

# A MEDICINES AGENCY UNDER CONSTRUCTION

Annual report 2007



## LIST OF ABBREVIATIONS AND DEFINITIONS

@ctua	Electronic newsletter of the FAMHP to its stakeholders	DMoon	DMoon is an Open Source integrator that implements eBusiness solutions for the private sector and eGovernment solutions for the public sector in Belgium, Luxembourg and Northern France
AIMD	Active Implantable Medical Devices	EC	European Community
APB	Algemene Pharmaceutische Bond - Association Pharmaceutique Belge : <i>the coordinating federation of the Belgian professional associations of independent retail pharmacies</i>	ECRIN	European Clinical Research Institute Network
API	Active Pharmaceutical Ingredient	ED	Export declaration
ASR	Annual Safety Report	EDQM	European Directorate for the Quality of Medicines
B&Mc	Budget and management control	EEC	European Economic Community
BAPCOD	Belgian Antibiotic Policy Coordination Committee	e.g.	Exempli gratia - as an example
BCFI-CBIP	<i>Belgian centre for pharmacotherapeutic information</i>	e-Health	Secure platform for electronic data exchange within the Belgian health sector
BEMA	Benchmarking European Medicines Agencies	e-HR	Electronic Human Resources
BPR	Business Process Re-engineering	EMA	European Medicines Agency
B.S.-M.B.	Belgisch Staatsblad - Moniteur belge : <i>Belgian journal of acts, orders and decrees</i>	e-MED	Project concerning the electronic prescription of medicines
BUM	Goed Gebruik van het Geneesmiddel - Bon Usage du Médicament : <i>proper use of medicines</i>	EURS	European Review System
CE	Marking that companies are required to display on products falling within the scope of the New Approach Directives - European conformity marking	FAGG - AFMPS	Federal Agentschap voor Geneesmiddelen en Gezondheidsproducten - Agence Fédérale des Médicaments et des Produits de Santé = FAMHP
CHMP	Committee for Medicinal Products for Human Use	FAMHP	Federal Agency for Medicines and Health Products = FAGG / AFMPS
CIBE	Public sector tailored communication	FANC - AFCN	Federaal Agentschap voor Nucleaire Controle - Agence Fédérale de contrôle nucléaire : <i>federal agency for nuclear control</i>
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedures - Human	FAVV - AFSCA	Federaal Agentschap voor de Veiligheid van de Voedselketen - Agence Fédérale pour la Sécurité de la Chaîne Alimentaire: <i>the federal food agency</i>
CMD(v)	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary	Fedict	<i>Federal Public Service Information and Communication Technology</i>
CMS	Concerned Member State	FPS	Federal Public Service
COM-Mnetkern	Network of communicators of the Belgian federal public services	FSD	First Safe Dilution
COMP	Committee for Orphan Medicinal Products	FTE	Full-time equivalent
CP	Centralised Procedure	GCP	Good Clinical Practices
CTFG	Clinical Trial Facilitation Group	GDP	Good Distribution Practices
CTG - CRM	Commissie Tegemoetkoming Geneesmiddelen - Commission de Remboursement des Médicaments : <i>commission for the reimbursement of medicines</i>	GMP	Good Manufacturing Practices
CVMP	Committee for Medicinal Products for Veterinary Use	GVP	Good Veterinary Practices
DCP	Decentralised procedure	HMA	Heads of Medicines Agencies
DG	Directorate-General	HMM	Homeopathic Manufacturing Methods
DGO - SCM	Dienst Geneesmiddelenonderzoek - Service de Contrôle des Médicaments: <i>medicines control laboratory of APB</i>	HMPC	Committee on Herbal Medicinal Products
DMF	Drug Master File	HMPWG	Homeopathic Medicinal Products Working Group
		HR	Human Resources
		HRM	Human Resources Management
		ICH	International Conference on Harmonisation
		ICT	Information and Communication Technology



## A WORD FROM THE CHIEF EXECUTIVE OFFICER

Dear Reader,

The Belgian Federal Agency for Medicines and Health Products (FAMHP) was officially created on 1 January 2007. The FAMHP has completely taken over the role and fields of competency of the Directorate-General for Medicinal Products (DG Medicinal Products) of the Federal Public Service (FPS) Public Health. The main difference from the DG Medicinal Products is the FAMHP's more autonomous way of working under the supervision and responsibility of the Minister of Public Health.

As the first Chief Executive Officer of the FAMHP, I wish to assess the progress made during the organisation's first year. On my appointment in May 2007 I had already announced that 2007 would be a transitional year. The Federal Agency for Medicines and Health Products faced numerous challenges in 2007: constructing a dynamic and efficient public service thanks to the newly acquired autonomy and transparent and professional management; developing into an institution with a national and international reputation; and becoming a learning organisation, capable of meeting people's expectations with regard to public health.

However, working well and accurately are not enough in themselves. It is also important to give the FAMHP the necessary visibility and to ensure that those with expectations of the FAMHP are accurately informed.

For the sake of transparency, I wanted to use this report to describe the efforts the FAMHP is making to achieve its objectives. In this first "annual report", we have chosen to describe the transition from the DG Medicinal Products of the FPS Public Health to an autonomous medicines agency and provide more details about a number of activities in 2007.

I hope you enjoy reading this report.

**Xavier De Cuyper**  
Chief Executive Officer

## CONTENTS

<b>A WORD FROM THE CHIEF EXECUTIVE OFFICER</b>	<b>1</b>	<b>MANAGEMENT AND GUIDANCE BY THE CHIEF EXECUTIVE OFFICER'S SERVICES AND THE SUPPORT SERVICES</b>	<b>43</b>
<b>MISSION, VISION AND AMBITION, VALUES AND ROLE</b>	<b>5</b>	<b>The Chief Executive Officer's services</b>	<b>43</b>
Mission	6	Communication & Scientific Support	43
Vision and ambition	6	International Relations	44
Values	6	Program Management Office	44
Role	6	<b>Support services</b>	<b>45</b>
<b>ORGANISATIONAL STRUCTURE</b>	<b>9</b>	Budget & Management Control	45
Operational departments	9	Information & Communication Technology	49
The Chief Executive Officer's services and support services	12	Legal service	52
Executive board	13	Translation service	53
Three FAMHP committees	14	Personnel & Organisation	53
FAMHP commissions, national consultation platforms and FAMHP representation	15	<b>THE "FAGG-AFMPs 2008" PROJECT</b>	<b>57</b>
<b>FIELDS OF COMPETENCY</b>	<b>19</b>	Central Working Group	57
<b>Activities of the operational departments</b>	<b>20</b>	Levers, key factors and strategic objectives, PMO projects	58
R&D (research and development)	20	Spearheads and other focus points	60
Registration (marketing authorisation)	22	<b>ORGANISATION CHART</b>	<b>62</b>
Vigilance	28	<b>CONTACT</b>	<b>64</b>
Production & Distribution	30	<b>LEGAL CONTEXT</b>	<b>66</b>
Proper Use of Medicines	38	<b>PUBLICATION INFORMATION</b>	<b>68</b>

*List of abbreviations and definitions*

*inside cover*

*“Your medicines  
and health products  
are our concern”*



## MISSION, VISION AND AMBITION, VALUES AND ROLE

On 23 December 2005, approval was granted by the Council of Ministers for the establishment of an autonomous medicines agency: the Federal Agency for Medicines and Health Products or FAMHP. The FAMHP was established by law on 20 July 2006 and as from 1 January 2007 completely took over the role and fields of competency of the Directorate-General for Medicinal Products (DG Medicinal Products) that was a part of the Federal Public Service (FPS) Public Health, Food Chain Security and Environment.

The basic activities of the former DG Medicinal Products have remained unaltered. All subjects relating to blood, cells and tissues of human origin have been added as extra fields of competency alongside the existing ones. The main difference from the DG Medicinal Products is that the FAMHP can function more autonomously under the supervision and responsibility of the Minister of Public Health.

The formation of the FAMHP is an important step towards an efficient, modern government service with sufficient management autonomy to respond flexibly to the expectations of the various stakeholders: the users of medicines, healthcare professionals, the pharmaceutical industry and the political authorities at the different levels of competency (European, federal, regional).

The FAMHP is a public service institution with a legal personality, classified under category A within the meaning of the law of 16 March 1954.



## 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, tissues and cells, which are also defined as health products”.\**

## Vision and ambition

To ensure the population the optimal use of the medicines and health products they need, the FAMHP’s team manages, in a recognised, effective and responsible manner, all aspects of this area in consultation with all relevant parties in the health sector and the other national and international authorities.

Central to this endeavour are the six key factors which represent the FAMHP’s vision and ambition:

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

## Values

The values nurtured within the FAMHP are carefully selected, and form the unifying theme in our day-to-day activities:

- Professionalism
- Integrity
- Sincerity and transparency
- Comprehensiveness
- Participation

## Role

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

\* Based on the law of 20 July 2006 (B.S. - M.B. 08.09.2006) on the establishment and functioning of the FAMHP

29 August 2007,  
quote from Xavier De Cuyper:

*“Based on the BPR of the DG Medicinal Products of 2003, the benchmark results of the European medicines authorities and the conceptual input provided by employees during the workshop of the Central Working Group, I have taken a decision regarding the new structure for the FAMHP. In addition to services of the Chief Executive Officer and the support services, three main pillars will be developed:*

- *PRE authorisation*
- *POST authorisation*
- *Inspection*

*Each of these three pillars will be run by an N-1 appointee. I will keep to my objective of determining the structure and taking all the administrative steps that will make it possible to have the appointees in place in the course of 2008.*

*This is the proposal that will be presented to the government for its approval.”*



# ORGANISATIONAL STRUCTURE

## Operational departments

### THREE PILLARS OF THE FAGG-AFMPS

With a view to the further optimisation of the working processes, structure and deployment of available resources, the FAMPS's structure was redesigned during the first main phase of the transition.

On 12 October 2007, the Council of Ministers approved the draft royal decree whose topics included the new structure with three Directorates-General. The transformation to the new organisation will take place in phases and become operational as soon as the three N-1 appointees (Directors-General) take up their positions. This is scheduled to occur in the course of 2008. Until then, the FAMHP's activities will continue to be organised in accordance with the previous division into five operational departments reflecting the fields of competency of the life cycle of a medicinal product.

