect on 25 June 2013.

SOME FIGURES FOR 2013

In the course of 2013, 64 applications for accreditation were submitted by existing organisations, while one new organisation submitted one accreditation application.
On 31 December 2013 there were 136 MLM-MCH organisations in our country.

During the course of the year, after inspection:
• 33 accreditations were granted;
• 1 accreditation was rejected.

Two organisations stopped their activities.
The remaining organisations have current accreditation or temporary accreditation until the introduction of a decision regarding their accreditation application.

In 2013, 77 inspections were carried out:
• 53 for MLM-MCH organisations;
• 24 for BB.

In 2013, the famhp received 989 reports of serious adverse reactions and cases relating to haemovigilance, as well as 47 relating to biovigilance.
Each week the blood organisations in our country provide the famhp with information about the blood stocks (erythrocyte concentrates) that they have available for supply to hospitals. Based on this information, an overview is drawn up of the total available blood stock and published on the famhp website, enabling people to follow the evolution of blood stocks, as well as the stock levels (optimal, critical). Each month an analogue overview is published of the number of erythrocyte concentrates distributed by the BBs and their distribution according to ABO/resus. This makes it possible to follow the evolution of the blood distribution.

In 2013 the Human Tissue Material Co-ordination was invited to give presentations on two international conferences and worked on bringing out the first Guide to the Quality and Safety of Tissues and Cells for Human Application of the EDQM of the European Council, published in 2013.

Since 2011, within the context of haemovigilance, a computer system has been used for online reporting of adverse reactions to do with blood and blood components. Thanks to improvements in the application, the system is now used by more than 95% of rapporteurs and 100% of BBs.
A NUMBER OF BUDGETARY ELEMENTS

2013 BUDGET

The 2013 budget of the famhp, as approved by parliament, was 77,664,727 euro in income and 78,883,191 euro in expenditure. The income included government endowment (19,489,305 euro) paid by the FPS Public Health.

REALISED INCOME FOR 2013 AND ITS DISTRIBUTION

In 2013 the realised income was 67,900,476 euro. This is in line with an income level 13% lower than the budget deposited. This income is comprised of our own income of 49,114,476 euro as well as the endowment paid of 18,786,000 euro. Our own income represents some 72% and the endowment 27% of the total income.

Analysis of our own income shows that 42% of this is made up of contributions and 58% from retributions or fees for service. Depending on the various regulation and guidelines, these taxes are mainly collected based on the number of packages of medicines and raw materials sold, on the turnover realised from medical devices or the number of MAs.

At our own income level there is also a special fee from the European Medicines Agency (EMA) for reimbursement of activities by the famhp at European level and this amounts to 3,845,180 euro.

Two other significant expenses were for checking and analysis tasks for medicines and for IT costs. These costs amounted respectively to 4,578,946 euro or 7% of the expenditure and 4,590,283 euro, or 7% of the expenditure.

Finally, two levies collected by the famhp that relate to medical devices are transferred integral to the RIZIV-INAMI. This amounts to a zero amount for the famhp. For 2013 these levies amounted to 5,530,644 euro, or 8% of the expenditure.

REGISTRATION OF THE TRANSACTIONS AND ACCOUNTING PRINCIPLES

Since the establishment of the agency, the B&Mc Division has performed double accounting and this is not only to meet the regulatory requirements, but also to ensure a transparent view of the various incoming and outgoing financial flows. This allows respective parties to have a clear view of the famhp’s financial operations. All expenditure and income are grouped within the same IT systems in order that they can be generated in a fast and straightforward way from the accounting system.

Famhp expenditure for 2013 was comprised of 4,900 invoices. These invoices were checked and, once approved, entered into the accounting system. Payment is made automatically (after two electronic

In terms of the various taxes, the taxes on packaging, the so-called “30 centimes and 15 centimes”, resulted in 5,379,918 euro, which amounts to 26% of the taxes. Another important tax is that one levied on packaging, the so-called “50 centimes”, that resulted in 4,721,277 euro or 23% of the taxes. This final tax, however, does not contribute to the agency’s financing, but is entirely intended for the (re-)control or permanent monitoring of medicines.

GENERAL EXPENDITURE FOR 2013 AND THE DISTRIBUTION THEREOF

The expenditure for 2013 amounted to 65,252,863 euro, of which 27,802,275 was for personnel costs (statutory and contractual), being 43% of the expenditure.

Another significant expense was the payment of the allowance for financing NAT blood tests (nucleic acid amplification test), amounting to 7,964,557 euro or 12% of expenditure.

Two other significant expenses were for checking and analysis tasks for medicines and for IT costs. These costs amounted respectively to 4,578,946 euro or 7% of the expenditure and 4,590,283 euro, or 7% of the expenditure.

Finally, two levies collected by the famhp that relate to medical devices are transferred integral to the RIZIV-INAMI. This amounts to a zero amount for the famhp. For 2013 these levies amounted to 5,530,644 euro, or 8% of the expenditure.
signatures) and within the month via the Isabel payment system.

Our own income for 2013 was comprised of 14,965 payments to eight bank accounts, to which specific revenues were deposited. These included accounts for receipts of EMA, research and development (R&D), medicated feeds, taxes on the number of packages and an account for a variety of fees.

After receipt of the liquidities, these are entered as income for the proper turnover. This turnover is then debited from the fee for each service request submitted. In 2013 this was done by recording 21,006 virtual sales invoices in automated logs. Entry of these is carried out manually. Information about entries, such as the agreement about fees and the respective service requests, is done mainly from the MeSeA system (Medicines electronic Submission and electronic Approval), more specifically via the public inbox payment tracking. The appropriation data not included in MeSeA are communicated the traditional way via administrative forms and financial files that come from the various divisions within the agency.

![Overview of income 2011, 2012 & 2013 (exclusive endowment)]
Overview of famhp expenditure 2011, 2012 & 2013

2013 famhp income (exclusive endowments)

- 45%
- 42%
- 11%
- 9%
- 22%

Overview of famhp expenditure 2011, 2012 & 2013

- NAT blood tests subsidy
- Controle and analysis medicines
- ICT expenditure
- Personnel costs
- Other expenditure
- Transfer RIZIV-INAMI

fahmp expenditure 2013

- NAT blood tests subsidy
- Controle and analysis medicines
- Transfer RIZIV-INAMI
- ICT expenditure
- Personnel costs
- Other expenditure
### The 2013 budget in euro

