THE FAMHP TIMES

Annual Report 2016

A Medical Technologies Pact for more clarity, simplification and better monitoring

Maggie De Block, Minister of Social Affairs and Public Health, and the Belgian Federation of the Medical Technologies Industry (beMedTech) have signed a pact aiming to improve the safety and accessibility of medical devices for the patient.

The pact contains five sections: measures applying to all medical devices, measures specific to implants, in vitro diagnosis, consumable products and medical apparatus. The pact comprises 32 initiatives covering all sectors of medical technologies. These initiatives are the result of close cooperation between the different parties. The government and the industry are committed to bringing more clarity, simplification and better monitoring of medical devices in order to improve their safety and their quality and to allow for better control.

The FAMHP is notably responsible for the following initiatives:

- Finalising the new European and Belgian legislation establishing stricter rules in terms of quality, safety, efficacy and monitoring. Aesthetic devices, for example, will be considered medical devices so they can come with more guarantees in this context.
- Setting up an autocontrolsystem in the medical technologies sector. The aim is for manufacturers, suppliers of products and services, European representatives, hospitals, laboratories and healthcare professional to assume joint responsibility for the quality, safety and efficacy of medical devices. First of all, the FAMHP will draw up an exact map of all the operators on the Belgian market. Current guidelines will be clarified, after which all registered operators will provide the FAMHP with the information required on their products and/or activities.
- Going ahead with the implementation, in Belgium, of the Central Traceability Register. This register allows the FAMHP to see if an implant has been used in Belgium and for whom. Of course, this is all in the greatest respect of the patient's private life. In doing so, the FAMHP follows incidents very closely so as to detect and eliminate any issues and quickly withdraw dangerous products from the market.

In this way, the Medical Technologies Pact reinforces the actions already taken by the FAMHP and pencils in the guidelines for the coming years.

The FAMHP has adopted new employment regulations

In March 2016, the FAMHP's new employment regulations came into effect. The biggest change? The work time recording system.

Why change the work time recording system? To provide a legal basis for an important aspect of the New Way of Working (NWOW), which consists of allowing employees to manage their working hours more independently.

What's changing?

With the new employment regulations, each of our employees can decide for themselves whether or not to record their working hours. The idea is simple: if the employee wants to leave the clocking-in/off system, they are no longer legally obliged to provide specific times. If, over time, the employee would like to change system, they can do so at any time.

What are the advantages?

When not clocking in or off, trust and accountability replace monitoring. The focus is placed on the team's goals and joint responsibility with regards to respect of our clients and of our colleagues.

For this freedom to be upheld, team agreements will need to be put in place. For a successful transition from clocking-in/off to unrecorded working hours, discussions, dialogue, and open-minded and responsible managers are also some of the keys to success.

WORD FROM THE CHIEF EXECUTIVE OFFICER

Dear readers, 2016 certainly was not boring!

At the end of this year, the FAMHP will be ten years old.

Our agency has seen many changes over ten year and, thanks to all FAMHP employees, the medicines and health products available in Belgium are safe, of high quality and effective. Controversial PIP breast implants have been withdrawn from the market, patient information leaflets are constantly being updated, adverse effect reports are being monitored, not to mention access to innovative medicinal products; each of our projects and each of our actions has contributed, and still contributes, to the protection of public health, your health.

2016 did not just mark the FAMHP's ten-year anniversary. Several advances and new features should be highlighted. Let's remind ourselves of the Medical Technologies Pact that aims to improve the safety and accessibility of medical devices for the patient, or the introduction of the Reporting Center for better monitoring of our projects, or even the changes made to the FAMHP's inspection policy.

A few international events have also popped up in our experts' daily lives, in particular the thirteenth Preclinical Assessors Meeting (PAM) that was hosted by us. This meeting, initiated by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), aims to harmonise the practices of non-clinical assessors at European level. Thanks to this shared vision of EMA and the HMA, the assessor training programmes are becoming increasingly aligned at European level, in particular with the establishment of the European Network Training Centre (EU-NTC). As a matter of fact, the FAMHP was able to organise the PAM 2016 with support from the EU-NTC. This meeting, spread out over two days, was useful in building a strong network amongst non-clinical assessors from all Member States and for strengthening cohesion within the existing networks.

Another large-scale event organised by the FAMHP was the Strategic Review and Learning Meeting of two important EMA committees: the Committee for Medicinal Products for Human Use (CHMP) and the Paediatric Committee (PDCO). This session, organised at the European Parliament, offered good visibility to both committees. This was also a chance to celebrate ten years of paediatric regulation, which still aims to improve the health of children in Europe, by facilitating the development and availability of health products for children.

But my colleagues did not just organise international events and share their expertise on a European level. A lot of effort was also put into improving our services.

Let's not forget, for example, the renewed Commission for Medicines for Human Use (GCH-CMH), officially introduced and operational. The commission itself is not new, but its new way of working and new composition, calling on multiple disciplines, allow it to expand its expertise to cover the whole life cycle of medicinal products. I would also like to emphasize the participation of patient representatives in the GCH-CMH, which has now been made possible. This reinforces the central role of the patient through greater transparency, more attentiveness, refined risk management, and better communication.

Continuous improvement is a way of meeting our stakeholders' expectations as best as we can. This is why, in September 2016, the FAMHP carried out its fourth comparative analysis exercise, called Benchmarking of European Medicines Agencies (BEMA). This analysis gives the European authorities competent for medicinal products the opportunity to assess their performance, identify any major difficulties in their organisation, gather more information about best practices and implement improvement actions. At the end of this exercise, our agency was generally found to be well-organised with, of course, many more possibilities for improvement, but also devoted employees who are able to respond creatively to any problems or restrictions of available resources.

Consequently, I am proud to talk about the excellent work of FAMHP employees in 2016, whom I would like to thank for their commitment towards a shared objective: the protection of your health.

This FAMHP Times 2016 is also our last publication of this kind. We're entering a new decade, which means modernisation, paperless and digital! In the future, we will publish articles on our various activities directly on our website, over the course of the whole year.

I hope you enjoy reading about us.

Xavier De Cuyper
Chief Executive Officer

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Renewed Commission for medicines for human use

In 2016, the renewed Commission for medicines for human use (CGH-CMH) was launched after undergoing significant modification, both in terms of its composition and of its areas of expertise. During this reorganisation, the expertise required of the commission members, the meeting frequency and the types of dossiers processed were adapted. Another new feature was the introduction of alternate members and patient representatives. Thanks to this renewal, the FAMHP wants to issue more qualitative opinions and expand them to include the full life cycle of medicinal products.

The renewed CGH-CMH acts as a central advisory body in the decision-making process. The commission issues opinions taking into account the elements and regulatory, legal and ethical requirements.

New composition

The CGH-CMH is now composed of eight full members and eight alternate members with experience and knowledge in the following areas of expertise: general healthcare, general medicine, paediatrics, pharmacology, innovative therapies, hospital pharmacy, internal medicine and genomic/personalised medicinal products. The commission also listens to patients thanks to representatives from health insurance companies, from the Vlaams Patiëntenplatform, from the Ligue des Usagers des Services de Santé (LUSS) and from Test Aankoop-Test Achats, guaranteeing that each opinion issued by the CGH-CMH is focused on the patient.

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New work method

In addition to an adaptation of case types, a change has also been made to the meeting frequency. In 2016, the CGH-CMH held sessions every Friday instead of once a month. The Board, who, in the past, assisted the CGH-CMH with its tasks, has been replaced by a weekly internal consultation which takes place on Thursdays.

An adapted legal framework

Several articles of the royal decree of 14 December 2006 on human and veterinary medicinal products have been amended. A ministerial decree on director fees and a ministerial decree on appointment of the commission have also been drafted.

News from the DG INSPECTION Distribution Division: three controllers on the field

Since 2015, three new controllers have been strengthening the ranks of FAMHP's DG INSPECTION Distribution Division: after specialised training that took place internally over several months, these controllers are now fully competent and are carrying out numerous checks in the field.

What are the differences between inspections and controls?

Legally, the controllers' prerogatives are the same as those of the inspectors. However, inspections cover a wide range of focal points and legal obligations, whereas controls are more focused on pre-determined issues. The three new controllers of the Distribution Division carry out specific monitoring of operators active in the various domains covered by the division: the distribution of medicinal products and the Good Distribution Practices (GDP) of medicinal products and medical devices and marketing-related legislation. Controllers also notably take action on matters relating to:

- temperature control by medicinal product distribution authorisation holders;
- compliance with legal requirements relating to medical samples and their distribution;
- compliance with the distribution circuit of medical devices.