The Chief Executive Officer and the members of the Central Working Group (see below) have opted for a logical arrangement of basic activities across the FAMHP's three Directorates-General or pillars:

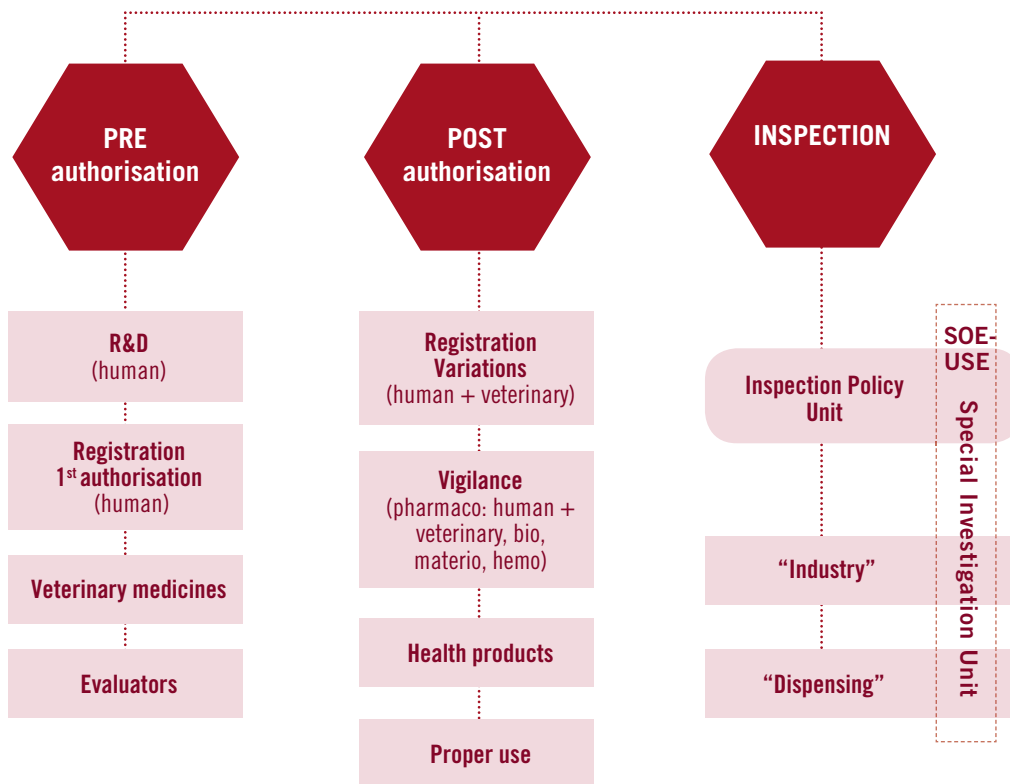
- 1 PRE authorisation**  
or all activities prior to the first marketing authorisation
- 2 POST authorisation**  
or all activities after the first marketing authorisation
- 3 INSPECTION**  
or all inspection and control activities

This classification applies to all medicines (for human and veterinary use, including homeopathic medicines and herbal medicines, pharmacy made and officinal preparations) and health products (medical devices and accessories, and raw materials for the preparation and production of medicines - active pharmaceutical ingredients-, blood, cells and tissues).

The “**PRE pillar**” monitors the development of medicines and health products until the point when the initial marketing authorisation (MA) is granted. The safety of participants in clinical trials with investigational products (IMP) and of the users of the authorised medicines and health products is of fundamental importance. The “PRE pillar” supports the industry during the development of products, among other means by giving scientific advice and contributing to the compilation of pharmacopoeia monographs. The “PRE pillar” is also responsible for the evaluation of the quality, safety and efficacy of the end products.

The “**POST pillar**” embraces the activities which take place after granting the first MA for medicines and health products. These activities are subdivided into three main groups. The first group relates to the monitoring of the first MA, the second covers vigilance aspects and the third group of activities covers all aspects relating to proper use. The latter involves, on the one hand, the provision of relevant information about authorised medicines and health products aimed at the different target groups, and, on the other hand, the partnership with bodies responsible for the distribution of independent information, such as the BCFI - CBIP.

All inspection units of the FAMHP are housed in the “**INSPECTION pillar**”. Its activities encompass the inspection, controlling and/or auditing of the various activities associated with the life cycle of medicines and health products. Both so-called routine checks in the field and measures to tackle illegal practices such as fraud and counterfeit medicines are included in this pillar. The inspection units also support the Judicial Authority and are, in addition to their control and inspection tasks, responsible for dealing with and investigating any complaints relating to the legal requirements on medicines and/or health products. There is also close cooperation with other government services and institutions (e.g. FANC - AFCN, FAVV - AFSCA, FPS Economy, FPS Public Health, the Customs, the Federal Police, VAR, WIV - ISP).



A number of departments have been defined for the three pillars. As far as possible, similar activities will be grouped together within the same department. Due regard has been given to cooperation between the different services, the coordination of information flow, decision-making powers and hierarchical lines. Efficient cooperation between the departments within a pillar and with relevant departments in the other pillars must be ensured. Provision has been made for the organised exchange of information with the national scientific commissions which give final opinions (e.g. evaluation commissions for medicines) and with the representatives on the international scientific or regulatory committees (e.g. CHMP, CVMP, CMD(h), CMD(v), COMP, PDCO).

The step-by-step implementation of the new organisation and the concrete realisation of each of the activities will be determined in consultation with the three Directors-General. The precise timing depends on the speed of progress of the selection procedure, which has been considerably held up by the negotiations over the formation of the new government.

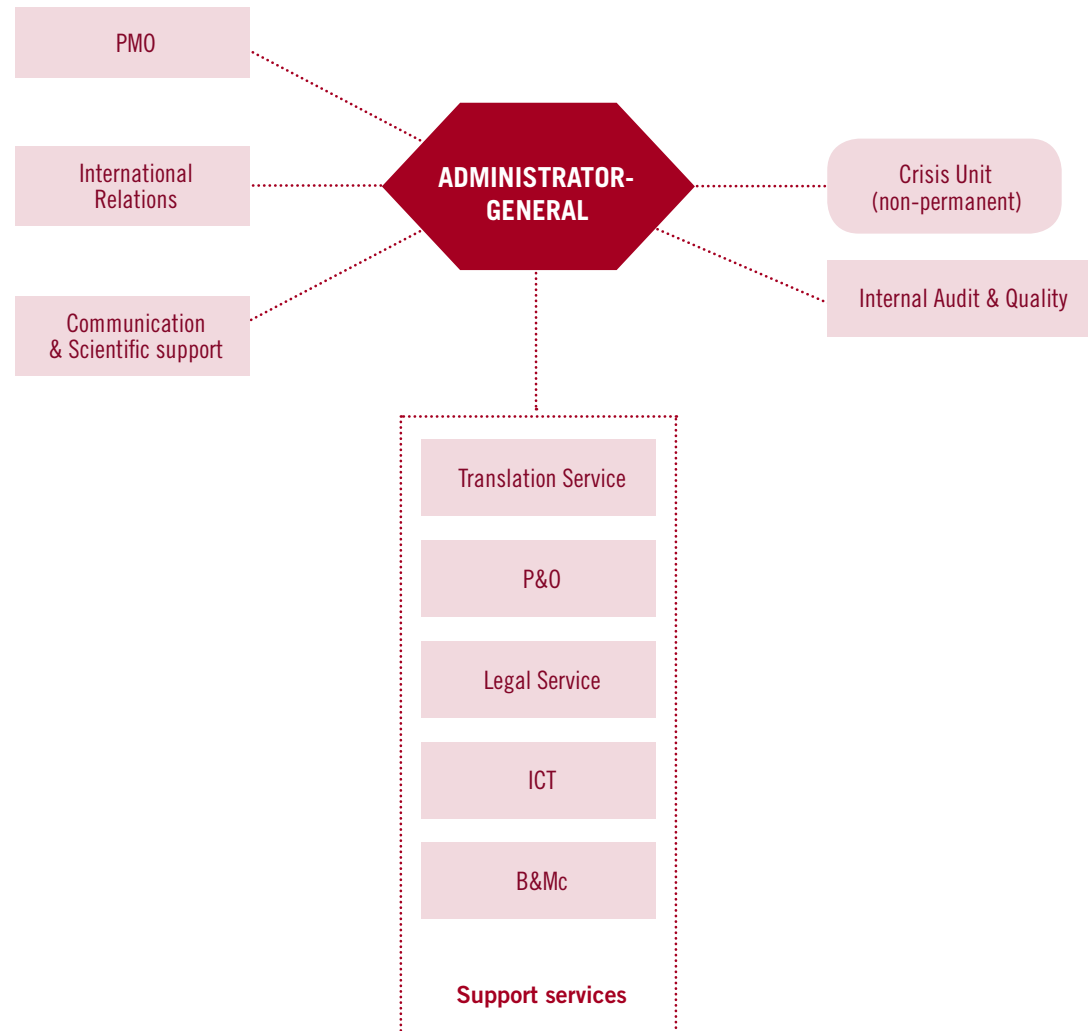
## The Chief Executive Officer's services and support services

The Chief Executive Officer's services and the support services are vital for the organisation and for the concrete execution of the "agency assignments". Among others, these include Budget & Management Control (B&Mc), Information & Communication Technology (ICT), the Legal service, Personnel & Organisation (P&O), the Translation service, Communication & Scientific support, International Relations, PMO (the support monitoring unit), Internal Audit & Quality and the Crisis unit (non-permanent).

As with the three pillars, the organisation of these services has also been the subject of reflection. The Chief Executive Officer's services and the support services are not included in the three pillars, but are controlled directly by the Chief Executive Officer.

The ICT and P&O services are currently operating on the basis of an SLA with the FPS Public Health.

The Internal Audit & Quality service will be developed at a later date.



## Executive boards

### EXECUTIVE COUNCIL

On the basis of the law establishing the FAMHP and the ministerial decree of 11 January 2007 on the composition and appointment of the members of the executive council of the FAMHP, the executive council consists of the Chief Executive Officer, the heads of departments and the heads of the different support services.

### INFORMAL EXECUTIVE BOARD

The Chief Executive Officer has supplemented the executive council with a few heads of his services.

### ROLE OF THE EXECUTIVE BOARDS AND BOARD MEETINGS

The purpose of the informal board meetings is to enable the members to discuss the various points on the agenda in an informal manner, with actions being set out in an action list.

By contrast, the agenda of the formal board meeting tends to consist of points that require a formal decision. Two sets of minutes of this board meeting are compiled, in Dutch and French. There is a set of minutes of “A points”, which may be consulted via intranet by all FAMHP employees, and one of the “B points”, which deals with more confidential and/or personal topics and is for that reason, only circulated to the members of the executive board.

In 2007, the FAMHP held frequent formal and informal board meetings. Formal board meetings are held once a month. The members of the informal board meet an average of three times a month.



## Three FAMHP committees

The law of 20 July 2006 on the establishment and functioning of the FAMHP provides for the creation of a Transparency Committee, a Consultative Committee and a Scientific Committee as advisory bodies to the medicines agency. The three committees offer direct advice to the Chief Executive Officer on the FAMHP's functioning and on the achievement of its objectives.

### TRANSPARENCY COMMITTEE

The Transparency Committee advises the FAMHP on management issues. The committee consists of representatives of the sectors that contribute to the FAMHP's income, an inspector of finance and a representative of the Minister of Public Health.

### CONSULTATIVE COMMITTEE

The Consultative Committee advises the FAMHP on its current and future policy. The committee consists of representatives of all sectors involved in the areas for which the FAMHP is competent and representatives of the relevant federal government services.

### SCIENTIFIC COMMITTEE

The Scientific Committee offers advice about the areas for which the FAMHP is competent. This Committee is the body competent for scientific expertise and cooperation between the different FAMHP commissions (see below). It consists of the chairpersons of all these FAMHP commissions.

The concrete composition of the Transparency Committee and the Consultative Committee and the setting of the date for the formation of the three committees are scheduled to take place during 2008.

## FAMHP commissions, national consultation platforms and FAMHP representation

In order to carry out its various tasks optimally, the FAMHP enlists the help of the FAMHP commissions, the national consultation platforms with other government services, institutions and stakeholders and the FAMHP representatives on national and international commissions, committees and working groups.