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Income</strong></td>
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<td></td>
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<td>Endowment</td>
<td>19,010,000</td>
<td>19,016,000</td>
<td>19,448,000</td>
<td>19,448,000</td>
<td>19,489,305</td>
<td>18,786,000</td>
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<tr>
<td>Reserves used</td>
<td>1,669,576</td>
<td>-999,060</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Own income</td>
<td>35,936,938</td>
<td>36,036,412</td>
<td>41,384,788</td>
<td>38,529,783</td>
<td>58,175,422</td>
<td>49,114,476</td>
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<td><strong>Total</strong></td>
<td>56,616,514</td>
<td>54,053,352</td>
<td>60,832,788</td>
<td>57,977,783</td>
<td>77,664,727</td>
<td>67,900,476</td>
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<td><strong>Expenditure</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Expenditure for personnel (salary and social security contributions)</td>
<td>26,101,246</td>
<td>23,131,679</td>
<td>29,512,246</td>
<td>25,878,955</td>
<td>31,572,741</td>
<td>27,802,275</td>
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<td>Other personnel costs</td>
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<td>975,477</td>
<td>1,067,000</td>
<td>1,140,793</td>
<td>1,366,734</td>
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<td>Non-ICT expenses</td>
<td>15,522,806</td>
<td>15,243,725</td>
<td>17,954,082</td>
<td>13,831,659</td>
<td>21,263,541</td>
<td>18,039,092</td>
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<td>ICT expenses</td>
<td>3,553,312</td>
<td>4,891,772</td>
<td>3,695,523</td>
<td>2,608,484</td>
<td>4,615,523</td>
<td>4,590,283</td>
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<td>Non-ICT capital expenses</td>
<td>76,500</td>
<td>74,148</td>
<td>76,499</td>
<td>40,741</td>
<td>85,704</td>
<td>29,615</td>
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<td>ICT capital expenses</td>
<td>408,000</td>
<td>206,611</td>
<td>408,000</td>
<td>50,836</td>
<td>228,000</td>
<td>205,371</td>
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<td>NAT blood test subsidy</td>
<td>10,087,649</td>
<td>9,529,940</td>
<td>9,994,891</td>
<td>9,994,891</td>
<td>9,891,794</td>
<td>7,964,557</td>
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<tr>
<td>RIZIV-INAMI Tax</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>9,859,154</td>
<td>5,530,644</td>
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<td><strong>Total</strong></td>
<td>56,616,513</td>
<td>54,053,352</td>
<td>62,708,241</td>
<td>53,546,359</td>
<td>78,883,191</td>
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</table>
Personnel Information

A variety of projects were set up in 2013 following the satisfaction survey conducted in 2012 amongst famhp staff and in line with the resulting action plan. In particular the internal market project in which every famhp job vacancy is first made known to internal staff that may be eligible to apply, enabling contracted and statutory staff to revitalise their career within the famhp.

23 selections started up in 2013 and a large number of selections were completed, including bilingual selections of inspector and inspector engineer within the context of the PMH-PDM.

SOME FIGURES

Number of employees

Distribution by statute
Distribution by language group

Distribution by level
Evolution of fulltime equivalents (ftes) in 2013

Distribution by ftes
Personnel costs

<table>
<thead>
<tr>
<th>Month</th>
<th>Personnel Costs</th>
<th>Holiday Premium</th>
<th>End of Year Premium</th>
<th>Variations, recalculations by the CDVU*</th>
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<td>1,174€</td>
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<td>02-2013</td>
<td>1,994€</td>
<td>1,161€</td>
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<td>03-2013</td>
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<td>04-2013</td>
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<td>05-2013</td>
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<td>06-2013</td>
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<td>07-2013</td>
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<td>09-2013</td>
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<td>10-2013</td>
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<td>09-2014</td>
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<td>11-2014</td>
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<tr>
<td>12-2014</td>
<td>1,976€</td>
<td>0€</td>
<td>0€</td>
<td>0€</td>
</tr>
</tbody>
</table>

Statutory
Contractual
Total personnel costs 2013 (statutory + contractual)
Total projects 2013
Total 2013

*Note: CDVU is the centralised service of the FPS Finances that pays the salaries of civil servants.

Total personnel costs and projects for 2013: 27,898,798,06€
Total personnel costs and projects for 2012: 24,405,738,43€
Total personnel costs and projects for 2011: 23,413,528,07€
THE THREE COMMITTEES OF THE FAMHP

SCIENTIFIC COMMITTEE

In 2013 the Scientific Committee focused on different themes: transparency of information and the declaration of interests of the experts, the experts database, follow-up of the development of the guideline regarding clinical trials, situation follow-up about the quality guarantee of materials for pharmacy made and officinal preparations, especially for those used in very small amounts.

The famhp is legally obliged to make the agendas, the minutes, the regulation and the interests of the members of all commissions public. These are published on the website of the famhp. Possible conflicts of interest of the commission members and of internal as well as external experts responsible for the assessments for the famhp are checked for every file. Hereby a balance has to be found between conflicts of interest and a qualitative scientific expertise.

The Scientific Committee also reflected about its role within a changing agency, for example because of the planned restructuring of the Commission for medicines for human use, and the possible implications of it for the other commissions and involved experts. The Scientific Committee wishes to keep playing and to reinforce further its transversal role by cooperating within therapeutic domains and around scientific themes that are crucial for the agency.

CONSULTATIVE COMMITTEE

In 2013 the Consultative Committee gathered twice. During these meetings a state of affairs was given about current themes. Thus the following themes were discussed in 2013:
- the new European regulatory framework for pharmacovigilance for human use which entered into force in July 2012 and the transposition of it into Belgian law;
- the new European regulation about clinical trials and the illustration of the discussions at the level of the European Council and the European Parliament;
- the transposition of the guideline about counterfeit medicines into national law;
- the progress of the Medical Devices Plan of the Minister of Public Health.

The main items of the plenary meetings were:
- the budget 2012 (final statement) and the follow-up of the budget 2013;
- the follow-up of the staff and recruitment plan 2013;
- the preparation of the budget 2014;
- the progress of the PMH-PDM of the Minister of Public Health;
- the pilot project auto control in the area of the medical devices. The stakeholders support the principle;
- the strategic plan of the famhp (presentation of its general direction);
- the establishment of an audit committee within the famhp.

An advice was given to the Minister of Public Health for the preliminary budget design for 2014. The members request among others to:
- let the famhp manage its staff in a more autonomous and flexible way with reference to the advice of 2012;
- use the built up reserves to help finance new initiatives. All stakeholders will engage themselves to come to a balanced financing according to the fee for service principle from 2015.

TRANSPARENCY COMMITTEE

In 2013 the Transparency Committee gathered five times. On 18 April 2013 Johan Eykens and Jan Depoorter were elected as respectively chairman and vice-chairman.

The new members of the Transparency Committee were officially appointed on Monday 25 March 2013 by publication in the Belgian Official Journal (BS-MB). The members of the committee are appointed for a period of four years and their appointment can be renewed.
- execute the financing for the sector of the pharmacovigilance in a phased way (for 2014 = 1/3rd of the requested investment from the reserves and from 2015 a financing by the stakeholders according to the fee for service-principle);
- execute the financing from the reserves for the restructuring of the Commission for medicines for human use, the project Unmet Medical Need, the restructuring of the clinical trials and the further extension of the spearhead by applying the 1/3rd principle with a phasing over the following years.