Reports are always produced on the controls carried out, sometimes requiring the introduction of corrective actions by the operators inspected.

The advantage of introducing these control is the ability to plan specific actions for a sensitive inspection point, and for full routine inspections to be based on the control report, thereby allowing more time to be spent on other parts of the inspection.

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Controllers also carry out investigations, for example, in case of a complaint, information requests or traceability requests.

Additionally, given their abilities, controllers offer added value and first line support to inspectors when it comes to managing inspection cases or complex investigations.

Face-to-face with Maggie De Block,
Minister of Social Affairs and Public Health

Mrs De Block, in your policy declaration for 2016, you identified twelve priorities for the Federal Agency for Medicines and Health Products (FAMHP). Amongst these projects are the implementation of new the European legislation on clinical trials, the control of medical devices and the further development of the VACCINES spearhead. What strategic and political ideas led you to choose these projects?

Healthcare should be focused on the patient, not the other way around. The patient's interests are therefore the governing principle of the policy of all operators in the healthcare sector. The Federal Agency for Medicines and Health Products is no exception.

As everyone knows, a successful recipe starts with choosing the right ingredients. The basic ingredients of good healthcare are medicines and health products. Their quality, safety and efficacy are crucial to the success of many treatments, and the FAMHP watches over them. In doing so, the agency contributes to the patient's good health.

Through the objectives of FAMHP's management plan, we try to strengthen this role as much as possible, and to correct it if necessary. We came up with this plan with input from the FAMHP itself. The agency has both expertise and knowledge in this domain and is therefore ideally placed to help us set a heading. We also met with all our other partners and we took the international context into account. From all that, we have come up with a list of actions and objectives that take priority, in the interest of our patients. Now, we have to put these objectives into practice over the coming months and years.

An important event in 2016 was the introduction of the Medical Technologies Pact, which includes, amongst other things, a section on the traceability of medical devices. What provisional reports are you getting from this?

There are currently millions of medical devices in our country and this number is constantly rising. However, legislation is still lagging behind and we want to remedy this thanks to the Medical Technologies Pact. We are working on a clear legislative framework, so that patients can always count on safe, high quality and effective medical devices.

In 2016, we outlined the key features for upcoming years and we are currently working with the FAMHP on their practical implementation through a series of concrete measures. One of these measures concerns the traceability of implants. A central register is going to be set up. It will allow us to find out who has been given which implant. In case of problem with a specific product, we can then act more quickly and in a more targeted manner to avoid any further problems. This is a big step forward, primarily for the patient's safety.

We are also looking into new areas of application of medical technologies. A good example is the use of medical devices in the treatment of patients in their own homes. We are also investing in innovation, such as in mobile health apps. I have allocated 3.25 million euros to finance 24 pilot projects on the use of mobile health in healthcare. Through these projects, we can test the use of apps in a real healthcare context. At the same time, we can study some of the more practical aspects, such as safety and the respect of private life in terms of the use of data, as well as the payment of healthcare professionals that prescribe this type of application.

« The patient's interests are the governing principle of the policy of all operators in the healthcare sector. »

Auto control is another theme to which the FAMHP is dedicated. The FAMHP has launched this extensive project with the introduction of a new inspection methodology in the medical device distribution sector. Are you planning on making this sector even more accountable in the future thanks to auto control, and expanding this methodology into other sectors?

The pharmaceutical sector and the medical technologies sector are developing rapidly. The number of products on the market is continuously increasing, they are becoming more complex and a continuous stream of new producers and other operators are entering the scene. In order to continually guarantee the quality, safety and efficacy of all these products despite the explosion in availability, we have to review our control system. It is impossible for the authorities to inspect each new product. We need an efficient and flexible system in order to quickly and appropriately respond to innovations. And this is what we are aiming at with the auto control principle. In this system, everyone is held accountable for the quality and safety of their products: manufacturers, product and service suppliers, hospitals, laboratories and health care professionals, European operators, etc.

First of all, we will be introducing auto control for medical devices. The sector will, itself, be responsible for validating several data on an annual basis, and based on the risk analysis of this data, targeted inspections will then take place. Efficiency is a key word here. We avoid a doubled workload or an unnecessarily heavy administrative burden, we explain all the procedures so everyone is clear about what is expected from them, we make clear decisions on the exchange and update of information and we look more closely at how the different inspection services can better work together. The FAMHP will then be able to carry out inspections more quickly and more effectively, which, in the end, will be in the patient's best interests.

At a later phase, we will expand this system to other sectors, for example the medicinal product sector and the blood products sector.

In your opinion, what are the next challenges for the FAMHP?

Every day, new products enter the market: medical devices, mobile apps, human tissue material medicinal products, etc. It is vital that they are all made quickly and safely available to the patient. And to do so, I, as well as patients in our country, am counting on the knowledge and expertise of the FAMHP.

These last months and years, we have launched quite a few large projects to prepare for the future. What is more, these projects are very ambitious: consider, in particular, the Medical Technologies Pact, the Pact for the future for the patient with the pharmaceutical industry and the implementation of the European regulation on clinical trials. Finalising these projects takes time, but that doesn't mean that we may drag our feet. It's up to us to register concrete results as quickly as possible so the patients can benefit from these results.

A particular challenge in this context is continuing to attract the best experts in order to strengthen the agency. This sector is booming, which means it's a battle to attract the best talents. For a public body like the FAMHP, it isn't always easy to compete with the private sector, but I am convinced that the FAMHP is still an attractive employer, thanks to its modern and innovative approach.

The FAMHP hosts a large-scale European meeting

In October 2016, the FAMHP hosted, under administrative supervision of the Slovakian presidency of the Council of the European Union, the Strategic Review and Learning Meeting of two European scientific committees: the committee for human medicinal products (CHMP) and the Paediatric Committee (PDCO) of the European Medicines Agency (EMA).

In total, around seventy committee members, EMA representatives and FAMHP assessors attended this meeting.

In addition to the usual meetings that take place at EMA in London, these bi-annual Strategic Review and Learning Meetings are normally organised in the country holding the European Union (EU) presidency. This time, the Slovakian competent authority for medicinal products, the State Institute for Drug Control (SUKL), asked the FAMHP to organise it. Part of the meeting took place in the European Parliament building and the visit of the European Parliament was made possible by Mrs Françoise Grossetête.

The members of the CHMP and PDCO during their visit at the European Parliament in Brussels.

Appraisal of paediatric regulation

The central theme of the meeting was the lessons drawn from the paediatric regulation, which came into effect in 2007, based on the EMA report "10-year Report to the European Commission".

Before the paediatric regulation was introduced in 2007, many of the medicinal products in Europe had not been sufficiently studied or were not approved for use on children. This caused problems for the healthcare professions responsible for treating children, as well as for the patients themselves.

The paediatric regulation introduced significant changes in the legislation of medicinal products for children, in the aim of guaranteeing better protection of their health. The primary change was the creation of the PDCO. The main task of this committee is to issue objective scientific advice on paediatric investigation plans (PIPs) for medicinal products used on children. Paediatric considerations are now an integral part of pharmaceutical development within the EU and are taken into account from the very beginning of each medicinal product's life cycle.

The report states that the paediatric regulation has actually had a very positive impact on the development of medicinal products for children, such as:

The paediatric regulation introduced significant changes in the legislation of medicinal products for children, in the aim of guaranteeing better protection of their health.

- more medicinal products available for children;
- an increase in the quantity and quality of available information for healthcare professionals and patients;
- high quality paediatric investigations and developments;
- more support in terms of regulation for paediatric issues, for which a good relationship between the CHMP and the PDCO is vital.

Improve collaboration between the CHMP and the PDCO

During this Strategic Review and Learning Meeting, the way in which these two committees work and their interaction has been explained. The participants themselves also looked for ways to optimise collaboration between the two committees.

Several action points were discussed.

- Working together during new marketing authorisation (MA) applications or the expansion of indications through paediatric expertise which can support the assessors and through CHMP versus PIP peer reviewed assessment reports.
- Learning from experience via inter-committee reporting accrued from problems encountered and decisions taken.
- Exchanging new relevant information, such as new relevant signals for PIPs, additional data on changes to a PIP.
- How to avoid paediatric trials being delayed, slowed down or even cancelled once an MA has been issued for adult indications, in other words, how can we still request these trials once the threat of non validation of the application has disappeared?