During the development of the FAMHP, due consideration will be given firstly to the role, functioning and composition of these commissions and consultation platforms and secondly to the representation of the FAMHP. The Scientific Committee has an important role to play in this. The functioning of the commissions and consultation platforms will be adapted with a focus on knowledge management and the optimisation of the information flow. Efforts will be made to ensure efficient harmonisation of the standpoint adopted by the different FAMHP representatives and the circulation of those standpoints within the FAMHP. The coordinator of the International Relations unit has a role to play in this.

### FAHMP COMMISSIONS<sup>1</sup>

- Advisory commission which is consulted e.g. in cases of non-availability of medicines
- Commission for the approval of institutions assigning preliminary approvals for scientific events
- Commission for the establishment of retail pharmacies and chambers of appeal (French-speaking chamber and Dutch-speaking chamber)
- Commission for the recognition of pharmacists-clinical biologists
- Commission for the supervision of advertising for medicines for human use
- Evaluation commission for active implantable medical devices
- Evaluation commission for homeopathic medicines
- Evaluation commission for medical devices
- Evaluation commission for medicines for human use
- Evaluation commission for medicines for veterinary use
- Evaluation commission for traditional herbal medicines
- Pharmacopoeia commission

### OTHER NATIONAL CONSULTATION PLATFORMS IN WHICH THE FAMHP IS INVOLVED<sup>2</sup>

Regular consultation platforms with other government services and institutions such as:

- BAPCOC (with FPS Public Health)
- Board for biosafety (with WIV - ISP and the Biosafety and Biotechnology service)

- Consultation platform with FAVV - AFSCA, FPS Public Health and Public Health Minister's Office
- DGO - SCM guidance committee (with APB and OPHACO)
- e-MED (electronic prescription of medicines) (with FPS Public Health and RIZIV - INAMI)
- "Grey area" consultation platform (with FPS Public Health and FAVV - AFSCA; a frame of royal decree is made to officialise this consultation)
- Guidance committee of the network of medical-pharmaceutical committees
- ICVV - CICSA
- Influenza (in cooperation with external partners)
- Interdepartmental committee of experts on blood, organs, cells, tissues and embryos (with FPS Public Health, KCE, RIZIV - INAMI and WIV - ISP)
- Interdepartmental network on "information society services" (with FPS Economy)
- Inter DG drugs (with FPS Public Health)
- Mdeon board of management
- Potassium iodide tablets campaign (with FPS Interior Affairs)
- Professional Ethics Committee (with FPS Public Health - DG Animals - Plants - Foodstuffs)
- Provincial medical commissions (with FPS Public Health)
- Strategic unit/RIZIV - INAMI
- Unavailability of medicines (with RIZIV - INAMI)
- Working group on blood of the Belgian Federal Supreme Health Council
- Working group on cells, tissues and organs of the Belgian Federal Supreme Health Council

<sup>1</sup> and <sup>2</sup> Free translations and explanations - see also list of abbreviations and definitions

Regular consultation platforms with stakeholders, such as:

- Clinical Task Force
- Consultation platform FAMHP - APB and OPHACO
- Consultation platform FAMHP - Industry
- Consultation platform FAMHP - Medical Devices
- Consultation platform FAMHP - Hospital Pharmacists
- TOR
- V-amazone

## FAMHP REPRESENTATION

### National representation

A number of FAMHP employees represent the Minister of Public Health on a number of commissions and consultation platforms, such as the commission for the reimbursement of medicines (CTG - CRM) and the technical pharmaceutical board (TFR - CTP) of the RIZIV - INAMI, the price commission for pharmaceutical proprietary products of the FPS Economy, and of the FANC.

### International representation

Medicines and health products are the subject of extensive legislative harmonisation at European Community level. In this context, the European Union also has mutual recognition agreements with Australia, New Zealand, Canada, Japan and Switzerland. Intensive consultation is also taking place on the harmonisation of standards with the USA and Japan (ICH).

Within the Council of Europe and the WHO, there are various consultation bodies, such as that for the compilation of the European Pharmacopoeia.

At United Nations level, there is consultation regarding the classification of substances as narcotics and psychotropic substances.

The FAMHP, as the competent national body, plays an active part in this work at international level through its representation on a number of formal and informal commissions, committees and working groups.

The FAMHP representatives at international level (e.g. CHMP, CVMP, CMD(h), CMD(v), COMP, HMPC and PDCO) are expected to cooperate closely with the three pillars. Moreover, these representatives are required to pay special attention to the chosen spearheads (see below).

At present, the role of FAMHP representative is usually combined with other activities within the FAMHP. A concrete mechanism for coordinating the information flow between the FAMHP and these commissions, committees and working groups and the distribution of this information within the FAMHP is being devised.

Thus the CHMP delegate is reliant on the experts for scientific evaluation and will defend the result of this as the "FAMHP standpoint" within the CHMP. Close cooperation with the representatives on the CHMP working groups (e.g. pharmacovigilance, scientific advice, quality, safety, biological) is necessary. Direct cooperation with dossier administrators who monitor the central procedure (CP) is also required. The CHMP delegate also has to ensure that European formal opinions are properly reported back to the FAMHP.





## FIELDS OF COMPETENCY

Much of the FAMHP's work is imposed by legislation and is important for public health, regardless of the class to which the medicine or health product in question belongs. Thus the FAHMP inspectors in the Production & Distribution department have a duty to control the relevant industry (medicines and health products), the blood establishments, the cell and tissue banks, the wholesale trade of medicines and health products, the retail and hospital pharmacies and the stocks of medicines at the veterinarians. The R&D (research and development) department is required to deal with all relevant applications for clinical trials. The Registration (marketing authorisation) department for its part is required to evaluate applications for a marketing authorisation (MA), for the sake of the National Procedure (NP), the European Decentralised Procedure (DCP), the Mutual Recognition Procedure (MRP) and the Central Procedure (CP). The Vigilance department has to oversee all medicines and health products on the market, while the Proper Use of Medicines department provides information about those products to anyone who requests it. We strive to carry out these activities, which constitute the basis of the FAMHP's work, correctly and efficiently.

## ACTIVITIES OF THE OPERATIONAL DEPARTMENTS

### R&D (research and development)

#### MISSION AND ROLES

The R&D (research and development) department of the FAMHP is responsible for the evaluation and approval of clinical research activities, ranging from the first “use” (concept) to extensive trials with medicines that are developed and carried out by university and other research centres and by the pharmaceutical industry.

It is the R&D department’s role to protect the participants in clinical trials by giving scientific advice and evaluating, approving, monitoring and checking applications for clinical research, on the basis of sound scientific knowledge.

The European Directive 2001/20, transposed in the law of 7 May 2004, forms the basis for the department’s core tasks:

- Validating, evaluating and assigning approvals for the conduct of clinical trials (including declarations)
- Strategic preparation of the associated GCP inspections
- Monitoring the approved clinical trials by:
  - Evaluating and approving amendments
  - Actively monitoring adverse effects and/or lack of efficacy

- Providing scientific advice in a regulatory context at:
  - National level
  - European level (SAWP)
- Acquiring relevant scientific knowledge and making it available to the FAMHP

The R&D (research and development) department is constructed around the following three roles:

- Clinical trials
- GCP
- Scientific advice

#### SOME ACHIEVEMENTS AND FIGURES FOR THE R&D DEPARTMENT IN 2007

In 2007, 560 new complete applications were submitted, 24% of which were for phase I trials, while 1214 amendments to existing or current applications were also submitted. Of the submitted applications, 95% were processed within the set time limits. Serious shortcomings were identified with 15% of the applications.

One striking point is the clear trend towards an increasing number of phase I trials, from 17% in 2004 to 24% in 2007, as well as the increase in the number of submitted academic clinical trials: from 3% in 2004 to 7% in 2007.

In regulatory terms, the R&D department played an active part in the elaboration of the guidelines relating to substantial amendments, (N)IMP and specific arrangements for non-commercial trials.

Considerable attention was focused in 2007 on increased cooperation on the part of the FAMHP with the ethics committees, with the following results:

- An interactive website with a web application that makes possible the “simple” management of communication actions between the different ethics committees, the FAMHP, the sponsors and researchers, and also monitors the different stages in the evaluation of each application by the ethics committees
- Systematic consultation for the more complex scientific applications
- Further optimisation of the functioning of the ethics committees for the activities falling within the scope of the law of 7 May 2004, with a view to maintain Belgium’s competitiveness and attractiveness as a host country for clinical research in a European context

In 2007, clear steps were also taken to represent Belgium actively on various European fora: CTFG, PDCO and SAWP. Moreover, new transversal projects (Advanced Therapies, Paediatric Regulation, “Compassionate Use - Medical Need Program”) were started from the R&D department. Recognition by the relevant parties at national level and by the other competent authorities at European level for early phase development has without a doubt been a significant achievement for the R&D department and the FAMHP. The publication of a guideline on “Exploratory Clinical Trials” and the various guest speaker presentations at various international fora have definitely contributed to this.

2007 also saw the launch of the new methodology for detecting and evaluating serious adverse effects, and it is now vital to put this into practice as soon as possible.

Another significant activity is the provision of national scientific and technical regulatory advice. In 2007, 60 formal scientific opinions were issued, a number of which were further coordinated by the Belgian delegation in the SAWP. The first phase in the implementation of a helpdesk in this area has been elaborated and received positive validation from the sector, so that further development work can take place in the course of 2008.

To raise Belgium’s profile even further in the European context, regulatory and scientific expertise needs to carry on being developed, and the quality of the services delivered needs to be monitored and improved continuously. Moreover, as the competent authority, the FAMHP intends to play a catalysing role in the stimulation and conduct of high-quality clinical research (e.g. general clinical research, academic clinical research, paediatric clinical research) in Belgium on an ongoing basis.



## Registration (marketing authorisation)

### MISSION AND ROLES

The Registration (marketing authorisation) department of the FAMHP is responsible for evaluating new applications and applications for changes to existing marketing authorisations (variations), with a view to grant the authorisation for marketing a medicine or health product. The evaluation is based on current standards and guidelines on the quality, safety and clinical efficacy of medicines and health products.

The department consists of four entities: medicines for human use, homeopathic and herbal medicinal products, medical devices and veterinary medicines.

### SOME ACHIEVEMENTS AND FIGURES FOR THE REGISTRATION DEPARTMENT IN 2007

#### Medicines for human use

On the basis of a decision in late 2006, a restructuring plan for the medicines for human use entity was implemented in 2007. In concrete terms, this has led to a more effective structure: the “dispatching” service has been retained, a “handling” service and an evaluators pool have been created and the “closing” service has been entrusted with the administrative finalisation of applications. This structure led to the more effective management of the 7968 applications for MA or variations and resulted in a 10% increase in 2007 compared with 2006.

In addition to the structural aspect, initiatives have also been taken to make better use of the

Registration department’s IT system, MeSeA: this means working with the pharmaceutical industry to ensure high-quality electronic applications and working with automatic e-mail messages. A call centre was also set up to deal with the most urgent applications.

An internal KPI was also defined to make better individual monitoring possible and a rational evaluation plan for applications was compiled, based on risk analysis.

During 2007, four European procedures were started up for which Belgium is (co)-rapporteur and seven for which Belgium is the reference member state (RMS).