Discussions between the sector, the strategic entities and other political responsibilities led to a proposition to start three projects in 2014 regarding the development phases of a medicine, namely Unmet Medical Need, the reinforcement of the EARLY PHASE DEVELOPMENT spearhead and the renewed Commission for medicines for human use.

By means of article 34 of the law of 30 July 2013, the famhp will be able to use in 2014 under certain conditions a part of its financial reserves.

The committee is a body where co-operation and transparency with the stakeholders are the key words. Fee for service is important.
THE SPEARHEADS OF THE FAMHP

EARLY PHASE DEVELOPMENT SPEARHEAD

The number of clinical trials in an early phase remains relatively constant in Belgium. For 2013 we note, on a total of 559 new clinical trials, 146 phase I-trials of which 33 trials with a first administration to humans. The time necessary to evaluate the requests for clinical trial for phase I which was short in the past in Belgium, remained also in 2013 below the statutory time frame of 15 calendar days in the vast majority (95.2%) of the cases. On average, 11.4 days were needed for assessment. With this, Belgium remains with the leaders in Europe, for the number of trials as well as for the treatment time needed.

The inspection activities in the domains of the Good Clinical Practices (GCP) and of the Good Manufacturing Practices (GMP) of early phase development were extended further. All classic phase I-research units that reported themselves with the famhp, were visited by our inspectors. Globally there were no critical shortcomings on the sites. Of course recommendations were formulated to improve where necessary. The introduction of circular letter 596, regarding the application of GMP for production activities in the practice of the clinical trials, was realised with this.

Another important step in 2013 is the reconfirmation of the EARLY PHASE DEVELOPMENT spearhead as an important strategic interest area. This decision contains a clear engagement of the famhp to proceed on the chosen path, to expand our commitment with the early phase development further and to keep delivering efforts to improve this kind of research. Hereby there will certainly be attention for the further improvement of the quality where necessary and we will strive to maintain it where it is already optimal.

At the end of 2013 a survey was organised with the partners involved: firms, researchers, sponsors or independent contract research organisations or Clinical Research Organisations (CRO’s), academic centres and hospital pharmacies. We received until now 25 reactions to this. Questions were asked about the obstacles and barriers for performing early phase trials, the needs of the stakeholders and the possibilities for the famhp to play a facilitating role. Of course the answers will be used to adjust our goals for 2014.

VACCINES SPEARHEAD

The VACCINES spearhead is situated in the domain of the assessment of data about vaccines, ranging from quality data to non clinical and clinical data, for example for requests for marketing new vaccines or formulating scientific advices to companies regarding their development of vaccines.

2013 meant perpetuating the network and the co-operations:
  • there was a lot of attention for the internal co-operation between the DG PRE authorisation and the DG POST authorisation when analysing notifications of possible adverse reactions or undesired effects after administering a vaccine, and with the DG INSPECTION to co-ordinate the recall of a vaccine and to assess the implications of it on a global scale;
  • the network with the external partners was expanded further;
  • the famhp got more attention through numerous national co-operations with other authorised institutions such as the Hoge Gezondheidsraad (HGR), the RIZIV-INAMI, academic centres, the Vlaams Agentschap Zorg en Gezondheid, and the Walloon and Brussels Regions. The co-operation with the Wetenschappelijk Instituut voor de Volksgezondheid (WIV-ISP) focuses on the quality aspects of vaccines on the one hand and on the epidemiology on the other of infectious diseases that can be prevented by vaccination. The co-operation with the Federaal Kenniscentrum voor Gezondheidszorg (KCE) accentuates the socio-economical analysis of the implementation of vaccination schemes in Belgium;
on a European scale this spearhead was acknowledged through the Belgian representation within the EMA, like in:
- the Committee for Medicinal Products for Human use (CHMP);
- the working group for vaccines, the Vaccines Working Party (VWP). Besides the official representation, internal assessors from different disciplines, quality, non-clinical and clinical, follow up the work of the VWP;
- the Paediatric Committee (PDCO), especially for the assessment of the paediatric development plan for vaccines;
- the working group biological medicines or Biologics Working party (BWP);
- the working group about safety aspects or Safety Working Party (SWP);
- the working group scientific advices or Scientific Advice Working Party (SAWP);
- even on a global scale the VACCINES spearhead led to important activities in 2013:
- through the co-operation with the World Health Organization (WHO) in the framework of the WHO Expanded Program on Immunization (EPI) for making vaccines available for use outside of the European Union (EU), and in the framework of the Global Polio Eradication Initiative (GPEI) for the transition of the trivalent to the bivalent oral polio vaccine in the primary vaccination scheme;
- the educational contribution to the Fondation Mérieux and to the Cours international francophone de vaccinologie (CIFV), an advanced professional Master in Public Health and International Public Health, accredited by the TropEd (European Network for Education in International Health), a network of European universities regarding tropical medicine.

ONCOLOGY SPEARHEAD

In 2013 the activities of the ONCOLOGY spearhead were mainly centred on the domain of research and development (R&D). These activities include Clinical Trial Applications (CTA’s), national and European scientific advice (WIA’s), activities in the framework of national and European regulations for paediatric medicines and the UMN issue. Additionally, the famhp was assigned in 2013 for the first time the co-rapporteurship for a MA application through the central authorisation procedure or Centralised Procedure (CP) for an oncology medicine (olaparib, for the treatment of ovarian cancer) and the rapporteurship for a CP for an oncology medicine (Lenvima, for the treatment of thyroid cancer) that will start in 2014.

Some specific figures/facts for 2013:
- 75 applications for CTA’s for oncology medicines were filed with the famhp, especially for phase I-III clinical trials (proportional distribution), of which several with ATMPs;
- 5 applications for Compassionate Use (CU) and 14 requests for Medical Need Programs (MNP’s) were approved;
- Belgium delivered the co-ordinator for 13 European oncology WTAs, of which 3 for biosimilar medicines;
- on a national level 3 WTAs were treated for oncology medicines;
- activities in the framework of the regulation for paediatric medicines:
  - rapporteur Paediatric Investigation Plans: 18;
  - peer review Paediatric Investigation Plans: 8;
  - non-clinical topic leader that assesses the non-clinical data of an application and presents the result to the Non-Clinical Working Group of the PDCO: 14;
  - Art. 45 Regulation N° 1901/2006 which provides that all data about old off-patent products that were never filed with an authorised institution to be assessed, have to be assessed by the nationally authorised institutions and the SPC adjusted if necessary, files as rapporteur: 2;
- in co-operation with the EMA, the non-clinical team also collaborates with a project to assess the impact of juvenile animal testing on the development of oncology medicines for children;
- regarding contacts with the involved industry, three portfolio meetings were organised in 2013.
The ONCOLOGY spearhead was represented at different national and international forums:

- Paediatric oncology taskforce of the PDCO;
- 15th Annual Meeting of the Belgian Society of Medical Oncology 2013 (BSMO), 01-02.03.2013;
- International Ovarian Tumour Analysis (IOTA), 26-27.04.2013, KULeuven,
- 16th Post-ASCO Meeting 2013 meeting, 29.06.2013;
- Symposium 25 Years of medical oncology, 13.09.2013, Cliniques Universitaires Saint-Luc;
- 17th European Cancer Congress (Amsterdam), 27.09.2013 – 01.10.2013;

The co-operation of the ONCOLOGY spearhead with the Cancer centre was further perpetuated in 2013 by the participation of the famhp to the project personalised medicine and will be continued in 2014.