EMA was asked to come up with other initiatives on this subject and to submit them to the committees.

Different sessions with different partners

The committee members and EMA representatives were welcomed by Xavier De Cuyper, General Administrator of the FAMHP, and Andrzej Rys, Director of Health Care Systems, Medicinal Products and Innovation management - the European Commission's Health and Food Safety General Management. After a brief introduction by Andrzej Rys, a discussion was led in the presence of several Members of the European Parliament on the challenges affecting paediatric medicinal products and the European Commission's vision. Interactions between the committees and the European Commission also took place.

During the session, in which only the CHMP took part, work was primarily focused on the collaboration between EMA and the Health Technology Assessment (HTA) bodies, who assess the various aspects of healthcare-related interventions through a multi-disciplinary analysis. It was decided that this collaboration would initially take place via the European network for Health Technology Assessment (EUnetHTA).

The CHMP also discussed ways of determining priorities in terms of Unmet Medical Need (UMNs) and have provided an overview of experiences with the Priority Medicines (PRIME) initiatives.

At the same time, the PDCO studied the action plan, the organisation of plenary meetings and internal thoughts on the paediatric regulation.

The ideal occasion to discuss important matters

Clear decisions were taken during this meeting and follow-up actions were planned. Both the committee members and the EMA representatives found the meeting highly fruitful.

Departure of a key player at European level

During this CHMP-PDCO Strategic Review and Learning Meeting, a tribute was made to Daniel Brasseur for his precious contribution to the European network. During his rich career, he was president of the CHMP (2001-2007), of the PDCO (2007-2013) and of the Vaccine Working Party. Since 2013, he was also the full member for Belgium in the CHMP.

In August 2016, Daniel Brasseur left the FAMHP to enjoy a well-earned retirement.

He was greatly celebrated during a visit to the European Parliament.

The EARLY PHASE DEVELOPMENT spearhead is still making progress in 2016

Keeping assessment deadlines short

It is important that assessment deadlines for clinical trials and, in particular, early-phase trials are kept short once EU regulation no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials for human medicinal products enters into effect. In 2016, the FAMHP and pharmaceutical industry representatives prepared a pilot project including early-phase clinical trials that should be implemented in 2017.

Knowing the territory: an training advantage

A new training programme offered to FAMHP employees in 2015 was continued into 2016. The aim? To give employees involved in early-phase clinical trials a chance to find out more about certain aspects of clinical research directly in the field.

This training was made possible thanks to the cooperation of several researchers and companies involved with the FAMHP. A European training programme has also been developed for clinical and non-clinical assessors involved in the assessment of early-phase clinical trials. This programme will result in a two-day training session aimed at assessors of the national competent authorities, taking place in March 2017.

Draft laws and revisions to improve European documents

Attending seven national and international forums, FAMHP experts communicated several times with actors in the early-phase medicinal product clinical trials field.

In 2016, employees of the FAMHP DG PRE authorisation and DG INSPECTION carried out negotiations with representatives of the sector in view of creating an early-phase clinical trial centre accreditation (phase I centres). The possibility of voluntary application for clinical trial centres has already been included in a draft law. During these discussions, a list of inspection points was also drawn up in order to avoid emergency situations wherever possible or, if a similar situation occurs, in order to take the necessary measures to approach the situation appropriately.

The FAMHP took part in the revision of the European guideline "Draft guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products". With this European collaboration in mind, the FAMHP also took the opportunity to share its expertise with other Member States.

The FAMHP aims for continuous quality improvement: BEMA 2016 results

From 20 to 22 September 2016, the FAMHP has completed its fourth benchmarking exercise, after the 2005 (DG Medicinal products), 2008 and 2012 editions. This comparative analysis exercise set up in 2004 by the Heads of European Medicines Agencies (HMA), is called Benchmarking of European Medicines Agencies (BEMA). This exercise gives the European authorities competent for medicinal products the option of assessing their performance, identifying any major difficulties in their organisation, gathering more information about best practices and implementing improvement actions.

BEMA consists of two parts. The first is a self-assessment questionnaire and the second is a visit by assessors from other European competent authorities to the FAMHP. During this visit, these assessors perform interviews based on the self-assessment questionnaire filled in by our colleagues.

Initially, the FAMHP staff set up a group of BEMA coordinators. Each one was given the role of carrying out the self-assessment of our agency by filling in the questionnaire with the key performance indicators (KPI). These are indicators that measure the performance of the authorities being analysed. The answers provided to the questionnaire make up the assessment report.

Then three assessors, from the United Kingdom, Finland and the Netherlands visited the FAMHP from the 20 to 22 September 2016. Over these three days, they met with a number of agency employees, asking them about the contents of the assessment report drawn up by the KPI coordinators. At the end of their visit, the assessors presented their general conclusions and the results of the assessment.

The FAMHP's strengths and points for improvement

Generally, it was noted that the FAMHP is well-organised, with devoted employees. It was also highlighted that the FAMHP responds very creatively to any problems or restrictions of its resources. The average result per KPI was 3.5 out of 5, which is a big improvement compared to previous BEMA exercises. The FAMHP is showing clear progress, but there is obviously still room for improvement.

Here are a few examples of the FAMHP's strengths underlined by the 2016 BEMA assessors:

- the CEO newsletter, that pro-actively communicates management decisions to the employees;
- the annual management plan translated into clear individual objectives for employees through annual planning and evaluation meetings;
- the FAMHP values linked to the 2014-2018 strategic plan;
- the transparency in the way the FAMHP's Transparency Committee and Audit Committee work;
- the transparency of the declarations of interest of internal and external experts;
- the risk-based method regarding file management.

Besides, a few areas with room for improvement have also been suggested, for example:

- the integration of the quality management system in the quarterly reporting. This system allows for the necessary monitoring of the management and improvement of our various processes;
- the continued development of the risk management system to include all of our main activities;
- the update of the business continuity plan;
- the optimisation of methods used to communicate with external experts;
- the standardisation of a whole series of quality documents describing the interactions between our organisation's various activities;
- the supply of additional information on the agency's website for patients with regards to clinical trials.

Based on a final report containing all the results of the 2016 benchmarking exercise, the FAMHP has drawn up several improvement actions. In doing so, the FAMHP aims for the continuous and global improvement of its operation.

Well-armed in the fight against antibiotic resistance

Excessive use of antibiotics presents a risk to public health and to animal well being insofar as it promotes the appearance and dispersal of resistant strains of bacteria. These strains make infections more difficult to treat. Both in human and veterinary medicine, measures have been taken and awareness campaigns are ongoing to ensure that antibiotics are used wisely. The frequent use of antibiotics is a cause of concern both for human health and for animal well-being (One Health).

Acting on a veterinary level

In 2016, the FAMHP's Medicines for Veterinary Use Division was once again closely involved in the various measures and initiatives taken against and antimicrobial resistance (AMR). AMR is a complex phenomenon but, in short, a reduction in antibiotics consumption leads to a reduction in bacterial resistance to antibiotics.

Excessive and incorrect use of antibiotics in animals leads to increased bacterial resistance. As a result, antibiotics then become less effective. Animals with diseases can no longer be treated as effectively and, eventually, the general public will also fall victim to this effect. Excessive consumption of antibiotics in animals also carries the risk of transmission of resistant germs or genes to human beings, for example, through the food chain.

Due caution must therefore be exercised when carrying out each veterinary treatment and, if necessary, antibiotics must be administered in the correct dose. In many cases, the preventative administration of antibiotics is unnecessary. Adequate biosafety in livestock farming and a good vaccination strategy prevent illness and, therefore, the need for treatment.

Tax on veterinary antibiotics

Since 1 June 2014, the FAMHP has been deducting a tax from each marketing authorisation (MA) holder on each package of antibiotics for animals sold in Belgium. It is charged both on medicinal products intended for food-producing animals and on those intended for pets. This tax is higher for critically important antibiotics, such as cephalosporins, fluoroquinolones or macrolides. The revenue collected is used to finance all of the FAMHP's anti-AMR activities.

Sale of antibiotics continually dropping

The quantity of antibiotics sold in veterinary medicine is monitored each year by the Belgian Veterinary Surveillance of Antimicrobial Consumption (BelVet-Sac) consortium. The data used comes from full-line retailers and producers of medicinal feed for animals. Currently, it appears that sales of antibiotics for animals are going down. Between 2011 and 2015, the use of antibiotics decreased by 15.9 %. If the operators from the sectors concerned want to meet their pledge of a 50 % reduction by 2020, they will, however, have to continue, and even intensify, their efforts.