	Number of MRP applications with Belgium as RMS
Before 2003	17
2004	8
2005	1
2006	5
2007	7 (MRP/DCP)

#### Some achievements of the Evaluation commission for medicines for human use in 2007

- 11 plenary meetings of the commission and 46 meetings of the front office
- Increased involvement of members in the European procedures in which Belgium was acting as RMS or (co)-rapporteur
- The switch from paper documents to electronic applications

## Homeopathic and herbal medicinal products

### *Homeopathic medicines*

All homeopathic medicines that are sold on the Belgian market are notified. This information is available on the FAHMP website.

There are two procedures for commercialising homeopathic medicines on the Belgian market: the simplified registration procedure and the “full” procedure, leading to the issue of a MA.

At present there are a number of registration procedures and procedures for obtaining a MA in progress. Applications for already notified homeopathic medicines will have to be submitted in line with a timetable which will be set by the Minister of Public Health in accordance with article 14 of the royal decree of 23 June 1999. Every new homeopathic medicine that has not yet been notified must be authorised/registered before being marketed.

### **Some achievements of the evaluation commission for homeopathic medicines in 2007**

The commission met five times and dealt with:

- The monitoring of the test phase
  - 18 module 3 evaluation reports: 8 unitary, 9 pharmaceutical forms, 1 complex
  - Concerning module 3: 16 revised evaluation reports: 9 complex, 5 pharmaceutical forms and 2 dilution types, with a compilation of the remarks
  - Concept of a standard comments to valorise the dossiers on the pharmaceutical forms as much as possible

- Preparation for and interaction with:
  - the HMPWG (e.g. for the first safe dilutions project, the GMP appendix for which Belgium is acting as rapporteur and the themes of stability and anthroposophy)
  - the EDQM, group HMM, for the general monograph on preparation methods for homeopathic raw materials and deconcentration
- The processing of applications for the modification of notifications

There were also two meetings at European HMPWG level, and Belgium is rapporteur for the FSD and GMP projects.

### *Herbal medicinal products*

In line with the provisions of the royal decree of 14 December 2006, three procedures are used for the issue of the MA or registration for herbal medicinal products: the full procedure, the “Well Established Use” procedure and a third specific procedure for traditional herbal medicines as stipulated in article 43 of the royal decree.

### **Some achievements of the evaluation commission for herbal medicines (plants working group) in 2007 were**

- The monitoring of applications
- The first applications for TU registration
- The TU notification project
- Interaction with the “grey area” consultation platform regarding health claims, and the safety of botanicals in the food sector
- Scientific advice, inter al. on Pau Pereira
- The link with the activities of the HMPC (experts are preparing monographs)

## Medical devices

The European medical devices directives are so-called New Approach Directives: the products can be commercialised without the involvement of the competent authorities. The conformity inspection of the producer is carried out by a third party (a notified body), which issues a CE certificate. This certificate permits the manufacturer to affix the CE conformity marking on the products concerned. Medical devices with the CE marking can move freely within the European Union.

On the basis of these European directives, the FAMHP is thus mainly responsible for supervision of the market by following up on incidents (materiovigilance) and by inspecting manufacturers, distributors and retailers established in Belgian territory. In view of the freedom of movement of goods, international cooperation is essential and Belgian participation in the meetings of the competent authorities and in the European working groups is necessary.

The FAMHP is also the competent authority for the notification and supervision of the notified bodies based in Belgian territory. Belgium has two such bodies: Apragaz and SGS Belgium. Finally, the FAMHP also provides authorisations for clinical evaluations of critical products.

## Some figures for 2007

KPI	2005		2006		2007	
	P	NP	P	NP	P	NP
ACTIVITY (number of applications)						
Tax declarations	650		644		582	
Notifications for distribution	134		203		209	
Export certificates	331		672		745	
Clinical trials	32		36		27	
Bespoke manufacturer notifications	14		22		13	
Class I manufacturer notifications	50	35	72	13	96	6
Materiovigilance	581	63	660	51	636	200
Mails sent through coordination process	1230		1340		1040	

P: processed

NP: not processed within the year

Class I medical devices present little risk. The manufacturer markets them after simple notification. The manufacturer also submits a declaration of conformity with the European medical devices directive. There is no intervention by a supervisory body and the products thus carry a CE marking without the supervisory body's number. The backlog relates to the entry of details into the database.

## Meetings

- National
  - 10 meetings of the evaluation commissions
  - 4 gatherings of the consultation platform
  - 12 gatherings of the “grey area” consultation platform
  - 12 meetings of the technical implants council
- International
  - 19 European meetings

### Conferences

- Lectures during the following sessions
  - Audiologists
  - Industrial pharmacists
  - Patient safety week
  - Radiotherapy round table

### Inspections

- Beauty products
- Bandages with counterfeit CE markings

### Projects

- The aim of proactive materiovigilance is to promote the reporting of incidents by users, among other means via an online reporting system
- Improvements to market supervision
- Clearance of the backlog, in particular for notifications from class I manufacturers

### Progress in 2007

The performance of the projects and clearance of the backlog depend on the available personnel. The personnel members who were specially recruited for the inspections of medical devices are currently undergoing training. Their presence will boost the level of supervision of the market, but will only really be effective once they are operational. Actions are also planned in the volume retail sector. The FAMHP has regulated the distribution sector by ensuring the registration of all distributors and publishing the list of recognised distributors on the FAMHP website.

### Veterinary medicines

The Veterinary Medicines unit ensures the quality, safety and efficacy of veterinary medicines in the interests of public health and animal welfare. This involves the following set of tasks:

- Granting MA for veterinary medicines
  - Evaluation of the quality, safety and efficacy of veterinary medicines
  - Processing of registrations, five-yearly renewals (RQ), variations for veterinary medicines via NP, DCP, MRP
  - Processing of applications for parallel import for veterinary medicines
  - Processing of applications for temporary use authorisations (TGV – ATU)
  - Processing of applications for registration for medical devices for veterinary use
- CP evaluation and rapporteurships
- Vigilance for veterinary medicines
  - Pharmacovigilance
  - Eudravigilance
  - Materiovigilance
- Research and development of veterinary medicines
  - Processing of applications for clinical trials with veterinary medicines
  - Scientific advice

### Some achievements and figures for the Veterinary Medicines unit in 2007

#### KPIs and measurement results

The most important KPI for this unit is the proportion of the number of finalised applications to the number of new, submitted applications, as a measure of the evolution of the unit's backlog.

This KPI does not relate to applications relating to vigilance for veterinary medicines, or to research and development for veterinary medicines.

	Submitted applications	Closed applications	Difference
Total 2007	829	915	-86

The figures in the table show a 10% increase for 2007 in applications finalised by the unit compared with applications received. Thus the historic backlog is being diminished.

In 2007 23 CP applications, including 1 new registration, were also started up with Belgium as (co)-rapporteur, and Belgium was RMS for 7 new registration applications via the DCP.

#### Some achievements of the evaluation commission for veterinary medicines in 2007

- 10 plenary meetings of the commission and 11 meetings of the front office
- 396 NP applications processed
- 28 MRP applications discussed
- 27 DCP applications discussed

### Some current and future projects of the Veterinary Medicines unit

In addition to active participation in numerous projects with an impact on different departments or services or even on the entire organisation, there are also a number of projects specifically for the Veterinary Medicines unit, such as:

- The computerisation of the databases for clinical trials with veterinary medicines and medical devices for veterinary use
- Reduction of the backlogs for veterinary medicine applications

The success of these projects obviously depends on the availability of sufficient personnel to support them. Finally, the implementation of the new structure of the FAMHP will have a considerable impact on the Veterinary Medicines unit, as the current powers/responsibilities relating to the PRE and POST pillars will be redistributed.

### Transition and backlog

In the first phase of the transition to a new structure for the FAMHP, the emphasis is on the reorganisation and restructuring of the Registration (marketing authorisation) department.

For 2007, an analysis has been performed of the number of submitted applications versus the number of MA of medicines for human use granted. This reveals a clear upwards trend. In 2007, the number of applications submitted in MeSeA on a weekly basis rose by approximately 30%. The backlog for the upload of applications was completely cleared in January and February 2007. The number of actually validated applications, not including the "Parking" procedure, has more than tripled. A clear reduction is also noticeable in the number of applications for the "Parking" procedure. This procedure can be defined as "parking" in the IT system of variations type IA, IB and II analytical for MRP registrations for which Belgium is CMS. The approval of the RMS is sufficient to implement these variations. There is no need to wait for the administrative finalisation of the application. These variations will then be closed in groups with a request for clinical variation or a five-yearly renewal (RQ).

The number of applications finalised every week has more than doubled in 2007. This is already a first step in the right direction.

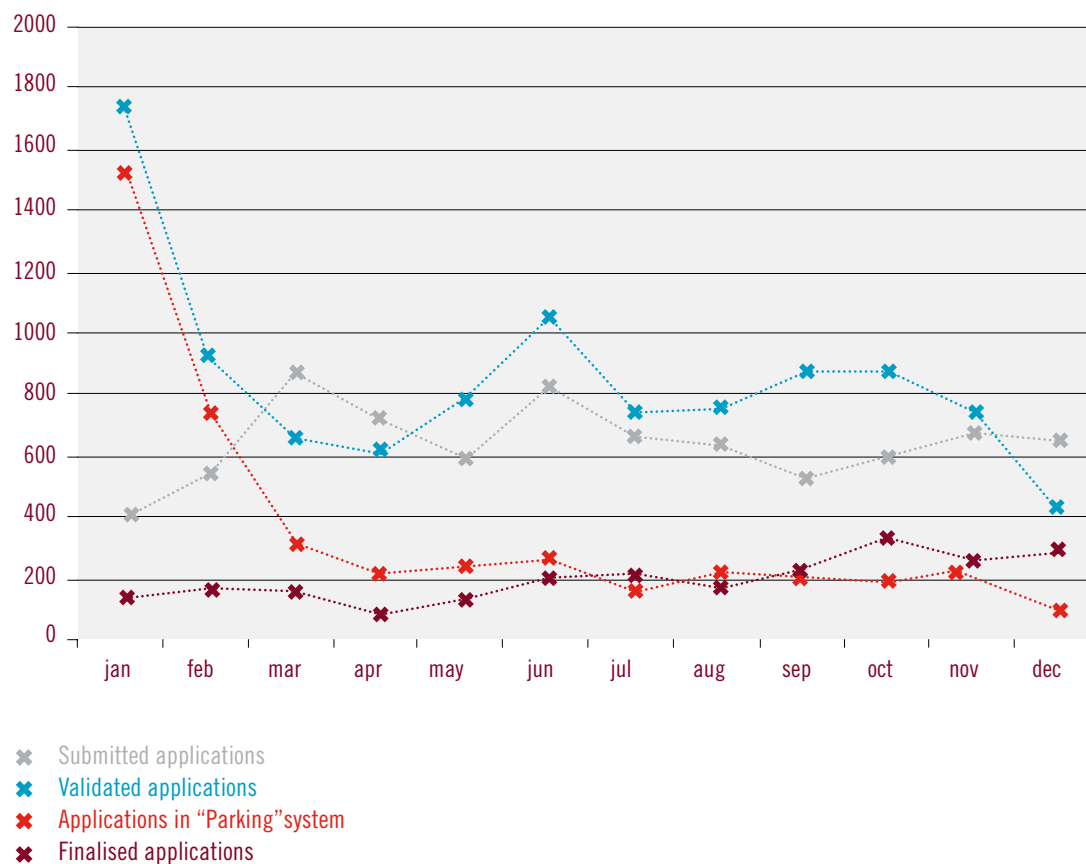
The increased productivity is the result of concrete measures within the Registration department and has ensured that more MA are issued for medicines.