The co-operation with the RIZIV-INAMI was also continued, among others by the participation to activities of the Begeleidingscomité Immunotherapie for the treatment of melanoma and glioma and by co-operating to the final assessment report of the expert working group established in the framework of the MNP Avastin in glioblastoma.

For 2014 the focus remains on the R&D-related activities combined with an increased involvement with the CP of oncology drugs.
INTERNATIONAL REPRESENTATION IN 2013

DG PRE AUTHORISATION

The DG PRE authorisation plays an important role in stimulating innovation, giving scientific advice (STA), evaluating clinical trials and treating applications for awarding a marketing authorisation (MA) for medicines for human and veterinary use. For medicines for human and veterinary use that are also authorised through the central authorisation procedure (CP), the DG PRE authorisation is also responsible for the follow-up of the changes to the MA or variations. The scientific assessment of the data that support the different types of applications is generally performed within the DG PRE authorisation, also if the application was filed in another DG. With this assessment European guidelines and directives are used, independent from the fact whether it’s about a national or European procedure.

It is extremely important that the DG PRE authorisation closely follows the scientific evolutions and evolutions in the regulations and assures on a European level a relevant active input in the discussions in that area. The DG PRE authorisation is also permanently represented in most European scientific committees and associated working groups. European evaluation tasks, for example as a rapporteur of the CP or as a co-ordinator in the European procedure for WTA, can only performed in an acquired and efficient way if the DG PRE authorisation is present in the relevant committees and working groups.

DG POST AUTHORISATION

The DG POST authorisation is in its turn represented in different European committees or working groups that work in the area of vigilance and proper use of medicines and health products. By this participation we always remain informed about the developments regarding medicines, medical devices, blood, cells and tissues. The Belgian knowhow is shared with our European colleagues and the consultation ensures a better harmonisation.

DG INSPECTION

In the framework of the harmonisation of inspection and control activities and the battle against pharmaceutical criminality, the employees of the DG INSPECTION are represented in international forums with other international authorised institutions.

Hereby an overview of a number of internal employees that represent our agency in the most frequent international committees, working groups and other platforms (info for 2014).
### EMA Management Board (EMA MB)

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Xavier De Cuyper</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>Greet Musch</td>
<td>DG PRE authorisation</td>
</tr>
</tbody>
</table>

### EMA Committees

**Committee for Advanced Therapies – CAT**
- Claire Beuneu (DG PRE authorisation)
- Belaid Sekkali (DG PRE authorisation)

**Committee for Medicinal Products for Human Use – CHMP**
- Christophe Focke (DG PRE authorisation)
- Valerie Lescrainier (DG PRE authorisation)
- Daniel Brasseur
- Bart Van Der Schueren
- Karima Ourdache (DG PRE authorisation)

**Committee for Medicinal Products for Veterinary Use – CVMP**
- Frédéric Klein (DG PRE authorisation)
- Bruno Urbain (DG PRE authorisation)

**Committee for Orphan Medicinal Products – COMP**
- André Lhoir (CEOs)

**Committee on Herbal Medicinal Products – HMPC**
- Gert Laekeman
- Heidi Neef (DG PRE authorisation)
- Wim Vervaet (DG PRE authorisation)

**Paediatric Committee – PDCO**
- Jacqueline Carleer (DG PRE authorisation)
- Koen Norga

**Pharmacovigilance Risk Assessment Committee – PRAC**
- Jean-Michel Dogné
- Veerle Verlinden (DG PRE authorisation)

### CHMP/CVMP Working Parties

**Joint CHMP/CVMP Quality Working Party – QWP (Standing Working Party)**
- Katrien Van Landuyt (DG PRE authorisation)
- René Hanselaer (DG PRE authorisation)

**Joint CVMP/CHMP ad hoc Working Group on the application of the 3Rs (Replacement, Reduction and Refinement) in the development of medicinal products (Temporary working party)**
- Sonja Beken (DG PRE authorisation)

### CHMP Working Parties

**Biologics Working Party – BWP (Standing Working Party)**
- Alan Fauconnier (DG PRE authorisation)

**Safety Working Party – SWP (Standing Working Party)**
- Sonja Beken (DG PRE authorisation)
- Karen De Smet (DG PRE authorisation)

**Scientific Advice Working Party – SAWP (Standing Working Party)**
- Minne Gasteels
- Dieter De Moor
- Walter Janssens (DG PRE authorisation)

### Similar Biological (Biosimilar) Medicinal Products Working Party – BMWP (Temporary Working Party)
- Karen De Smet (DG PRE authorisation)

### Vaccine Working Party – VWP (Temporary Working Party)
- Daniel Brasseur
- Karen De Smet (DG PRE authorisation)

### EMA and its Working groups

**EudraCT**
- Kristof Bonnarens (DG PRE authorisation)
- Erik Everaert (DG PRE authorisation)
- Pieter Vankeerberghen (Ss)

**EudraGMP**
- Pieter Vankeerberghen (Ss)

**EudraLink**
- Nicolas Leroy (Ss)

**Eudranet**
- Nicolas Leroy (Ss)

**EudraPharm**
- Godefroid Wokala Libambu (Ss)

**EudraVigilance Human**
- Nicolas Leroy (Ss)
- Olivier Bouffeux (DG POST authorisation)
- Dieter Conens (DG POST authorisation)