European sales figures, sourced from various farming systems, show that, for 2014, Belgium is still a large user of antibiotics, ranking sixth out of the 29 Member States according to the 6th ESVAC (European Surveillance of Veterinary Antimicrobial Consumption) report.

Furthermore, in 2016, the FAMHP helped with the signing of an agreement between the public authorities and the various operators concerned, such as agricultural sector representatives, veterinary representatives, the medicinal product industry organisation, medicated feed for animals representatives, specifications managers, and animal health organisations. The agreement has been signed by Maggie De Block, Minister of Social Affairs and Public Health, and Willy Borsus, Agriculture Minister. The initial objective for the 2011-2020 period is a 50 % reduction in the use of antibiotics in farming and, more specifically, a 75 % reduction in the use of critical antibiotics.

An online application to monitor all antibiotics used on each farm

The majority of antibiotics are used on pigs, poultry and veal calves. This is why the FAMHP has decided to take action to monitor these sectors by means of a new data collection system: SANITEL-MED. This is an online application that veterinarians can use to electronically record all provisions, prescriptions and administrations of antibiotics. There is a help desk available to assist the veterinarian and the farmer.

Excessive use of antibiotics presents a risk to public health and to animal well-being.

A team of scientists has been appointed to analyse the recorded data, in the aim of making suppliers and users of antibiotics individually accountable. It is therefore easier to see, through the veterinarian - farmer combination, where the farm's use lies compares to that of other operators.

Development of a legal framework

In 2016, the FAMHP worked alongside the Federal Agency for the Safety of the Food Chain and the FPS Public Health, Safety of the Food Chain and Environment on the establishment of a royal decree aiming to legislate on the AMR action plan. The mandatory recording of antibiotics in SANITEL-MED is set out, as well as provisions relating to the restricted use of critical antibiotics, which may only be used if a prior diagnosis has been made and if sensitivity to the antibiotics has been determined. This royal decree came into effect at the end of 2016. In coming years, the DG INSPECTION will therefore also be given the important task of speeding up controls relating to the correct recording and the correct use of antibiotics.

Financial support for the AMCRA

In 2016, the FAMHP also financed the operation of the AMCRA (AntiMicrobial Consumption & Resistance in Animals) a non-profit association and centre of expertise. AMCRA primarily promotes awareness in all sectors concerned regarding the judicious use of antibiotics. AMCRA achieves this through, amongst others things, the production of guides on the correct use of antibiotics, the organisation of awareness campaigns, the proposal of self-regulatory measures and the creation of messages to be broadcast on television.

A single place for reporting: the Reporting Center

Since the beginning of April 2016, all of the FAMHP's project monitoring reports have been placed together on SharePoint, the document sharing and management tool, in a single location called the Reporting Center. The progress towards the FAMHP's 2016 operational plan's objectives, the primary tasks of each entity and the associated projects are summarised and analysed each quarter via a document sent to the Executive Council.

The FAMHP must be able to use this system to detect problems early on, to better allocate resources and to reassign them if needed. The objectives of the operational plan and the projects are updated in real time in the Reporting Center. The figures for the primary tasks of each entity are generated and entered into the Reporting Center so they can be processed at the end of each quarter.

Reading for everyone, update for owners

All FAMHP employees are entitled to read what's in the Reporting Center. This means that all employees have an overview of the FAMHP's projects at any time. Some employees have been appointed by the head of their entity as owner of an objective or of a project, which also gives them editing rights in the Reporting Center. An objective or project owner is responsible for any data linked to their objective or project and for keeping it updated.

Reporting Center and Quarterly Management Review Document

All Reporting Center information is compiled each quarter into a Quarterly Management Review Document (QMRD). The QMRD establishes the link between the information from the Reporting Center and the expectations set out in the operational plan. In other words, this document summarises all progress made, any problems that may have been encountered, corrective actions and decision proposals. The aim is to find out where we are and where we want to go.

Benefits

Any change to data is immediately reported in the Reporting Center. There are several benefits to be gained from this.

- Data must be validated once per quarter. When everything is up-to-date, validation is very simple. This time-saving is needed to be able to create monitoring reports in time for the Executive Council and the Minister of Public Health.
- When management has any questions about the progress of an objective or a project, all they have to do is look at the desired data in the Reporting Center. All persons concerned work together more efficiently.
- The data is used as a basis for the monthly bilateral meeting between the Chief Executive Officer and the heads of the other entities.
- This data can also be a starting point for bilateral discussions between employees and their functional manager.

Reporting Center off to a good start

The first experience feedback from the Reporting Center is positive. However, there is still room for improvement. User comments and questions will result in the system being adapted over time.

Four big projects for the ICT Division

Besides carrying out its daily tasks, the Projects and Development team of the FAMHP's ICT Division also took time to work on four big projects over 2016.

SAM 2: the new version of the Authentic Medicines Source

The data model used up to this point in the application linked to the database of all medicinal products authorised in Belgium has been completely adapted to add more details about medicinal products composed of several products authorised and sold in Belgium.

SAM is used by different healthcare professionals, in applications on the eHealth platform, as well as by various federal organisations that need data on medicinal products, such as the RIZIV-INAMI or the FPS Economy.

The application linked to the database for all medicinal products authorised in Belgium has also been adapted to send all changes made in the database directly to SAM, all while managing all of the different statuses linked to a medicinal product: authorised, marketed, unavailable, suspended and withdrawn.

PhiwebRegis

The PhiwebRegis interface is the consultation module for the database of medicinal products that are authorised, suspended and withdrawn in Belgium. For performance reasons, PhiwebRegis uses a copy of this database which is updated every evening. PhiwebRegis allows users to consult data for medicinal products on request, pre-determined or not. The search criteria and the results have been determined based on the users' needs.

Sunset Clause

The Sunset Clause application has been completely rewritten in order to allow users to extract a list of authorised medicinal products for which no packaging has been marketed for three years. This application can automatically generate a letter for each authorisation holder concerned, including a list of the medicinal product(s) that are subject to withdrawal.

SANITEL-MED

SANITEL-MED is an online application in which all veterinary antibiotics prescribed, supplied and administered are recorded. This medicinal product management module was designed to trace animals that are part of the food chain. To this end, the FAMHP's ICT Division has developed the module to allow the transfer of data related to veterinary antibiotics to the SANITEL-MED application.

A National Innovation Office at the FAMHP

The FAMHP's Scientific-Technical Advice & Knowledge Management (STA-KM) Unit is actively represented in the European Innovation Network (EU-IN), formally accredited in November 2016 as a working group of the Heads of Medicines Agencies (HMA). The STA-KM Unit then set several important processes under way in view of creating a National Innovation Office at the FAMHP, to promote and facilitate the research and development of innovative medicinal products in Belgium.

The Innovation Office will act as a single and central access point to FAMHP expertise concerning legislation and scientific knowledge. Furthermore, this department's end goal is to speed up availability of innovative medicinal products to patients. In order to develop future activities through a step-by-step approach, the National Innovation Office will focus on the three following key areas: national, technical and scientific advice services, help with innovation in the R&D area and specific services intended to support small and medium-sized enterprises (SMEs) and the academic sector.

Different workshops to get the basics down

In May 2016, the STA-KM Unit organised its first workshop with around 100 participants, primarily from SMEs, academic research centres, spin-off companies, academic hospitals, professional associations and Technology Transfer Offices (TTOs) from Belgian universities, with the aim of promoting cooperation between universities and their partners. The main objective of this National Innovation Office was, on the one hand, to demonstrate the importance of the services provided as part of scientific advice and, in terms of legislation, at both national and European level, as a support mechanism in the development of medicinal products. On the other hand, this workshop gave an insight into the main innovation support mechanisms and the specific advantages to SMEs, currently being developed by the European Medicines Agency (EMA) and of their importance for, amongst other things, local Belgian SMEs, academic research centres and spin-off companies.

The Innovation Office's end goal is to speed up availability of innovative medicinal products to patients.

Two case studies were discussed to illustrate the various obstacles and challenges faced by researchers and SMEs during the transition from basic academic research to applied clinical research.