It is also clear that the number of submitted applications continues to rise sharply compared with previous reference periods. Naturally, the ultimate goal is for the number of granted MA to equal the number of submitted applications, but the ever-increasing influx of applications means that this will not yet be reachable as an objective for 2008.

Other concrete initiatives were also taken to increase the effectiveness of the FAMHP, such as the stabilisation and improvement of the MeSeA system, as well as the commencement of a new project to clear the backlogs within the Registration department within the entity for medicines for human use. This project will actually start on 2 January 2008, when the employees recruited for the purpose take up their positions.

## Development of applications in 2007

### Development in the number of registration applications for medicines for human use



## Vigilance

### MISSION AND ROLES

The mission of the Vigilance department is to supervise the safety of medicines for users (pharmacovigilance), blood and labile blood derivatives (haemovigilance) and tissues and cells (biovigilance). This task includes gathering information, evaluating that information and taking measures where necessary.

### Some achievements and figures for the Vigilance department in 2007

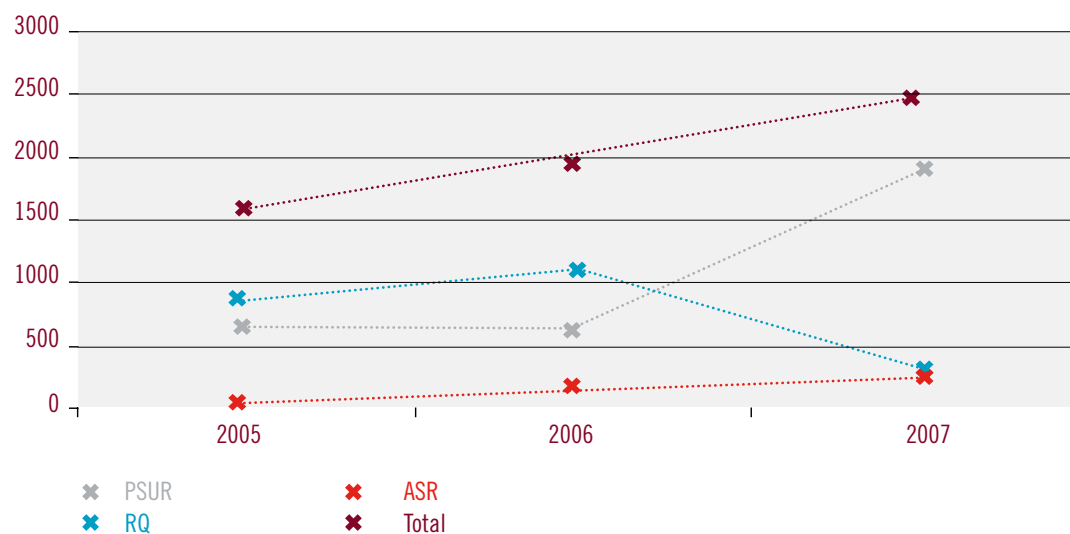
#### Pharmacovigilance

- Collecting and evaluating individual reports of adverse effects from healthcare professionals and MA-holders.  
There were 4350 of these in 2007
- Collecting and evaluating periodic reports in the area of pharmacovigilance (PSUR) and safety reports regarding clinical trials (ASR) with medicines authorised in Belgium
- Processing and evaluating applications for renewals (RQ) of the MA approved via the NP
- Participation in activities in connection with European pharmacovigilance
- Distributing information in the area of pharmacovigilance for the attention of healthcare professionals and the public
- Carrying out the measures proposed in relation to the evaluation of the pharmacovigilance data

- Active pharmacovigilance  
In the context of the FAMHP's decision to promote proactive pharmacovigilance, a decision was made at the end of 2007 to encourage healthcare professionals to pay extra attention to adverse effects that arise after taking medicines with a new active ingredient (the "black triangle" project - during

the first three years after the marketing of the medicine). By definition, these are the medicines for which it is very important to gather data so as to be able to determine their safety profile more accurately. The list of medicines concerned has been published on the FAMHP website

### Change in the number of vigilance applications for evaluation



The table below shows the development in the number of PSUR, RQ and ASR submitted to the FAMHP for evaluation. There was an increase in the total number of applications for evaluation, with a significant rise in particular in the number of PSUR. This is related to the entry into force of the royal decree of 14 December 2006, which requires the submission of a PSUR every three years compared with the limitation to just one RQ.

**Haemovigilance**

- Collecting and evaluating information about serious adverse events associated with the collection, testing, processing, storage and distribution of blood or blood components that may have an effect on their quality or safety
- Collecting and evaluating information about serious adverse reactions in blood donors and recipients of blood components
- Proposing measures for the evaluation of haemovigilance data and monitoring their implementation
- The first annual report of the Haemovigilance Centre was published in 2007  
Since November 2005, hospitals and blood establishments have been required to report to the Belgian Centre for Haemovigilance of the FAMHP serious reactions during the collection or administration of blood components and serious events relating to the quality or safety of blood components. Reactions and events reported in 2006 were analysed and summarized in a first annual report which gives an overview of the notifications, the most important findings and a number of recommendations
- In 2007 a total of 848 reactions and events were reported (16% more than in 2006): 314 from hospitals and 534 from blood establishments

**Biovigilance**

- The reporting of serious adverse reactions in the donor or recipient of tissues or cells and of serious events from the donation to the distribution of tissues or cells will become obligatory. In preparation, a test phase has been organised and the responsible persons of tissue and cell banks have been asked to start making reports to the FAMHP on a voluntary basis in the course of 2008. In December 2007, a briefing was held about this test phase

**Blood, cells and tissues**

- Authorisation of blood establishments and cell and tissue banks
- Pricing of blood components, tissues and cells



## Production and Distribution

### MISSION AND ROLES

The Production & Distribution department of the FAMHP is responsible firstly for overseeing the conformity to current standards, guidelines and legal requirements for the manufacture, distribution and dispensing of medicines and health products and secondly for granting authorisations, recognitions and certificates, as well as for combating illegal practices and monitoring pharmacies.

### ORGANISATION OF THE DEPARTMENT

#### Unit I

Unit I is responsible for the tasks of the secretariat of the commission for the establishment of retail pharmacies, of the secretariat of the commission for the recognition of pharmacists-clinical biologists, of the retail pharmacies registry and plays an important role in the problems of products in the “grey area” (these are “borderline” products whose exact status has to be determined: is it a medicine or not?).

Unit I also deals with inspections of retail and hospital pharmacies, stocks of medicines in care institutions and at the veterinarians, and is charged with the supervision of the distribution of medical devices.

#### **Some achievements and figures for Unit I in 2007**

With the current team of inspectors, 733 routine inspections were performed at retail pharmacies and 89 at hospital pharmacies and of stocks of medicines in care institutions in 2007.

The registry of retail pharmacies closed a total of 1058 applications.

## Unit II

Unit II is responsible for:

- The recognition of industrial pharmacists
- The granting of authorisations for the manufacture, import, export, wholesale, distribution of medicines
- Dealing with quality problems (RAS – Rapid Alert System), regardless of their origin (Belgian, within or outside the European Union)
- Dealing with the non-availability of essential medicines for Belgian patients
- The secretariat of the advisory commission which is consulted e.g. in cases of non-availability of medicines)
- The administrative checking and monitoring of sampling (medicines and health products)

The external services of Unit II inspect manufacturers of medicines (in Belgium and non-EU countries), the wholesalers, the recognised laboratories, the companies recognised on the basis of the royal decree on raw materials used by the pharmacist, the manufacturers of “Active Pharmaceutical Ingredient” (API), blood establishments and cell and tissue banks.

## Some achievements and figures for Unit II in 2007

### Rapid alerts relating to the quality of medicines

The Rapid Alerts System or RAS network is an international network whose purpose is to circulate information as quickly as possible about batches of medicines that have been identified as non-conforming, which were produced in non-GMP conditions or which do not belong to the distribution circuit that complies with the GDP. The speed of circulation of the information and of the response to that information is essential, given that the alerts relate to problems that may have serious or even life-threatening consequences for patients. The handling of such applications involves collecting information, risk analysis, suspending distribution and if necessary recall of the medicine. All of this takes place within a period lasting from 24-48 hours up to a maximum of one week. If a non-conforming medicine is marketed outside Belgium and the medicine manufacturer is based in Belgium, the FAMHP is responsible for alerting other medicine authorities via the RAS. If investigation and follow-up on the initial causes of the incident prove necessary, the processing of the case must take no more than one month, naturally after the first urgent and necessary measures have been taken.

In theory, the RAS network only relates to medicines. However, quality problems may also arise with products other than medicines for which information can be circulated via this channel. The seriousness of the situation, the differences in regulations from country to country, the difficulty of determining at the start of an incident whether it is a quality problem or a problem of pharmacovigilance, are factors which have to be taken into account. It is therefore important to cooperate with other departments or bodies in order to tackle problems jointly or simply in order to pass the information on to the competent parties.

Finally, in recent years a troubling phenomenon has been on the rise: the counterfeiting of medicines and health products. Here too, effective cooperation between the different parties concerned is vital. At present, a parallel circuit is under preparation at international level for dealing with this kind of problem.

#### Some figures from 2007

- The number of RAS incidents dealt with in 2007 remained relatively stable in general (150 instead of 144 in 2006, representing a 4% increase). However, a fall in the number of RAS incidents originating in Belgium was recorded (30% instead of 47%)
- The number of class 1 alerts (problems involving life-threatening risks or serious disturbances for the patient) and class 3 alerts (minor deficiencies) remained stable
- For class 2 alerts (problems that can cause health problems or inappropriate treatment), a fall was recorded from 50% to 33%
- Unfortunately, there was a clear increase in the number of counterfeits in the international network (13% instead of 4%)

- In terms of actions, there were fewer withdrawals on the Belgian market (20% instead of 33%) and there was more cooperation with other departments (in 11% of cases instead of 4%)

#### Inspections

In the planning of inspections, account has to be taken of the legal requirements imposed by European or national regulations, the available personnel and a rational risk analysis.

The medicine market itself determines the rate of inspections resulting from authorisation applications and variations. However, from a historical viewpoint the number of FTE that is required for this can be predicted. As companies are dependent on the issued authorisations and in view of the legally imposed deadlines, inspections cannot be postponed. The rate of routine inspections is determined by international regulations or recommended by European or national guidelines. A certain margin also has to be left for complaints, thematic actions or judicial proceedings. The planning of the inspections is also adjusted depending on how much time is devoted to the inspection process. However, the decisive factor is personnel. Their number and their various fields of competency have to be taken into account. Thus part of the inspectors' time also has to be set aside for their continuing training, for the instruction of trainees and for offering support to junior inspectors.

Finally, a risk analysis is performed when making the final choice of inspections: type of medicine (pharmaceutical form, production method, therapeutic index), type of company (size, past record, specific activity or range of activities).