**EudraVigilance Veterinary**
- Els Dewaele (DG POST authorisation)
- Nicolas Leroy (Ss)

**Eur**
- Pieter Vankeerberghen (Ss)

**GCP Inspectors Working Group**
- Dominique Delforge (DG INSPECTION)
- Sarah T’kindt (DG INSPECTION)

**GMP/GDP Inspectors Working Group**
- Karin Froidbise (DG INSPECTION)
- Catherine Planchon (DG INSPECTION)
- Wim Van Linden (DG INSPECTION)
<table>
<thead>
<tr>
<th>Group Name</th>
<th>Chairs/Representatives</th>
</tr>
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<tbody>
<tr>
<td>Homeopathic Medicinal Products Working Group – HMPWG</td>
<td>Marie-Anne Mouyart (DG PRE autorisation) Patricia Bodart (DG PRE autorisation)</td>
</tr>
<tr>
<td>Telematics Support Group</td>
<td>Magali Durieux (Ss) Pieter Vankeerberghen (Ss)</td>
</tr>
<tr>
<td>Working Group of Communication Professionals – WGCP</td>
<td>Ann Eeckhout (CEOs)</td>
</tr>
<tr>
<td>Working Group of Enforcement Officers – WGEO</td>
<td>Roy Vancauwenbergh (DG INSPECTION)</td>
</tr>
<tr>
<td>Working Group of Quality Managers (WGQM)</td>
<td>Christelle Beeckmans (CEOs) Véronique De Troyer (CEOs)</td>
</tr>
<tr>
<td>Council of Europe</td>
<td></td>
</tr>
<tr>
<td>Committee of Experts on the Classification of Medicines as Regards their Supply – CD-P-PH/PHO</td>
<td>Eline Vanderbiest (DG POST autorisation)</td>
</tr>
<tr>
<td>European Committee on Blood Transfusion – CD-P-TS</td>
<td>Ludo Muylle (DG POST autorisation)</td>
</tr>
<tr>
<td>European Committee on Organ Transplantation – CD-P-TO</td>
<td>Leen Coene Ludo Muylle (DG POST autorisation)</td>
</tr>
<tr>
<td>European Committee on Pharmaceuticals and Pharmaceutical Care – CD-P-PH</td>
<td>Josiane Van der Elst (DG INSPECTION)</td>
</tr>
<tr>
<td>Committee of Experts on minimising the public health risks posed by counterfeiting of medical products and related crimes – CD-P-PH/CMED</td>
<td>Roy Vancauwenbergh (DG INSPECTION)</td>
</tr>
<tr>
<td>Committee of Experts on quality and safety standards in pharmaceutical practices and Pharmaceutical Care – CD-P-PH/PC</td>
<td>Tom Brusselmans (DG INSPECTION)</td>
</tr>
<tr>
<td>European Pharmacopoeia Commission</td>
<td>Katrien Van Landuyt (DG PRE autorisation)</td>
</tr>
<tr>
<td>Council of European Ministers</td>
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<tr>
<td>Working Party on Pharmaceuticals and Medical Devices</td>
<td>Els Geeraerts (CEOs) Ad hoc experts</td>
</tr>
<tr>
<td>European Commission</td>
<td></td>
</tr>
<tr>
<td>Ad-hoc Group on Clinical Trials</td>
<td>Greet Musch (DG PRE autorisation) Kristof Bonnarens (DG PRE autorisation)</td>
</tr>
<tr>
<td>Central Management Committee – CMC</td>
<td>Vanessa Binamé (DG POST autorisation) Anne Van Nerom</td>
</tr>
<tr>
<td>(Invented) Name Review Group – NRG (Associated groups) (Standing Working Party)</td>
<td>Vanessa Binamé (DG POST autorisation) Valerie Leschamier (DG PRE autorisation) Valerie Willox (DG PRE autorisation)</td>
</tr>
<tr>
<td>Pharmacovigilance Inspectors Working Group – PhV IWG</td>
<td>Christophe Debryne (DG INSPECTION) Nele Matthijs (DG INSPECTION)</td>
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<tr>
<td>Process Analytical Technology Team – PAT Team</td>
<td>Catherine Planchon (DG INSPECTION) Wim Van Linden (DG INSPECTION)</td>
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<tr>
<td>Virtual Advertising Network</td>
<td>Alain Denis (DG INSPECTION)</td>
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<tr>
<td>EU Telematics Controlled Terms – EUTCT</td>
<td>Pieter Vankeerberghen (Ss)</td>
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<tr>
<td>TIGes-veterinary subgroup</td>
<td>Pieter Vankeerberghen (Ss)</td>
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<tr>
<td>HMPC Working party</td>
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<tr>
<td>Quality Drafting Group – DG Q (Temporary Working Party)</td>
<td>Heidi Neef (DG PRE autorisation)</td>
</tr>
<tr>
<td>HMPC Working Party on Community Monographs and Community Lists (MLWP) (Standing working party)</td>
<td>Gert Laekeman Arnold Vlietinck</td>
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<td>PDCO Working party</td>
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<tr>
<td>Non-Clinical Working Group</td>
<td>Jacqueline Carleer (DG PRE autorisation)</td>
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<tr>
<td>Paediatric Formulation Working Group</td>
<td>Isabelle Delneuville</td>
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<tr>
<td>HMA and its Working groups</td>
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<tr>
<td>Working Group implementation of the AMR Revised Action Plan</td>
<td>Greet Musch (DG PRE autorisation)</td>
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<tr>
<td>HMA Management Group – HMA-MG</td>
<td>Xavier De Cuyper, Chief Executive Officer</td>
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<tr>
<td>Clinical Trials Facilitation Group – CTFG</td>
<td>Kristof Bonnarens (DG PRE autorisation) Greet Musch (DG PRE autorisation)</td>
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<tr>
<td>Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human – CMDh</td>
<td>Sophie Coly (DG PRE autorisation) Katrieljne Van Keymeulen (DG PRE autorisation)</td>
</tr>
<tr>
<td>Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary – CMDv</td>
<td>Valerie Van Merris (DG PRE autorisation)</td>
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<tr>
<td>EMA COLEX</td>
<td>Steven Hippe (CEOs)</td>
</tr>
<tr>
<td>Task Force on Improvement of Veterinary Medicines Legislation</td>
<td>Greet Musch (DG PRE autorisation)</td>
</tr>
<tr>
<td>Heads of Medicines Agencies – HMA</td>
<td>Xavier De Cuyper, Chief Executive Officer Els Geeraerts (CEOs)</td>
</tr>
</tbody>
</table>
| Competent Authorities for Medical Devices (CAMD) | Vanessa Binamé (DG POST autorisation)  
| Anne Van Nerom |
| Electronic Labelling Working Group | Frédérique Meulders (DG POST autorisation) |
| Eudamed Working Group | Damien Lambot (DG POST autorisation)  
| Frédérique Meulders (DG POST autorisation)  
| Philippe Scohy (SS)  
| Anne Van Nerom |
| Medical Devices Expert Group on Borderline and Classification | Frédérique Meulders (DG POST autorisation)  
| Anne Van Nerom |
| Meeting of the Competent Authorities for blood and blood components | Ludo Muylle (DG POST autorisation) |
| Competent Authorities for TISSUES AND CELLS | Ludo Muylle (DG POST autorisation) |
| Medical Devices EXPERT Group – MDEG | Frédérique Meulders (DG POST autorisation)  
| Anne Van Nerom |
| Notice to Applicants – NTA | Sophie Colyn (DG PRE autorisation) – human  
| Valerie Van Merris (DG PRE autorisation) – veterinary  
| Anne Wespes (CEOs) |
| Pharmaceutical Committee – human | Els Geeraerts (CEOs)  
| Wim Penninckx (DG PRE autorisation) |
| Pharmaceutical Committee – veterinary | Els Geeraerts (CEOs)  
| Greet Musch (DG PRE autorisation) |
| Process on Corporate Responsibility in the field of Pharmaceuticals | Els Geeraerts (CEOs) |
| Regulatory Committee on quality and safety of blood | Ludo Muylle (DG POST autorisation) |
| Regulatory Committee on Tissues and Cells | Ludo Muylle (DG POST autorisation) |
| Regulatory Committee on Medical Devices | Vanessa Binamé (DG POST autorisation)  
| Anne Van Nerom |
| Standing Committee – human | Els Geeraerts (CEOs)  
| Greet Musch (DG PRE autorisation) |
| Standing Committee – veterinary | Els Geeraerts (CEOs)  
| Greet Musch (DG PRE autorisation) |
| Transparency Committee | Els Geeraerts (CEOs) |
| TSE/BSE Working Group | Damien Lambot (DG POST autorisation)  
| Sébastien Vanackere (DG POST autorisation)  
| Anne Van Nerom |
| Vigilance Working Group (Materiovigilance) | Damien Lambot (DG POST autorisation)  
| Sébastien Vanackere (DG POST autorisation)  
| Anne Van Nerom |
| Working Group on Clinical Investigation and Evaluation - CIE | Steve Eglerm (DG POST autorisation)  
| Greet Mush (DG PRE autorisation) |
| IVD Technical Group | Greet Mush (DG PRE autorisation)  
| Anne Van Nerom |
| New & Emerging Technologies Working Group (NET) | Anne Van Nerom |
| Compliance and Enforcement Group (COEN) | Anne Van Nerom |
| Notified Body Operations Group (NBOG) | Katrien Martens (DG INSPECTION)  
| Anne Van Nerom |
| Working Group on coding of tissues and cells | Ludo Muylle (DG POST autorisation) |
| PIC/s | Karin Froidbise (DG INSPECTION)  
| Josiane Van der Elst (DG INSPECTION) |
| PIC/s Committee | Greet Declerck (DG INSPECTION)  
| Josiane Van der Elst (DG INSPECTION) |
| UNO | Greet Declerck (DG INSPECTION)  
| Ad hoc experts |
| Commission on Narcotic Drugs – CND | Greet Declerck (DG INSPECTION)  
| Ad hoc experts |
| International Narcotics Control Board – INCB | Greet Declerck (DG INSPECTION)  
| Ad hoc experts |
| WHO | Daniel Reynders  
| Roy Vancauwenberge (DG INSPECTION) |
| International Medical Products Anti-Counterfeiting Taskforce (IMPACT) | Daniel Reynders  
| Roy Vancauwenberge (DG INSPECTION) |
NATIONAL REPRESENTATION
Commissions and consultation platforms of the famhp in 2013