Understanding the public's expectations

The workshop also sought to critically brainstorm, with the public, about other possible expectations in terms of assistance, support and dialogue prior to more formal procedures. With this in mind, a national questionnaire was created after this first workshop in order to identify current and future challenges in the innovative medicinal products research and development field, as well as any necessary support and assistance mechanisms. This questionnaire was sent to around four hundred operators concerned.

The results of this national survey were used as a common thread in the development of an action plan for the creation of the FAMHP's National Innovation Office, planned for 2017.

Spanish inspiration

In December 2016, the FAMHP presented the results of the national survey, the primary focuses of the Belgian National Innovation Office action plan, and the future role and operation of the EU-IN to the participants.

Experts from FAMHP's STA-KM Unit also gave the operators concerned a concrete example of Innovation Office with the activities and experiences of the Spanish agency competent for medicines and health products or Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).

This end-of-2016 meeting closed with a brainstorming and discussion session about the proposed objectives and the main priorities of FAMHP's action plan.

The STA-KM Unit gets involved with science fairs

After the aforementioned workshops, FAMHP's STA-KM Unit also held a stand at two scientific fairs for the first time. These were the Knowledge for Growth 2016 fair, organised by FlandersBio in Flanders, and the Science for Business - BioWin Day 2016 fair, organised by BioWin in Wallonia. The aim of these appearances was to actively promote FAMHP's essential tasks and, in particular, its services dedicated to the support of clinical research and innovation in research and development in Belgium.

Adaptation of the DG INSPECTION control policy

While 2015 saw the conceptual implementation of a new control policy by the FAMHP, 2016 is a year marked more by concrete initiatives and fruitful consultations with our partners.

The concept

In the 2015 edition of the FAMHP's annual report, we introduced the outlines of the auto control project developed by the Directorate-general INSPECTION. Between 2015 and 2017, DG INSPECTION undertook to progressively implement a an auto control system for the medical devices domain.

Based on available resources, this ambitious project began in the last quarter of 2015, with the aim of implementing the new market surveillance methodology in the medical devices distribution sector in 2016. More specifically, by beginning with an initial pilot group: Belgian medical device distributors registered with our agency.

From 2017, we plan on continuing the effective implementation of the auto control system in the other distribution sector segments, as well as in the other medical device sectors, namely import and manufacturing.

An intense 2016

For the implementation of this project, a team composed of inspectors and employees from the ICT and Legal Divisions of our agency took part, as a priority, in the creation of legal and technical feasibility studies, as well as in the definition of requirements and means and the inventory of the available and anticipated resources.

A steering committee was set up to monitor the project on a quarterly basis.

In March 2016, all useful administrative elements were combined to convince both the steering committee and our agency's Executive Council to give the formal approval required to continue with the project. The auto control project then became a programme combining three converging projects:

- The auto control portal project, aiming to create a structure to host IT applications.
- The auto control project, comprising administrative simplification, risk analysis and the exchange of information.
- The Decommissioning project, concerning electronic authentication and the single database of operators, activities and medical device classifications.

The first two projects have been placed under the direction of DG INSPECTION and the third is under that of FAMHP's DG POST authorisation. Around twenty of the agency's employees are involved.

Smals, the service provider, is carrying out the necessary developments for the implementation of the IT tool. Meetings and workshops are organised between our agency's ICT Division, Smals and the points of contact for the project at DG POST authorisation and DG INSPECTION.

In the second quarter of 2016, the FAMHP organised two information sessions and four consultation meetings with the external partners concerned, namely the Belgium Federation of Medical Technologies (beMedTech), the national federation of independent retail pharmacists (APB), the General Association of the pharmaceutical industry in Belgium (pharma.be), the association of co-operative retail pharmacies in Belgium (Ophaco), the national association of wholesaler-distributors of medicines (NVGV-ANGR), the Belgian Federation for Commerce and Services (Comeos) and the Belgian Association of Hospital Pharmacists (BVZA-ABPH). This constructive discussion allowed us to determine the indispensable legal framework (ad hoc adaptations of the Law of 18 December 2016 containing various provisions regarding health and the drafting of a royal decree), to draw up a questionnaire for IT-based risk analysis and to consolidate the initial guidelines covering auto control.

At the same time, the project's exhaustive IT content was defined.

In the third quarter, a chain of consultations took place to finalise the initiatives that where started during the previous quarter. Furthermore, the portal's features were specified, the architecture was developed and the first demonstrations took place internally.

At the end of 2016, two information sessions were held at the FAMHP to present the project to our employees. The IT portal also took shape and internal users (ICT Division, DG INSPECTION and DG POST authorisation) tested its application components during an integration phase. Several series of tests in the approval phase are indispensable to validate the features before entering production. These tests are expected to take place in 2017 with FAMHP users, as well as a sample of testers from the medical devices sector. We plan to make the portal available to the public in 2017, at the same time as the publication of the royal decree on the registration of medical devices distributors.

This royal decree was finalised at the end of December to be sent to the Minister's cabinet. This decree, which includes amending or repealing provisions of the royal decree of 18 March 1999 on medical devices, sets out a number of provisions relating to medical devices distributor registrations, the transmission of information to the FAMHP and the publication of guidelines.

Finally, the 2016 health law, comprising various provisions relating to auto control, was published on 27 December 2016.

In 2016, the investments required for the auto control project's IT development, as well as the effort made internally at human resources level, have been substantial and allow us to envisage the smooth and progressive implementation of auto control in the medical devices domain in 2017.

Auto control

The first results of the Management Support Network

Why a Management Support Network?

In 2015, the FAMHP created a consultation platform between its five entities (DG PRE authorisation, DG POST authorisation, DG INSPECTION, Support Services and Chief Executive Officer's Services): the Management Support Network (MSN), bringing together the staff members of each entity. The first objective of this network is to better prepare the Executive Council meetings in order to facilitate decision-making. To this end, the dossiers featured on the Executive Council's agenda are initially discussed within the MSN in order to determine whether or not the supporting documents contain all the information required to make a decision. If necessary, additional information can be requested to complete the dossier.

In 2016, the MSN has become an effective platform for facilitating dialogue between FAMHP's staff and management.

The MSN also aims to optimise the processing of transversal dossiers. Within their entity, staff members are the single point of contact for their colleagues in charge of the management of transversal dossiers or dossiers that can also affect other entities.

In 2016, the MSN has become an effective platform for facilitating dialogue between FAMHP's staff and management.

Reports for effective monitoring

An important achievement of the MSN in 2016 lies in the quarterly reports and the quarterly management review. Each quarter, staff members work closely with colleagues in their entity to exhaustively identify, compile and analyse the results of the various FAMHP services. This exercise is an opportunity to monitor the objectives set out in the operational plan. The results are available on SharePoint, notably in the Reporting Center.

Yet more to come in the future

In 2017, clusters will be integrated into the operational plan to make the document more readable and more usable. This reform arises from the lessons learned from the 2016 operational plan monitoring by the MSN.

Mobile Health: the future of healthcare

Mobile Health allows the patient, those around him/her and various healthcare service providers to intelligently and continuously collect, view, share and use information about health and well being in a computerised way, through software apps and equipment.

Typical examples are apps where different physiological factors are measured on the patient using sensors, such as blood pressure, blood sugar or the activity level. These measurements are then sent remotely to the healthcare professional through a smartphone app. The healthcare professional can analyse the data and, if necessary, for example if certain thresholds have been exceeded, contact the patient. Some apps also make remote video consultations possible, through a video call.

One of the objectives of the national eHealth plan is to create, between now and 2019, a framework to integrate Mobile Health apps into the Belgian healthcare system, taking into account several qualitative, legal, organisational and financial factors.

Mobile Health can therefore contribute to the improved health of the patient, thanks to, amongst other things, continuous monitoring of bodily functions and an adaptation of treatment if necessary, as well as increased comfort for the patient and those around him/her as a result of, amongst other things, fewer trips to see a healthcare professional. Additionally, the use of some mobile health applications will limit certain expenditure in the future and may replace the need for costly and unnecessary consultations. With benefits for both the patient and the healthcare professional, Mobile Health will result in significant changes to processes, relationships and cost models.

Develop an ecosystem based on pilot projects

Based on a selection of pilot projects, the quality criteria for mobile health apps and a financing model for their use needs to be developed. A coordinated approach is also necessary to join together all the various initiatives, incubators, accelerators, etc. that currently co-exist, and to create an ecosystem that stimulates the development and growth of Mobile Health start-ups in Belgium.