Overall, the number of inspectors rose in 2007, with four new trainees starting their year of training. This increase makes it possible to move from the 2007 inspection schedule, which was the weakest ever since the introduction of these arrangements, to a more optimistic one for 2008. Whereas there were 58 programmable inspections (routine + new inspections) of GMP companies in 2007, the increase in the number of personnel during the year means that 122 such inspections can be planned for 2008.

From 2008, inspections of API suppliers and inspections abroad can be scheduled again. Acute personnel shortages meant that these had to be almost completely neglected in 2007.

### Export

Export to non-EU countries is an important economic activity for Belgian companies. However, it is also important for the population of these countries to have access to medicines of the same quality as those on the European market.

### Export declarations

Medicines with an “export declaration” (ED) are medicines that are exclusively intended for non-European markets and hence not subject to a full registration process. However, such medicines do have to meet a number of quality and efficacy conditions, which are investigated in connection with the ED.

These relate to:

- Quality: GMP production, precisely known formulations, production in line with the standards of the European or equivalent Pharmacopoeia

- Efficacy: the active ingredient is as such subject to an authorisation or prequalification by the WHO or a positive opinion from the EMEA

During this first year of activity, The Production & Distribution department issued 149 EDs. 79% were validated within 10 days and 83% were processed within 60 days.

### Export certificates

Manufacturing sites under FAMHP supervision have to be able to provide documents quickly which demonstrate that the GMP conditions are being complied with. In many countries, exported batches have to be accompanied by proof that they were produced in accordance with the GMP conditions.

After a drop in the number of certificates in 2006, 2007 was a particularly good year in terms of the certificates applied for by pharmaceutical companies (+ 15%).

In comparison with 2006, this increase was distributed evenly across the different categories of requested documents: GMP certificates, certificates for medical devices, certificates for pharmaceutical products. On average it takes 10 days to obtain such a certificate.

### Pharmacopoeia

Unit II is also charged with the Pharmacopoeia/Therapeutical Magistral Formularium (TMF - FTM) service and ensures the secretariat of the Belgian Pharmacopoeia commission in collaboration with the European Pharmacopoeia commission. This unit also takes care of the tasks related to the issue of the quality of raw materials

used by the pharmacist and the preparation of the document “Good officinal practices” for retail pharmacies. This document is almost ready for publication.

### Unit III

Unit III takes care of granting authorisations and import and export licences for hormonal, antihormonal, anabolic and anti-infectious substances, for precursors, for narcotics and for psychotropic substances.

The inspectors and controllers in this unit are responsible among other things for checking sites with specially regulated products (e.g. narcotics, precursors, hormones).

#### Precursors unit

The Precursors unit is an administrative unit set up to support the application of the regulations in the area of drug precursors (agreement of 13 April 1993 no. 47118/F 79.339 between the Minister of Finance and the Minister of Public Health). It consists of representatives from the FAMHP and representatives from the Customs services (National Detection Division, Customs and Finance Administration). Through intense cooperation, the combination of knowledge and experience of the legal trade and customs techniques, the unit fully supports the goal of exposing and combating the illegal trade in and abuse of precursors.

#### Some achievements and figures for the Precursors unit in 2007

In order to provide more effective support for granting authorisations and the generation of the European reporting, the database for the administrative monitoring of authorisations and registrations for market participants and licences for import and export was thoroughly overhauled in 2007.

- In 2007, 88 licences/registrations were issued to market participants
- For the export of precursors, 200 export authorisations and 11 import authorisations were issued. Each application for such licences is accompanied by an extensive investigation of the legitimacy of the application and of the market participants
- 280 Pre export notifications (PEN)
- 1224 preliminary notifications of intra-Community transactions

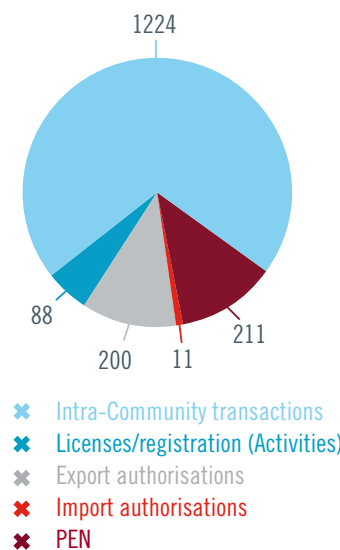
The Precursors unit also took part in the international Cristal Flow action in connection with the PRISM project in 2007.

Work was done on a brochure on drug precursors in which, alongside the compulsory reporting of suspect orders and transactions, market participants are also urged to report suspect orders and transactions of non-regulated substances. All relevant sectors are called on to contribute to this reporting system. The brochure also forms part of a project file in execution of the national safety plan.

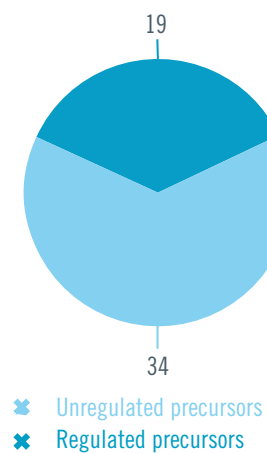
53 reports of suspect orders and transactions were declared acceptable for 37 different products:

- 19 reports relating to regulated precursors
- 34 reports relating to unregulated precursors

2007



Reports of suspect orders and transactions 2007

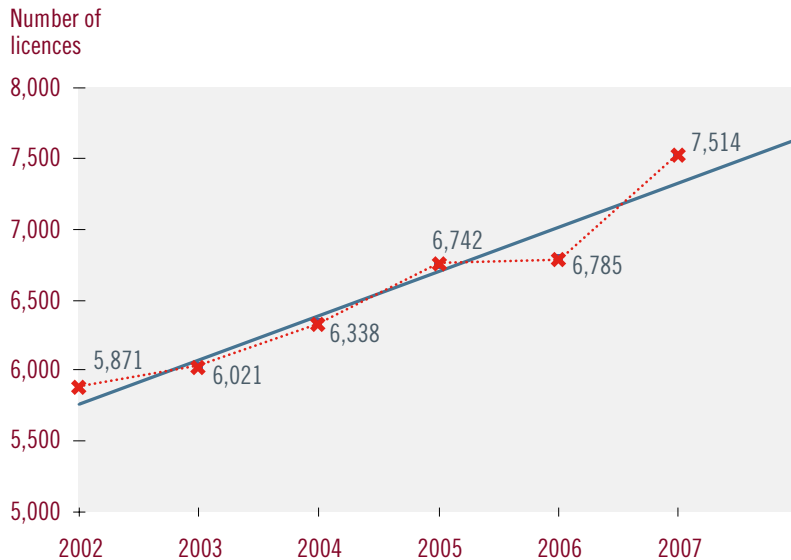


**Narcotics and Psychotropic Substances unit**

**Import-Export licence**

The graph below shows the upward trend since 2002, with the number of applications increasing from 350 to 400 per year. The halt in growth in 2006 (+50 applications compared with the figures for 2005) was offset by the applications in 2007, which rose by 700 units compared with 2006. This growth will continue in 2008, and the FAMHP will pass the 8,000 mark for import-export licences.

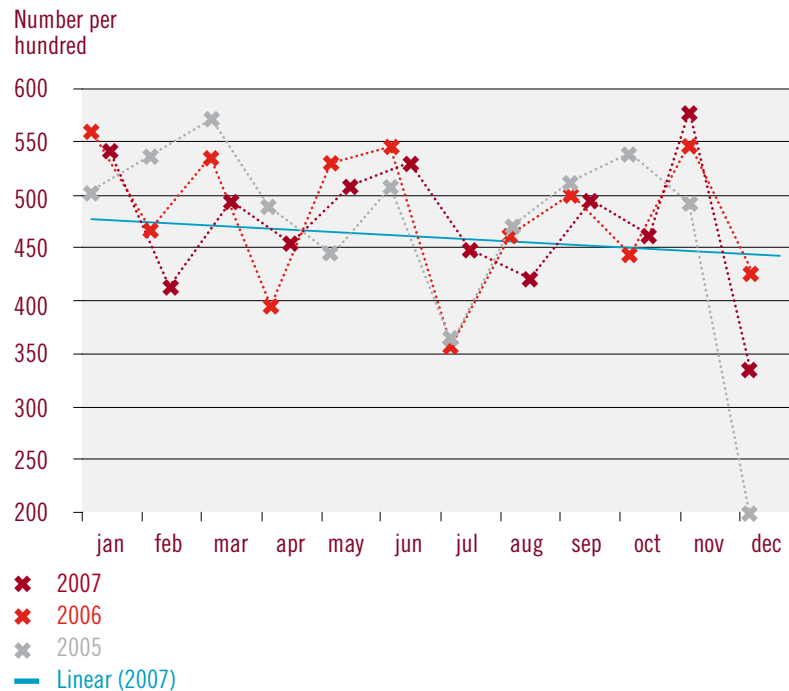
**Overall import and export licences**



**Narcotics forms**

The graph below shows the fluctuation in the number of narcotics forms issued per month. It shows a dip in the number of applications in July and August and in December in past years. The overall number remains stable, at between 5,600 and 6,000 per year, corresponding to the dispatch of 560,000 to 600,000 narcotics forms per year.

**Narcotics forms**



### The Hormonal, Anti-Hormonal, Anabolic and Anti-Infectious Substances unit

This unit takes care of granting authorisations to companies for possessing and trading in these substances.

### Special Investigation unit (SOE - USE)

The INSPECTION pillar of the new structure includes the Special Investigation unit (SOE - USE), whose task is to combat pharmaceutical crime in general. Examples of such crime include copying, counterfeiting, illegal trading, fraud, doping and Internet fraud. This unit works across the inspection units.

Among others pharmaceutical crime means:

- Copying and counterfeiting medicines and the trade in food supplements with therapeutic indications (and in some cases the infringement of intellectual property rights)
- Racketeering involving narcotics and psychotropic substances in the form of medicines
- Problems relating to the import, export and transit of medicines. In these cases, the necessary authorisations are often lacking (e.g. for production, release of batches, import, wholesale and distribution, distribution within the European Union, export, possession)
- Internet and distance selling
- Human and veterinary doping (e.g. bodybuilding, cycling, show-jumping, pigeon-racing)
- Veterinary crime relating to veterinary medicines (e.g. abuse of antibiotics)
- Crime and fraud within GCP, GDP, GMP, GVP

- Borderline products and medicines without a market authorisation
- The trade in traditional medicines such as TCM (Traditional Chinese Medicines, Ayurveda and others)
- The theft of medicines and their resale on the black market

The formation of this unit is consistent with the overall design of the FAMHP's inspection services. The priority is to create a Control Policy unit. In this context, the SOE - USE will then also be involved in control policy, and the current demarcation between this and other inspection services may change. At present, the unit is working under the direction of the coordinator of Unit I within the Production & Distribution department.

Responsibility for these issues used to lie with just one inspector. Since late 2007, however, four additional employees have been active in this investigation unit, since it is clear that this area requires a specialised approach.

The SOE- USE's first objectives are to train employees in their period of training and to develop an infrastructure that will make cooperation and the exchange of information between members possible. A model for a uniform working method in the treatment of cases, the exchange of information and other tasks is also being devised within the service.