THE FAMHP REPRESENTATION
To optimally perform the tasks of the famhp, the agency calls on different institutions: the famhp commissions, the national consultation platforms with other public services, institutions and partners and the famhp representatives in national and international commissions, committees and working groups.

In the overview below you can find the famhp commissions, the consultation platforms organised by famhp and the consultation platforms with public services and institutions, based on a protocol.

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<tr>
<th>Commissions of the famhp</th>
<th>DG PRE authorisation</th>
<th>DG POST authorisation</th>
<th>DG INSPECTION</th>
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<tr>
<td>Advisory Commission</td>
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<tr>
<td>Commission for the supervision of advertising for medicines for human use</td>
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<td>Evaluation commission for medicines for veterinary use</td>
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<td>Evaluation commission for medicines for human use</td>
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<td>Evaluation commission for homeopathic medicines for human and veterinary use</td>
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<td>Evaluation commission for traditional herbal medicines for human use</td>
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<td>Commission for the recognition of pharmacists-clinical biologists</td>
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<td>Evaluation commission for medical devices</td>
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<td>Pharmacopoeia commission</td>
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<tr>
<td>Mixed Commission (human + veterinary sections)</td>
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<tr>
<td>Commission for the establishment of retail pharmacies and chambers of appeal (for applications in French and for applications in Dutch)</td>
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</table>
### National consultation platforms of the Famhp, organised by the Famhp

<table>
<thead>
<tr>
<th>Consultation platform</th>
<th>Authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation platform Patients</td>
<td>DG POST authorisation</td>
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<tr>
<td>Consultation platform Regulatory (before TOR)</td>
<td>DG PRE authorisation</td>
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<tr>
<td>Consultation platform Wholesalers-Distributors (before NVGV/ANGR-Ophaco)</td>
<td>DG INSPECTION</td>
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<td>Consultation platform Dispensing (before APB-Ophaco)</td>
<td>DG INSPECTION</td>
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<tr>
<td>Consultation platform Medical Devices</td>
<td>DG POST authorisation</td>
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<td>Consultation platform Human Tissue Material</td>
<td>CEOs</td>
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<td>Consultation platform Blood</td>
<td>DG POST authorisation</td>
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<td>Consultation platform Ethics Committees</td>
<td>DG PRE authorisation</td>
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<tr>
<td>Consultation platform Hospital Pharmacists</td>
<td>DG INSPECTION</td>
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<tr>
<td>Consultation platform Veterinary</td>
<td>DG INSPECTION</td>
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</tbody>
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### Consultation platforms with public services and institutions, based on a protocol

<table>
<thead>
<tr>
<th>Consultation platform with FAVV-AFSCA</th>
<th>DG INSPECTION</th>
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<tr>
<td>Consultation platform with WIV-ISP</td>
<td>DG PRE authorisation</td>
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<td>Consultation platform with CODA-CERVA</td>
<td>DG PRE authorisation</td>
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<tr>
<td>Consultation platform with FANC-AFCN</td>
<td>DG PRE authorisation</td>
</tr>
<tr>
<td>Consultation platform with FPS Economy</td>
<td>DG POST authorisation</td>
</tr>
</tbody>
</table>
Regulations that determine the organisation, functioning and activities of the famhp: see www.fagg.be.
New regulatory elements: laws, Royal Decrees (RD), Ministerial Decrees (MD) and circulars published in 2013.

LAWS AND DECREES PUBLISHED IN 2013

Contribution to:
Law of 19 March 2013 containing various provisions regarding health (I);
Law of 20 June 2013 to amend the law of 25 March 1964 on the medicines;
Law of 15 December 2013 regarding medical devices;
Program law (I) of 26 December 2013;
RD of 12 July 2013 to amend the RD of 18 March 1999 regarding the medical devices;
RD of 12 July 2013 to amend the RD of 14 November 2001 regarding medical devices for in vitro diagnostics.