The eHealth plan's Mobile Health objective can therefore be summarised as follows:

- Start with pilot projects
  - Set out the criteria to award a quality label to Mobile Health applications.
  - Establish a financing model for the use of Mobile Health with the quality label.
  - Set out the conditions and terms under which Mobile Health can be prescribed.
- Develop an ecosystem for Mobile Health start-ups.

With regards to the pilot projects, five use cases have been selected due to their impact, evaluated based on the number of patients concerned and the seriousness of the situation, as well as the Mobile Health technical tools available. For these situations, existing Mobile Health apps have been selected. They are monitored and analysed according to quality criteria, the financing model and prescription possibilities.

Here are the five areas of use:

- stroke,
- cardiovascular care,
- diabetes,
- mental health care,
- chronic pain.

Quality criteria examined as a priority:

- private life,
- data security,
- interoperability, which means the possibility of connecting to other applications,
- compliance with requirements for medical devices,
- proof, which means the documented added clinical value.

The FAMHP as an assessor of pilot project proposals

Pilot project proposals could be submitted up to 30 September 2016. The call for tender was aimed at healthcare professionals in the broader sense, who want to add a mobile app to their healthcare process. It can also be for acute treatment (e.g. remote supervision or remote consultation) or the use of support apps or mobile connected objects, depending on the patient's health.

Each pilot project proposal had to describe three factors.

- The use case, demonstrating the added value offered by the use of this Mobile Health application with our healthcare system and the health of our fellow citizens as part of a "triple aim" concept: increased satisfaction among patients because their quality of life improves, more effective use of resources and improvement of public health.
- The Mobile Health app(s) used as part of the modified healthcare process, describing the quality guarantees on offer in terms of security, private life, interoperability with medical files, and what proof can be provided.
- The financing model, describing the way in which the benefits and direct costs of the solution and the indirect cost savings for the healthcare system can be calculated and predicted in the medium term.

The FAMHP took part in the evaluation and selection of the 98 pilot project proposals that complied with the three required factors.

In the first round, a written selection was carried out. Within the FAMHP, two or three specific indicators were set out for the different quality criteria and a score was awarded by the relevant experts, namely clinical assessors, medical devices assessors and IT experts. The various projects were then split into categories depending on the results obtained, followed by a discussion by a multi-disciplinary team to choose FAMHP's proposal. The proposals selected by the various public bodies involved (FAMHP, the eHealth platform, RIZIV-INAMI and FPS Public Health, Security of the Food Chain and Environment) were all collected and debated by the selection committee.

The winning projects from the written selection were also presented and discussed orally. From these results, a final project proposal selection was made.

The use of some mobile health applications will limit certain expenditure in the future and may replace the need for costly and unnecessary consultations.

Around twenty pilot projects selected

The pilot projects selected will be part of an agreement between the RIZIV-INAMI and the managers of these projects, whose aim is to integrate the Mobile Health apps in a regular healthcare process. These projects are therefore also a simulation of the real healthcare process.

The FAMHP will monitor the selected products and will determine, based on acquired experience, the quality criteria that are the highest indicators of proof.

Mobile Health might be a brand new domain for the FAMHP, but the combination of expertise in the multi-disciplinary team has resulted in the effective management of this new challenge.

Inspection of good clinical practices for medical devices: first assessment

Since 2015, two inspectors from the Industry Division of DG INSPECTION have been specifically responsible for clinical trials involving medical devices.

For a medical device to be placed on the market and to remain there, its manufacturer must prove that it complies with the essential requirements set out in legislation, notably in terms of performance and safety. Just like medicinal products, this means, in particular for the most potentially dangerous classes of medical devices, the performance of clinical trials in respect of Good Clinical Practices (GCP).

GCP apply to four types of operators: the sponsor who organises and finances the clinical trial, then compiles the results, the Contract Research Organisation (CRO) who performs various tasks on behalf of the sponsor, the investigator who treats patients and sends the data to the sponsor, and the ethics committee who must give its approval.

In the past, the FAMHP has already carried out specific inspections of these operators, primarily following complaints or denunciations, or within the framework of clinical inspections of medicinal products also involving a medical device. Following the reorganisation of DG INSPECTION in 2014, 59 inspections have been carried out specifically on clinical trials with medical devices. They were primarily routine inspections on investigation sites, for the purpose of assessing the quality level of clinical trials concerning medical devices.

Medical devices versus medicines

In practical terms, the checks carried out during the GCP inspection are based around two main axes: the respect of the rights and the well-being of the participant, on the one hand, and the quality, reliability and completeness of the data collected, on the other hand. The majority of requirements are similar for both clinical trials with medical devices and clinical trials with medicines, but some aspects differ from one domain to the next, for example:

- the reporting system to the competent authorities;
- the role of the sponsor as technical advisor for all new equipment, in particular in the case of medical devices intended for operating rooms;
- the report and compilation system for serious adverse events;
- the inspection of conservation conditions, which tend to be more strict for medicines;
- transport and storage logistics, which are sometimes more complicated for medical devices;
- the length of follow-up of the participants, which is often longer for medical devices;
- the single-blind (the patient doesn't know) or double-blind (neither the patient nor the investigator knows) nature of clinical studies/trials, which is often more difficult to implement for medical devices.

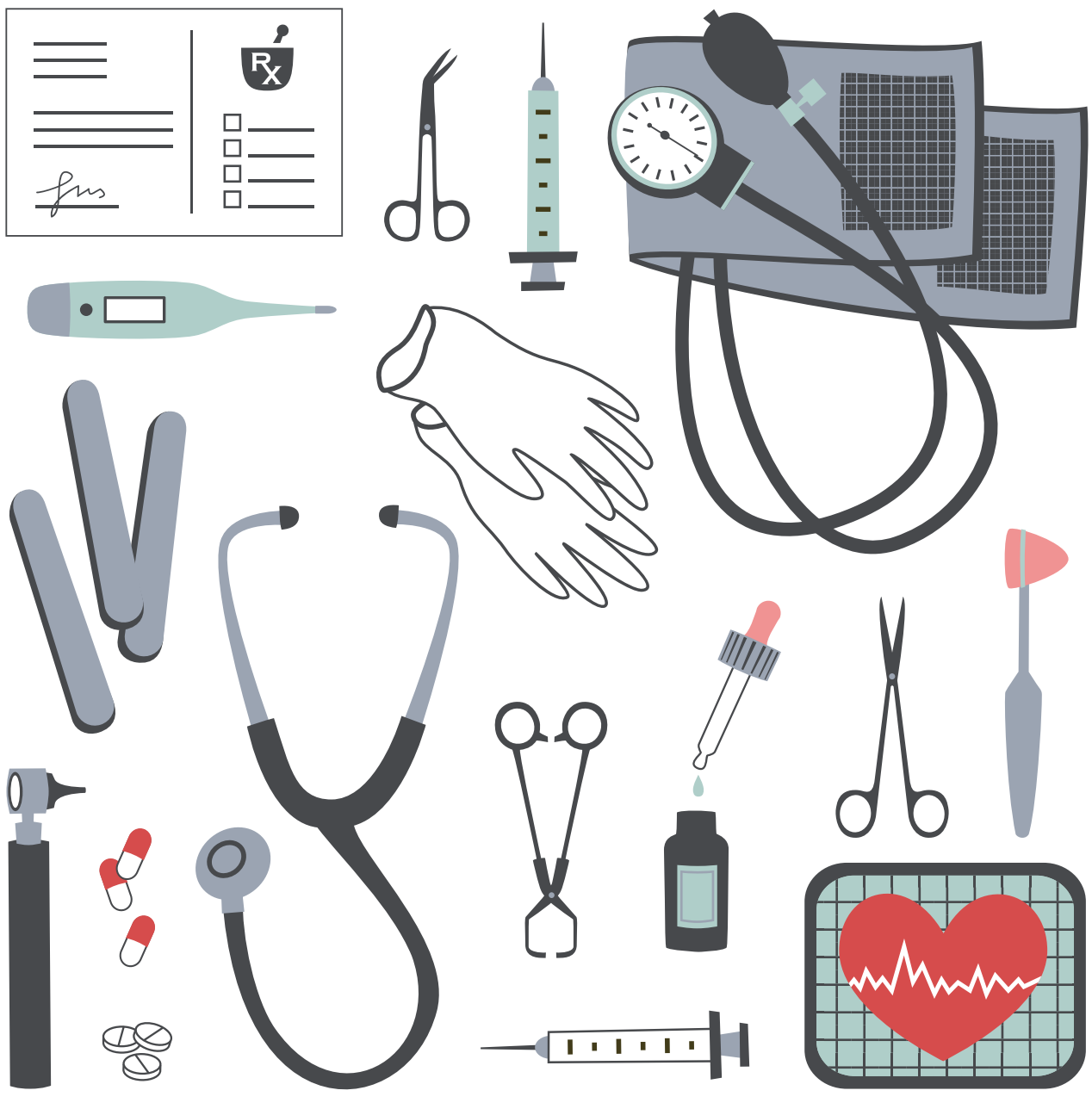
Notify, inform, explain

It should be noted that there is generally a large disparity between the operators concerned by these investigations.