### Commissions linked to the Production & Distribution department

- Commission for the establishment of retail pharmacies and chambers of appeal (to be discontinued, as there is no further provision for an appeal procedure for newly submitted applications)  
This commission consists of a Dutch-speaking and a French-speaking Chamber

#### Some achievements and figures in 2007

- French-speaking chamber of appeal of the commission for the establishment of retail pharmacies:
  - 52 applications
  - No backlog
 There are no more applications to be presented to the chamber of appeal for the French linguistic register, and all appeal cases have been finalised
- Dutch-speaking chamber of appeal of the commission for the establishment of retail pharmacies:
  - 70 new applications
  - Backlog: increased efforts to clear the backlog and reduce the turnaround time
 For the Dutch-speaking chamber of appeal 39 current dossiers in backlog will be cleared by April 2008, which solves all backlog
- A number of applications for the temporary or permanent closure of pharmacies were also finalised. The current moratorium on opening new pharmacies runs until 2009
- The renewal of the commission members' mandates is in progress

On 1 January 2007, the FAMHP took over 325 Dutch-language applications that had not yet been finalised on the basis of the establishment regulations (royal decree of 25 September 1974 on the opening, transfer and merger of retail pharmacies).

Applications for new opening (and renewed applications) that go back to 1981 are particularly problematic.

The finalisation of these cases is very difficult, mainly due to the rules of precedence that apply. Dealing with the backlog is a priority matter, and such applications will be processed in chronological order of application.

Work is proceeding on adjusting the existing regulations in order to introduce administrative simplifications, such as the accelerated determination of the acceptability of submitted applications.

#### The following priorities have been set

- Finalisation of dossiers within a reasonable time
- Administrative and procedural simplification
- Link with the services of the pharmacy registry, including through computerisation



### "Grey area" consultation platform

The "grey area" consultation platform involves representatives of the FAMHP, the DG Animals - Plants - Foodstuffs, the DG Environment and the FAVV - AFSCA. The objective of this consultation platform is to determine an indicative status for products that lie on the boundaries between medicines, medical devices, foods or food supplements, cosmetics or biocides.

In 2007, 17 meetings were held: 8 for products for human use and 9 for products for animals. The cases dealt with in these meetings may be complaints by consumers or producers, requests for advice from inspection services, formal opinions on the formulation of regulations, formal opinions for companies wishing to market products and to ensure that they are presenting their product correctly, and internal cases that serve for the compilation of guidelines for the consultation platform.

Additionally, the finalised version of the royal decree should make it possible to turn this consultation platform into a formal "joint commission" as stipulated in the law of 25 March 1964. The official role of this commission is to issue advice to determine the status of products when there is any doubt or uncertainty about whether or not they are medicines.

## Proper use of medicines - BUM

### MISSION AND ROLES

The quality, safety and efficacy of medicines are closely associated with their proper use. To promote the proper use of a medicine, all relevant parties need to have objective, appropriate, up-to-date and readily accessible information.

The FAMHP and the BUM department in particular ensures that all parties have access to such information, so that medicines can be used rationally and safely.

### SOME ACHIEVEMENTS AND FIGURES FOR THE BUM DEPARTMENT IN 2007

The BUM department collects and circulates relevant information about medicines on behalf of the various parties concerned. At the same time it is responsible for independent and objective pharmacotherapeutic information for healthcare professionals, among other means via a partnership with independent institutions. The department also sees to it that the information, advertising and promotional activities of companies that produce medicines and health products, are conform to the regulations.

### General information about medicines

- The FAMHP manages the database of authorised medicines in Belgium. This database is an important instrument for the administrative processing of applications and for responding to the numerous requests for information about medicines. In 2007, the database was adapted several times, and in the course of 2008 it will be made directly and freely accessible on the FAMHP's website. The database can be used to look up extensive information about authorised medicines without having to contact those responsible for providing information, as is currently the case
- Healthcare professionals and veterinarians need to be encouraged to rationalise the use of medicines. For "Evidence Based Medicine" it is important to be able to use objective and recent information. With this in mind, the FAMHP has formed a partnership with independent institutions that provide objective information about medicines. This meets healthcare professionals' expectations in terms of quality and accessibility:
  - Partnership with BCFI vzw - asbl (written information, website, e-mails)
  - Partnership with PROJECT FARMAKA vzw - asbl (oral information for family doctors from independent medical representatives)

### Supervision of advertising

- Every advertisement for medicines for human use intended for the general public is checked before publication. For radio or television advertising, this check is organised by means of a preliminary approval that is granted on the advice of the commission for the supervision of advertising of medicines. For other media channels, preliminary notification of the FAMHP is required

#### Some figures for 2007

- The commission for the supervision of advertising of medicines for human use dealt with 61 approval applications for radio/TV advertising during 16 meetings
  - 276 advertisements via other media were notified. For 123 of these, the FAMHP requested modifications in order to comply with legislation
  - To check the quality and relevance of the messages conveyed to the public, a preliminary check was introduced in 2007 for radio/TV information campaigns about human health and human diseases that refer directly or indirectly to medicines
- #### Some figures for 2007
- The commission for the supervision of advertising of medicines for human use dealt with 7 approval applications for radio and television information campaigns

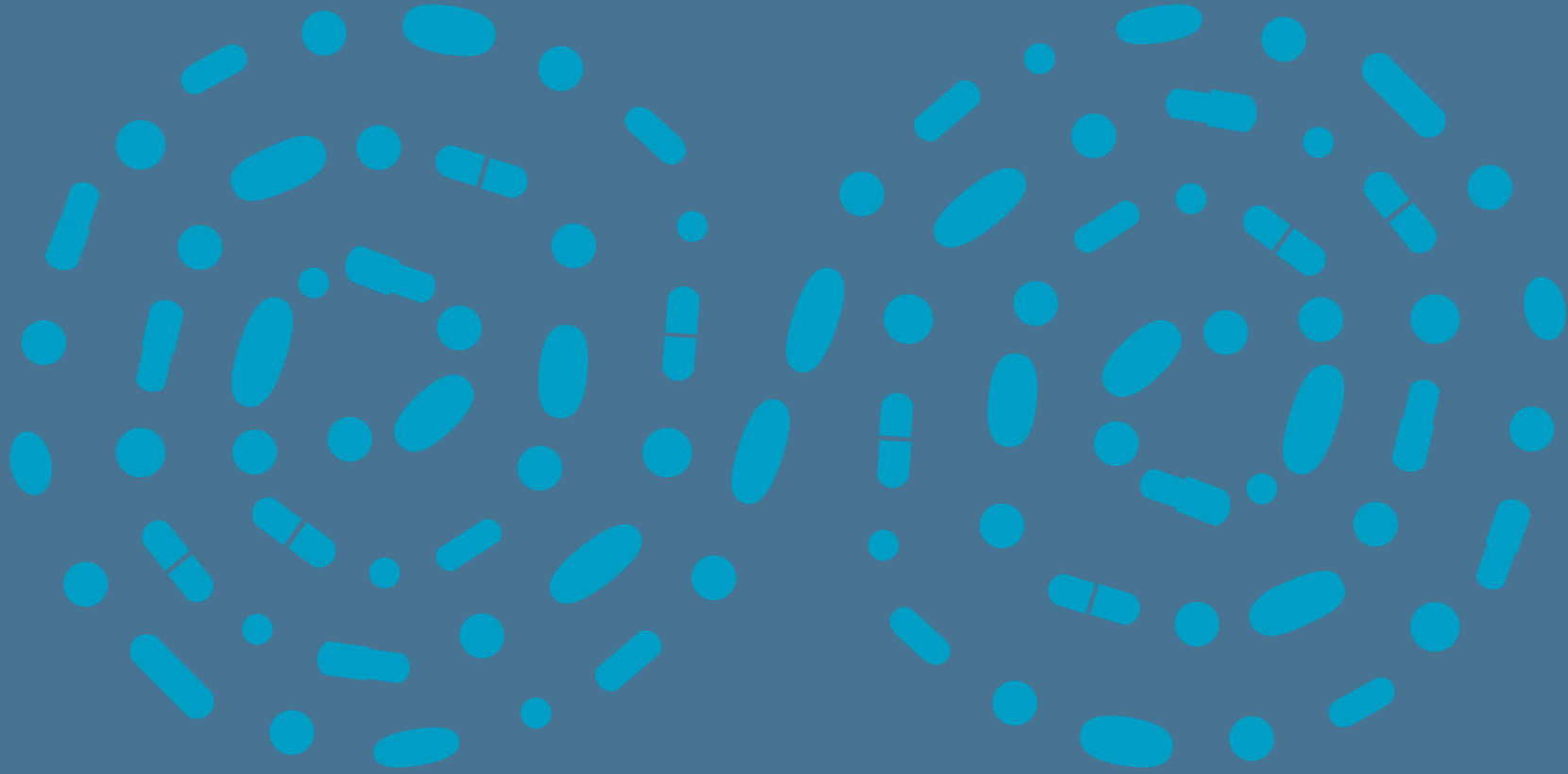
- Since 1 January 2007, the law has been in force requiring a preliminary approval for the payment by pharmaceutical companies or producers of medical devices of the participation costs of healthcare professionals in scientific events involving at least one night's accommodation. As legally stipulated, the approval procedure is carried out by a recognised institution, Mdeon vzw - asbl. Mdeon follows the guidelines authorised in connection with its recognition and ensures strict compliance with the legal requirements (article 10 of the law of 25 March 1964 on medicines). Mdeon cooperates closely with the FAMHP. In 2007 it issued its first annual report and the external audit report to which it is subject ([www.mdeon.be](http://www.mdeon.be)). In close cooperation with Mdeon, the FAMHP has mainly focused on the provision of information to the relevant parties, i.e. companies and healthcare professionals, during this first operational year
- A "contact point" collects and processes information about actions that may constitute an infringement of the legal requirements about advertising.

In terms of advertising for healthcare professionals, attention is particularly being focused at present on the conformity of the legally required information

#### **Some figures for 2007**

- 63 complaints about advertising or the offering of premiums or benefits in the sector of medicines for human use
- 2 complaints about advertising for implantable medical devices or behaviour in connection with their fitting
- 10 complaints about advertising or the offering of premiums or benefits in the veterinary medicines sector
- After investigation, these complaints and other spontaneous checks gave rise to the issue of 11 formal charges and 27 warnings





## MANAGEMENT AND GUIDANCE BY THE CHIEF EXECUTIVE OFFICER'S SERVICES AND THE SUPPORT SERVICES

### CHIEF EXECUTIVE OFFICER'S SERVICES

#### Communication & Scientific Support

The transition from the DG Medicinal Products to the autonomous FAMHP necessitated the organisation of a fully fledged communication service. The Communication & Scientific Support service assists the different departments and services of the FAMHP with internal and external communication and with information about the organisation and also acts as the FAMHP's spokesman. It is essential for the FAMHP's communication actions to be the outcome of mutual harmonisation between the relevant departments and services, with the results being communicated unambiguously. For everyday tasks, activities and work, the service currently consists of four FTE. For larger projects, the help of an informal internal working group may be enlisted, in which each department and service is represented.

The priority task assigned to the Communication & Scientific Support service is to publicise the FAMHP. To strengthen the identity of the new autonomous organisation, the first and most important steps were to design a logo and "house style".

For optimal information flow and the active involvement of all employees, an intranet was launched in October 2007. The Communication & Scientific Support service started its own internal electronic newsletter "Vit@", published every two weeks. For urgent notices, "Vit@ Express" has been launched.

In late December 2007, "@ctua", a quarterly electronic newsletter for stakeholders, was also realised.