Royal and Ministerial Decrees:
RD of 17 December 2012 about awarding the grant 2010 to ethical committees and for the application of article 30 of the law of 7 May 2004 about experiments on the human person;
MD of 19 December 2012 to approve the internal rules of the Commission for herbal medicines for human use;
RD of 19 December 2012 to grant an allowance for the year 2013 to the Belgian Centre for Pharmacotherapeutic Information;
MD of 1 February 2013 regarding the recognition of institutions for the drawing, preparation, conservation and distribution of blood and unstable blood products of human origin;
MD of 28 February 2013 regarding the recognition of institutions for the drawing, preparation, conservation and distribution of blood and unstable blood products of human origin;
RD of 20 March 2013 to amend the RD of 22 January 1998 containing the regulation of some psychotropic substances and regarding risk limitation and therapeutic advice;
RD of 3 April 2013 for the recognition of the institutions meant in article 10, § 3, of the law of 25 March 1964 on the medicines;
RD of 16 April 2013 to amend the RD of 15 July 2004 to determine the contributions to be paid in the framework of an application for advice or permission for performing a clinical trial or an experiment;
RD of 23 April 2013 for the granting of an allowance to the association Farmaka;
RD of 21 May 2013 to amend the RD of 19 December 2012 to award an allowance for the year 2013 to the Belgian Centre for Pharmacotherapeutic Information;
RD of 28 May 2013 to amend the RD of 14 December 2006 regarding medicines for human and veterinary use;
RD of 6 June 2013 to amend the RD of 7 April 1995 regarding the information and advertising about medicines for human use;
RD of 17 June 2013 about the packing, labelling and delivery of pharmacy made and officinal preparations against coughing and cold and to amend the decree of the Regent of 6 February 1946 containing the rules for conserving and selling poisons;
RD of 17 June 2013 to amend the RD of 28 June 2009 to amend the RD of 4 April 1996 regarding the drawing, preparation, conservation and delivery of blood and blood products of human origin;
RD of 24 June 2013 containing the grant of an endowment to famhp;
RD of 19 September 2013 to amend the RD of 21 January 2009 containing directions for pharmacists;
RD of 19 September 2013 to amend the RD of 14 December 2006 regarding medicines for human and veterinary use;
RD of 18 October 2013 to amend the RD of 14 December 2006 regarding medicines for human and veterinary use;
RD of 22 November 2013 for the grant of an allowance for the year 2013 to the antimicrobial consumption and resistance in animals;
RD of 26 November 2013 to amend the decree of the Regent of 6 February 1946 containing the regulations about conserving and selling poisons;
MD of 17 December 2013 to fix the model of application form for recognition as completely accredited ethics committee;
Several appointment decisions with the Commissions established with the famhp.

CIRCULAR LETTERS IN 2013

23.12.2013: circular letter 605 - To the holders of the marketing authorisation or registration of medicines for human or veterinary use. Administrative simplification: one central point for information about the availability of authorised medicines.

23.09.2013: circular 603 + application form - For the attention of the holders of a marketing authorisation or registration of medicines (changes the circular letter 532 bis of 8 July 2011).


15.07.2013: circular letter 600 + annex 1 + annex 2 + document Q&A - For the attention of the holders of an authorisation for marketing (MA) medicines for veterinary use. Notifying the local contact person and current information regarding pharmacovigilance (veterinary) to the famhp by the holders of a marketing authorisation.

15.07.2013: circular letter 599 - For the holders of an authorisation for marketing or registration of medicines for human use. New European regulations regarding pharmacovigilance for medicines for human use (national MA and registration) - national application.

13.05.2013: circular letter 598 - To the sponsors and applicants of clinical trials. Payment for the applications of clinical trials.

28.03.2013: circular letter 597 - For the attention of the chairmen of the ethics committees. Outstanding payments for the ethics committees (year 2010).