On the one hand, experienced sponsors and investigators who usually carry out clinical trials with medicines and clinical studies with medical devices at the same time, and for which the quality level is very good. On the other hand, less well-developed structures, which work on a limited number of products, and investigators who are involved in clinical research on a rarer basis. With these operators, the educational and informative role of the FAMHP is really crucial. For example, it can sometimes be useful to remind them that:

- they must have approval from the ethics committee before beginning any clinical study/trial;
- verbal informed consent from the patient is not enough, and written informed consent must be given via a document approved by the ethics committee;
- it is also important to archive essential documents and source data;
- all serious adverse events must be reported, even if they do not initially seem to have a direct relationship with the clinical study/trial itself.

All these factors contribute to the protection of the participants and to the generation of high quality data. All these points and factors will be improved in the future, thanks notably to a (pro)active presence of FAMHP inspectors on the field.



New Way of Working (NWOW): how far has the FAMHP come?

What exactly is NWOW?

- BYTES: tools that allow for mobility and flexibility in work.
- BRICKS: a dynamic, stimulating and pleasant working environment that facilitates communication.
- OBJECTIVES: result-orientated via SMART (specific, measurable, agreed-upon, realistic, time-based) goals, feedback and communication within and between teams.
- BEHAVIOUR: the behaviour and the working methods, like trust, respect, accountability and team spirit, without strict control.

In 2016, the FAMHP focused on the BRICKS aspect. At the beginning of the year, the federal administration approved a relocation process which included the FAMHP. Our agency, short of time, had to find ways of responding quickly and efficiently to this huge challenge, which meant moving towards a more dynamic working environment, commonly known as a dynamic office.

The P&O Division suggested to the Executive Council that they should take this opportunity to try out a new work method on the organisational level: co-creation.

Co-creation, but yet ...

The principle of co-creation is to directly involve the actors concerned in the creation of a project. Here, this meant involving FAMHP's employees in the creation of their new working environment. This is an active, creative and social process, based on the free and positive collaboration of anyone who wants to take part and has the time and energy to invest, within a pre-defined framework and with specific objectives. The traditional hierarchical approval principles are strongly limited and are replaced by trust and freedom, to promote creation. Similarly, there is no project leader as such, but rather a central team of coordinators, created on a voluntary basis, each with their own objectives that are as clear as possible.

NWOW

For our project, the relocation of the FAMHP, the Executive Council simply set out a very broad basic framework during a workshop. The project drawn up is comprised of three parts: two parts are focused on hard skills and placed under the responsibility of the ICT Division and of the B&Mc Division, and the third part is based on change management, the transformation into a dynamic office and communication. This last part is expected to work according to the co-creation principle, making greater use of soft-skills. A central team representing these three parts takes care of the global coordination of all activities, which are strongly dependent upon one another.

In the rest of this article, we will concentrate more on this last part, dedicated to change management, and to the principle of co-creation, which is a significant new step towards the adoption of new working methods at the FAMHP.

The voluntary principle is the key to success

Three calls for volunteers were launched in 2016, to create three teams with three separate themes: Organisation, Cleandesk and Life. In total, over a period of 8 months, over 50 colleagues (10% of staff) took part directly or indirectly in the project. The rate of voluntary participation is higher than we hoped and was proof in itself of the staff's motivation to develop and modernise the organisation.

What results have already been achieved in 2016?

A large amount of data in numbers has been collected to measure the use of offices and meeting rooms, and for profiling the teams. Thanks to this data, teams of volunteers for the Organisation theme were able to create a dynamic working environment that meets our organisation's needs. Once the macroplans had been created, the needs analysis in the form of microplans and the promotion of the new environments and work spaces could begin.

As for Cleandesk, the team of volunteers essentially worked together to increase staff awareness through new organising and sorting days, called jeansdays, thereby encouraging the different sections to give more consideration to their paper use and to rationalise it.

Finally, the Life team carried out a large communication campaign to make all of the aforementioned factors a reality and bring them to life: a model, as well as several posters introducing the future working environment, were created.

So, we are on the right track to move into our new offices, once they have been determined, without too much stress.

How satisfied are readers of the VIG-NEWS, the FAMHP's Vigilance Division's news bulletin?

In 2016, colleagues from the Vigilance Division asked subscribers to their news bulletin to fill in a satisfaction survey. Let's take a look at the results.

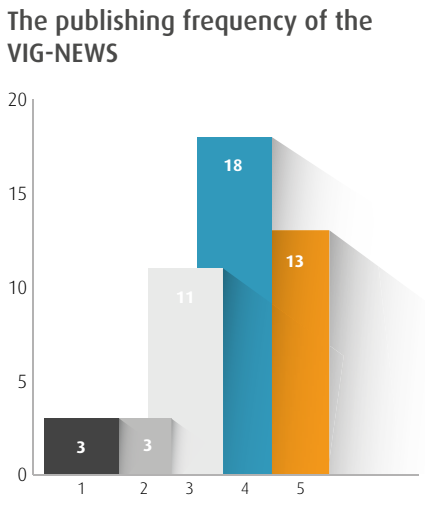
In 2016, the FAMHP's Vigilance Division measured the satisfaction of subscribers to the VIG-NEWS, a half-yearly news bulletin containing a selection of articles on pharmacovigilance and materiovigilance. Put together by pharmacovigilance experts, VIG-NEWS is aimed at all healthcare professionals and is available on the FAMHP website.

Satisfied readers

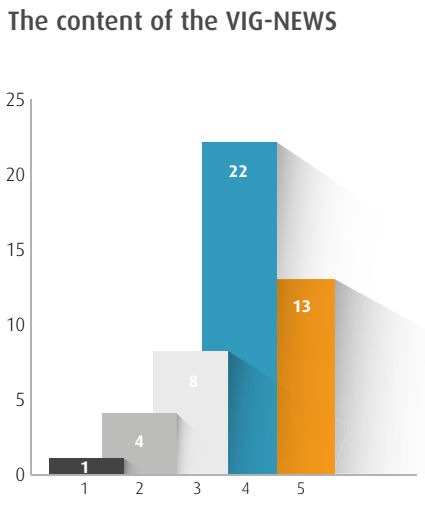
The results of the satisfaction survey are encouraging for the FAMHP. Around 85 % of the 48 survey respondents said they were **positively satisfied on the whole** with VIG NEWS.

The survey looked at three points, with satisfaction being rated between 1 (= not at all) and 5 (= completely).

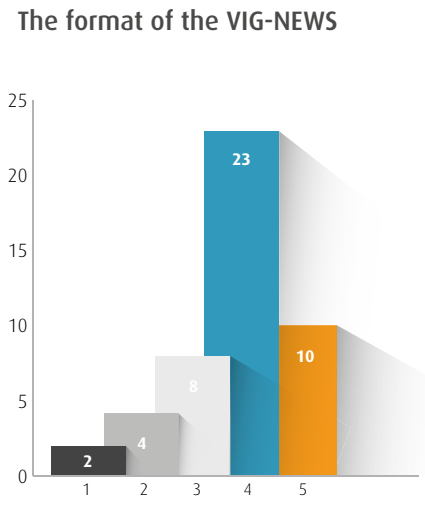
The publishing frequency of the VIG-NEWS



The content of the VIG-NEWS



The format of the VIG-NEWS



What are the points for improvement?

Amongst the comments received, some subscribers would have preferred more frequent editions, to break up the content.

In answer to a request for more frequent VIG-NEWS, the Vigilance Division is looking into offering a more concise VIG-NEWS, sent more frequently, in line with the news items.

The communication of information on the safety of medicinal products is one of the objectives of pharmacovigilance and is, therefore, particularly important to the Vigilance Division.

Thirteenth edition of the Preclinical Assessors Meeting declared a success

This year, the FAMHP organised the Preclinical Assessors Meeting (PAM) with the support of the EU Network Training Centre (EU-NTC), a joint initiative of the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). The thirteenth edition of this meeting took place in Brussels on 17 and 18 May 2016. The PAM is organised every eighteen months, each time by a different competent authority for medicinal products.

The PAM's main goal is to standardise the work of non-clinical assessors at European level. Just like every year, this is done through an update on ongoing activities. This year's themes were pharmacology, with a focus on replacement, reduction and refinement in the use of laboratory animals, European activities relating to the environmental risk assessment of medicinal products. A special session was organised during which, through case studies in small groups, the 57 participants discussed the issuance of objections in the delivery of a marketing authorisation (MA) for a medicinal product, in view of standardisation between European non-clinical assessors.

The PAM's main goal is to standardise the work of non-clinical assessors at European level.

There was also an opportunity for the informal exchange of knowledge between non-clinical assessors, which contributes to the strengthening of the network of European non-clinical assessors, in particular within the EMA's Safety Working Party (SWP).

A useful workshop between the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the SWP

On 19 May 2016, a workshop run jointly by the EFPIA and the SWP took place.

On the programme were several critical points that had been identified by both parties, in view of improving and renewing current legislation on non-clinical studies. One session, for example, was dedicated to the use of disease models for safety tests. In order to promote standardisation in the interpretation of non-clinical studies by the pharmaceutical industry and the European competent authorities, a session in small groups was organised concerning the establishment, communication and use of non-clinical studies on harmful effects.

The vast majority of European Member States were represented, with 47 participants from the 24 national competent authorities and 18 EFPIA representatives.

A new coordinator from the FAMHP's VACCINES spearhead

The Pact for the Future for the patient, with the pharmaceutical industry, by Maggie De Block, Minister of Social Affairs and Public Health, encourages the development of a VACCINES spearhead to promote Belgium as a benchmark country in the vaccine development field.

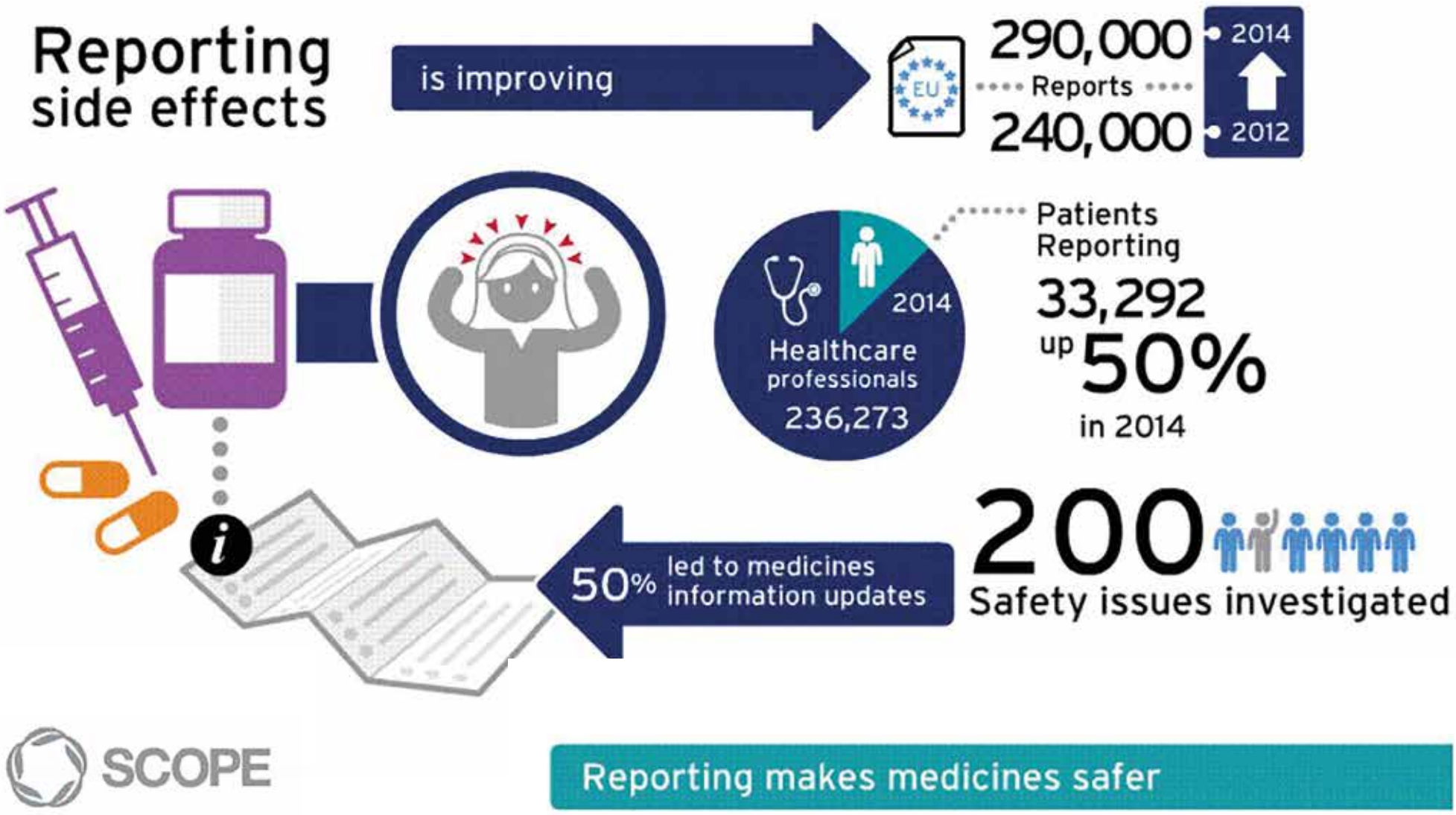
With this in mind, a steering committee composed of representatives from the pharmaceutical industry, the academic sector, federal organisations (the Superior Health Council (CSS) and the Belgian Health Care Knowledge Centre (KCE)) and Minister Maggie De Block's strategic unit was set up in 2016. This committee meets every quarter to set out the objectives to be met in this field. The coordination of this spearhead was entrusted to a new FAMHP coordinator in April 2016. The primary task is to set up projects to achieve strategic objectives and to monitor them through the steering committee.

The four priorities defined for 2016 and 2017 concern prophylactic vaccines for human use:

- draw up a map of all actors involved in the development of vaccines;
- optimise vaccine-related activities within the FAMHP;
- evaluate the existing barriers with regards to the enrolment of subjects in vaccine-related clinical trials;
- draw up a communication plan and organise a one-day symposium on vaccines in September 2017.

The projects set up to achieve these priorities are all already well under way and are at different stages of progress. They are already developing or strengthening cooperation between the FAMHP and different external partners. This is a first step. New projects are currently being developed to consolidate the agency's expertise in the vaccines domain.

SCOPE: the European campaign to encourage the reporting of adverse effects



At the end of November 2016, the FAMHP and the competent authorities for medicinal products in other Member States worked together on the first European awareness campaign on the reporting of adverse effects from medicinal products. This campaign was the initiative of a joint action project, Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE).

All European competent authorities for medicinal products note that adverse effects are not reported often enough. The reporting of these adverse effects, even if they are only suspected, can allow them to spot any possible problems and intervene more quickly. The campaign's aim was, therefore, to encourage both patients and healthcare professionals to automatically report any adverse effects, whether suspected or proven.

An adverse effect that shows up in one country is, of course, likely to show up elsewhere in the world, which is why a cross-border collaboration is so useful.

Report, analyse, communicate

The reporting of adverse effects allows, amongst other things, for us to detect rare reactions to a medicinal product, in other words, reactions that were not observed during clinical trials before the medicinal product was available on the market. After an analysis of the reported cases, it is then possible to inform healthcare professionals and patients and, if necessary, to adapt the summary of product characteristics (SPC), the package leaflet or to add a warning to the packaging. The aim is to make the use of the medicinal product even safer, because an adverse effect that shows up in one country is, of course, likely to show up elsewhere in the world, which is why a cross-border collaboration is so useful.

The campaign tells the story of a patient who experiences a suspected adverse effect. The animation shows the appearance of an adverse effect after taking a medicinal product and how the patient or healthcare professional's report can reach the competent authority in each Member State. In Belgium, this is the FAMHP. The animation also shows how reporting an adverse effect may help other patients.

You can view this animation or report any adverse effects yourself on the FAMHP's website.

Contact | Useful information

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