25.02.2013: circular letter 596 - To the sponsors, manufacturers and/or distributors of medicines for research, the hospital pharmacists, the chief doctors of hospitals, the hospital directors, the phase I-centres, the directors of institutions for human body material. Production and distribution activities with medicines for research.
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The electronic version of this 2013 annual report is available on the famhp website
(www.fagg.be – www.afmps.be)
<table>
<thead>
<tr>
<th>ADR</th>
<th>Adverse Drug Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSM</td>
<td>Agence nationale de sécurité du médicament et des produits de santé – French competent authority for medicines and health products</td>
</tr>
<tr>
<td>APB</td>
<td>The co-ordinating federation of the Belgian professional associations of independent retail pharmacies</td>
</tr>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient – Active substance or ingredient in medicines</td>
</tr>
<tr>
<td>ASMF</td>
<td>Active Substance Master File – File that only refers to the active ingredient. This consists of an open part and a closed part. The open part can be part of an application to obtain a marketing authorisation or for a variation of it</td>
</tr>
<tr>
<td>ASR</td>
<td>Annual Safety Report</td>
</tr>
<tr>
<td>ATMP</td>
<td>Advanced Therapy Medicinal Product</td>
</tr>
<tr>
<td>BEMA</td>
<td>Benchmarking of European Medicines Agencies</td>
</tr>
<tr>
<td>BI</td>
<td>Blood transfusion institution</td>
</tr>
<tr>
<td>BRAS</td>
<td>Belgian Regulatory Affairs Society</td>
</tr>
<tr>
<td>BS-MB</td>
<td>Belgian journal of acts, orders and decrees – Belgisch Staatsblad-Moniteur belge</td>
</tr>
<tr>
<td>CAF</td>
<td>Common Assessment Framework – The CAF is a common European quality framework which can be applied in the entire public sector as an instrument to perform an organisational self-assessment</td>
</tr>
<tr>
<td>CAT</td>
<td>Committee for Advanced Therapies – The committee at the European Medicines Agency that is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products (ATMPs) and following scientific developments in the field</td>
</tr>
<tr>
<td>CEOs</td>
<td>Chief Executive Officer’ services</td>
</tr>
<tr>
<td>CHMP</td>
<td>Committee for Medicinal Products for Human Use – The committee at the European Medicines Agency that is responsible for preparing opinions on questions concerning medicines for human use</td>
</tr>
<tr>
<td>CMDh</td>
<td>Co-ordination Group for Mutual Recognition and Decentralised Procedures, Human – The group that examines questions relating to the marketing authorisation of human medicines in two or more European Union Member States in accordance with the mutual recognition or the decentralised procedure, and questions concerning variations of these marketing authorisations</td>
</tr>
<tr>
<td>CMDv</td>
<td>Co-ordination Group for Mutual Recognition and Decentralised Procedures, Veterinary – The group that examines questions relating to the marketing authorisation of veterinary medicines in two or more European Union (EU) Member States in accordance with the mutual recognition procedure or the decentralised procedure</td>
</tr>
<tr>
<td>CMS</td>
<td>Concerned Member State</td>
</tr>
<tr>
<td>CKG-CMP</td>
<td>Evaluation commission for traditional herbal medicines for human use</td>
</tr>
<tr>
<td>COC</td>
<td>Combined oral contraceptive</td>
</tr>
<tr>
<td>CODA-CERVA</td>
<td>Veterinary and Agrochemical Research Centre</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>COMP</td>
<td>Committee for Orphan Medicinal Products – The committee at the European Medicines Agency that is responsible for reviewing applications from people or companies seeking “orphan-medicinal-product designation”</td>
</tr>
<tr>
<td>CP</td>
<td>Centralised Procedure – Centralised authorisation procedure for medicines</td>
</tr>
<tr>
<td>CTA</td>
<td>Clinical Trial Application – File to obtain an authorisation for a clinical trial</td>
</tr>
<tr>
<td>CU</td>
<td>Compassionate Use – A treatment option that allows the use of an unauthorised medicine</td>
</tr>
<tr>
<td>CVMP</td>
<td>Committee for Medicinal Products for Veterinary Use – The committee at the European Medicines Agency that is responsible for preparing opinions on questions concerning medicines for veterinary use</td>
</tr>
<tr>
<td>DCP</td>
<td>Decentralised procedure – Decentralised authorisation procedure for medicines</td>
</tr>
<tr>
<td>DG</td>
<td>Directorate-General</td>
</tr>
<tr>
<td>DHPC</td>
<td>Direct Healthcare Professional Communication – Information sent to healthcare professionals by the pharmaceutical companies to inform them of potential risks</td>
</tr>
<tr>
<td>DMS</td>
<td>Document Management System</td>
</tr>
<tr>
<td>DSUR</td>
<td>Development Safety Update Report – Annual safety report in the framework of clinical trials</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EDQM</td>
<td>European Directorate for the Quality of Medicines &amp; HealthCare – European bureau (Council of Europe) for the assessment of the quality of medicines and healthcare</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EUDAMED</td>
<td>European Database on Medical Devices</td>
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<tr>
<td>EudraVigi-lance</td>
<td>Central database of the EMA with reports of adverse reactions of medicines for human and veterinary use authorised within the European Union, obtained from national competent authorities of European Member States and pharmaceutical companies</td>
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<tr>
<td>famhp</td>
<td>Federal agency for medicines and health products</td>
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<tr>
<td>FANC-AFCN</td>
<td>Federal agency for nuclear control</td>
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<td>FASFC</td>
<td>Federal Agency for the Safety of the Food Chain</td>
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<td>FPS</td>
<td>Federal Public Service</td>
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<td>GCP</td>
<td>Good Clinical Practices</td>
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<td>GDP</td>
<td>Good Distribution Practices</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<tr>
<td>GTP</td>
<td>Global training plan</td>
</tr>
<tr>
<td>HCG-HCM</td>
<td>Evaluation commission for homeopathic medicines for human and veterinary use</td>
</tr>
<tr>
<td>HGR-CSS</td>
<td>Superior Health Council</td>
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<tr>
<td>HMA</td>
<td>Heads of Medicines Agencies – Network of the European competent authorities</td>
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<tr>
<td>HMPC</td>
<td>Committee on Herbal Medicinal Products</td>
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<tr>
<td>HMPWG</td>
<td>Homeopathic Medicinal Products Working Group</td>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment – Multidisciplinary research that assesses different aspects of an intervention in the healthcare</td>
</tr>
<tr>
<td>IMP</td>
<td>Investigational Medicinal Product – A medicinal product for research</td>
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<tr>
<td>KCE</td>
<td>Federal Health Care Knowledge Centre</td>
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<td>KM</td>
<td>Knowledge Management</td>
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<td>MA</td>
<td>Marketing Authorisation</td>
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<tr>
<td>MAH</td>
<td>Marketing Authorisation Holder</td>
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<tr>
<td>MeSeaA</td>
<td>Medicines electronic Submission and electronic Approval – Electronic system for submission and approval of files on medicinal products</td>
</tr>
<tr>
<td>MIDMA</td>
<td>Middle management</td>
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<tr>
<td>MLM-MCH</td>
<td>Human tissue material</td>
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<td>MNP</td>
<td>Medical Need Programme</td>
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<tr>
<td>MRL</td>
<td>Maximum Residue Limit – The legally allowed maximum residue level (residue) of a substance in or on food</td>
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<tr>
<td>MRP</td>
<td>Mutual Recognition Procedure – Mutual recognition authorisation procedure for medicines</td>
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<tr>
<td>NAT-TestS</td>
<td>Nucleic Acid Amplification Test – Blood test with nucleic acid amplification</td>
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<td>NP</td>
<td>National Procedure – National authorisation procedure for medicines</td>
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<td>NVGV-ANGR</td>
<td>National association of wholesaler-distributors of medicines</td>
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<td>Ophaco</td>
<td>Belgian professional association of cooperative retail pharmacies</td>
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<td>PAC</td>
<td>Post Approval Commitment</td>
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<td>PAR</td>
<td>Public Assessment Report</td>
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<td>PDCO</td>
<td>Paediatric Committee – The committee at the European Medicines Agency that is responsible for assessing the content of paediatric investigation plans and adopting opinions on them</td>
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<tr>
<td>PEN</td>
<td>Pre Export Notification</td>
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<td>PhV</td>
<td>Pharmacovigilance</td>
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<td>PhVWP</td>
<td>Pharmacovigilance Working Party</td>
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<td>PIP</td>
<td>POLY IMPLANT PROTHESE, former French company that produced breast implants</td>
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<td>PRAC</td>
<td>Pharmacovigilance Risk Assessment Committee</td>
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<td>PSUR</td>
<td>Periodic Safety Update Report</td>
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<td>PMH-PDM</td>
<td>Medical Devices Plan – Plan Medische Hulpmiddelen-Plan Medical Devices</td>
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<td>R&amp;D</td>
<td>Research &amp; Development</td>
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<td>RIZIV-INAMI</td>
<td>National Institute of Health and Disability Insurance</td>
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<td>RMA</td>
<td>Risk Management Plan</td>
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<td>RMS</td>
<td>Reference Member State</td>
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<td>RQ</td>
<td>Five-yearly renewal</td>
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<td>SAWP</td>
<td>Scientific Advice Working Party</td>
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<td>SPC</td>
<td>Summary of Product Characteristics</td>
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<tr>
<td>SOE-USE</td>
<td>Special Investigation Unit</td>
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<td>SOP</td>
<td>Standard Operating Procedure – A series of written working instructions</td>
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<tr>
<td>Ss</td>
<td>Support services</td>
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<tr>
<td>STA</td>
<td>Scientific-Technical Advice</td>
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<tr>
<td>TMD-FTM</td>
<td>Therapeutic Magistral Formularium – Therapeutisch Magistraal Formularium – Formulaire Thérapeutique Magistral</td>
</tr>
<tr>
<td>UMN</td>
<td>Unmet Medical Need – Faster access to reimbursement of molecules for which the authorisation procedure is ongoing, based on the therapeutic value, potential for access to a reimbursement “outside indication”</td>
</tr>
<tr>
<td>Variations IA</td>
<td>Type IA variations are changes to a MA that have only a minor impact or none at all on the quality, safety or efficacy of the medicinal product</td>
</tr>
<tr>
<td>Variations IB</td>
<td>Type IB variations are all changes to a MA that cannot be defined as type IA variation, type II variation or as line-extension, and which have no significant impact on the quality, safety or efficacy of the medicinal product</td>
</tr>
<tr>
<td>VHP</td>
<td>Voluntary Harmonisation Procedure</td>
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<tr>
<td>WIV-ISF</td>
<td>Scientific Institute for the Public Health</td>
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</tbody>
</table>