Other external communication actions are currently confined to answering questions from the press and the public. Proactive contacts with the general and specialised press, various publications and information campaigns will be included together with future internal communication actions in a proper communication plan so as to implement a strategic communication policy as quickly as possible. A "living" manual will describe the various communication actions, the parties concerned and the role of each one.

The Communication & Scientific Support service represents the FAMHP within COMMnetkern, the network of communicators of the federal government services. In the international context, the FAMHP is also represented in the HMA Working Group of Communication Professionals.

## International Relations

With a view to the organisation of the FAMHP under construction, there are plans to set up an International Relations unit. This unit is responsible for coordinating the internal and external information flow in a national and international context with a view to harmonising Belgian standpoints.

Since the FAMHP's complete separation from the FPS Public Health, it has had autonomous responsibility for the coordination of international relations, under the hierarchical supervision of the Minister of Public Health. However, agreements are in place with the FPS Public Health, for example about participation in committees and working groups in which "public health topics" are discussed that exceed the competency of the FAMHP. An example of these are the committees within the WHO or the Council of Europe.

## Program Management Office

In order to take care of monitoring, planning, coordinating and communicating about the numerous actions associated with the "FAGG-AFMPS 2008" project (see below), a support monitoring unit, the Program Management Office (PMO) unit, has been set up.

The intention is to:

- Ensure a general overview of all programmes and actions
- Guaranty proper coordination
- Make internal and external resources available for the different projects
- Set up an internal change and communication plan
- Offer an information platform for the different projects

The unit is supported in its weekly meetings by a PMO Working Group.

## SUPPORT SERVICES

### Budget & Management Control

The main tasks of the Budget & Management Control (B&Mc) service consist of:

- Compiling and monitoring the annual budget
- Recording income and expenses and compiling the annual accounts
- Paying invoices

### SOME ELEMENTS OF THE BUDGET

The FAMHP's 2007 budget, approved by Parliament, provided for income of 45,854,134 euros and expenses of 45,524,781 euros.

Income includes the government grant (17,300,000 euros), paid via the FPS Public Health, and the organisation's own income from the application of various laws and regulations.

In addition, as an exceptional measure under the law on the formation of the FAMHP, the "Medicine Fund's account" balance of 27,534,000 euros has been transferred from the State to the FAMHP. This amount is in addition to the above income of 45,854,134 euros.

### DISTRIBUTION OF INCOME FOR 2007

After the closure of the accounts for the year, the income for 2007 came to a total of 50,019,281 euros. This is 9.08% better than in the submitted budget. The difference relates entirely to the organisation's own income.

The generated income is composed of 32,719,281 euros of own income and 17,300,000 euros of

granted funds. The organisation's own income represented 65% of its total income (see graph); the grant thus represented 35%.

In 2007, the organisation's own income included an exceptional contribution of 4,793,620 euros allocated in connection with the formation of the FAMHP by articles 241 and following of the programme law of 27 December 2006. This contribution was calculated on the basis of the turnover for medicines (according to the RIZIV -INAMI definition) for 2007 and was not renewed in the programme law of December 2007.

The analysis of the FAMHP's own income shows that 60% of it comes from fees for service and 40% from taxes. These taxes are, depending on the various items of applicable legislation and regulations, collected on the basis of the number of packages of medicines and raw materials sold or on the basis of the turnover generated from medical devices.

In terms of the FAMHP's own income, mention should be made of a special fee of 2,914,155 euros from the EMEA to pay for the FAMHP's activities at European level.

There is one other fee that is notable for its intended purpose, since the "clinical trial" contribution (1,670,042 euros) will serve not just to cover the FAMHP's costs but also and above all to finance the Ethics Committees.

As far as the taxes are concerned, it should be



pointed out that the exceptional tax alone, which brought in 4,813,933 euros, represented 38% of total taxes collected (see graph).

### DISTRIBUTION OF EXPENSES FOR 2007

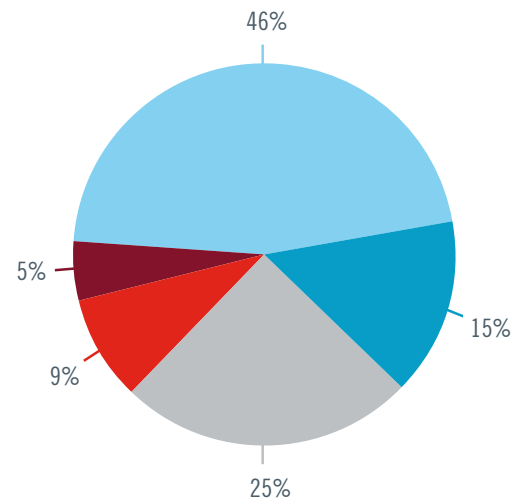
Expenses for 2007 came to 43,618,258 euros, including 16,313,289 euros of personnel costs (statutory and contractual employees), representing 38% of expenses.

Another significant expenditure item is payment of the subsidy for financing NAT blood tests, which came to 9,751,000 euros or 22% of expenses.

Two other important items were the costs incurred on inspection and analysis assignments in connection with medicines and IT expenses. These amounted to 4,795,334 and 3,414,400 euros respectively, representing 11% and 8% of expenses.

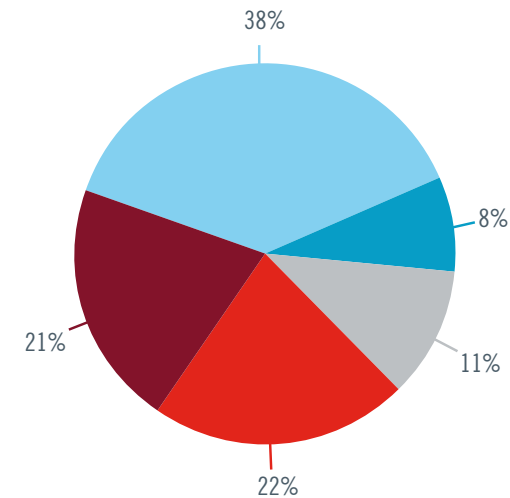
These amounts include some invoices from 2006 that could only be paid in 2008. These deferred expenses amounted to 5,283,330 euros.

FAGG - Own income 2007



- ✘ Other "fees"
- ✘ Exceptional contribution
- ✘ Other contributions
- ✘ EMEA fee
- ✘ Clinical trial fee

FAGG - Expenses 2007



- ✘ Personnel costs
- ✘ ICT expenses
- ✘ Control and analysis of medicines
- ✘ NAT test subsidy
- ✘ Other expenses

## REGISTRATION OF TRANSACTIONS AND ACCOUNTING TREATMENT

Since the creation of the FAMHP the B&Mc service has performed double accounting. As well as complying with legal requirements, this also makes it possible to bring more transparency to the different incoming and outgoing financial flows, bringing more clarity to the financial functioning of the FAMHP for the various stakeholders.

All expenses and items of income are collected within the same IT system so that the accounting statement is simple and can be consulted directly.

For its expenses in 2007 the FAMHP had a total of 3,845 invoices. These invoices are checked and entered into the accounting system after approval. The system automatically (after a double digital signature) performs the payment within the month via the "Isabel" payment system.

The FAMHP's own income for 2007 came from 8,957 payments into 5 bank accounts, into each of which specific income is paid. The accounts are for receipts from the EMEA, R&D, medicated animal feed, taxes on the number of packages and miscellaneous fees.

After cash has been received, it is booked as income under the correct turnover entry. The turnover is then debited against the fee for each submitted service application. In 2007 this involved booking 17,657 virtual sales invoices in the "computerised day books".

Data input happens manually. Information about the bookings, such as the reconciliation of the fees and corresponding service applications, is mainly obtained from the MeSeA system, more specifically through verification of "public inbox payment tracking". Account allocation data that is not included in MeSeA is communicated by conventional means using the administrative forms and financial folders of the FAMHP's different departments and services.

## FAMHP - 2007 Budget in euros

	Budget	Actual
<b>Income</b>		
Grant	17.299.134	17.300.000
Own income	28.555.000	32.719.281
<b>Total</b>	<b>45.854.134</b>	<b>50.019.281</b>
<b>Expenses</b>		
Cost of labour and social charges	19.131.281	15.719.523
Other personnel costs	612.000	593.766
Non-ICT operating costs	14.312.320	11.536.913
ICT operating costs	1.522.000	2.605.074
Non-ICT capital expenditure	100.000	103.775
ICT capital expenditure	611.000	875.401
NAT blood test subsidy	9.751.000	9.751.000
Purchase of antivirals	-	2.348.991
<b>Total</b>	<b>46.039.601</b>	<b>43.534.443</b>

## Information & Communication Technology

The FAMHP's Information & Communication Technology (ICT) service gives support in the area of IT and provides the FAMHP with suitable and effective tools. At present there are five agents who belong to the internal FAMHP team and ten agents who are supplied by the ICT service of the FPS Public Health, with which an SLA has been concluded in order to bring to a successful conclusion the transfer of tools and IT skills from the former DG Medicinal Products to the FAMHP and ensure the continuity of service provision.

The ICT service is responsible for the planning, coordination and monitoring of projects and operations, as well as for the allocation, control and running of government contracts in the area of IT. It also defines the partnerships with the FPS Public Health, SMALS or partners from the private sector.

During the first few months after the creation of the FAMHP, a "PMO ICT" was set up within the organisation in order to consolidate the ICT strategy and coordinate initiatives in the area of IT, including the monitoring of European groups. This is an ICT steering group that sets the priorities for projects and developments in consultation with the various heads of the "core business" in order to meet the needs of the new organisation.

Cooperation is in place with the European Commission, the EMEA, the Establishment Groups for telematics, the European Member States and the medicine industry for the mapping out of a common vision of the development of IT standards and their implementation.

### FOCUS POINTS

To ensure that the FAMHP develops into a benchmark organisation at Belgian and European level, it is vital for it to have the necessary means to perform even more effectively in terms of:

- The administrative simplification of procedures, among other means by putting the finishing touches to the MeSeA system (e.g. by simplifying procedures, making the ICT system more effective and adapting the system to users' needs) and by the continuing integration of ICT systems
- Integration and cooperation in the context of e-government at national and international level by creating a synergy with external partners such as the KBO - BCE, RIZIV - INAMI, e-Health and the EMEA

In this context, the ICT service is closely involved in five main challenges:

#### **Optimisation of the integrated MeSeA system**

At the time of the FAMHP's creation, the organisation had just one integrated system, MeSeA, to support its core business, i.e. the electronic submission of registration applications and variations for medicines for human use and the pharmacovigilance applications. In view of the serious problems with the availability and effectiveness of MeSeA, FEDICT recommended, after examining the system, entrusting the application and infrastructure to an external partner who could solve the problems and extend the application with a portal for external partners. In response to this recommendation, the FAMHP issued a general invitation for tenders at European level. The aim has been to ensure the FAMHP's continued ability to remain at the forefront of European countries for those aspects for which electronic submission becomes obligatory from 2009.

#### **Enhancing the organisation's image and improving online communication**

In 2007 an intranet was launched in cooperation with the Communication & Scientific Support service and there are plans to develop a brand-new website with the BUM department that will group existing sites and optimise internal and external communication.

The BUM department is legally required to provide support with putting online the list of medicines authorised in Belgium for new medicine MA and of the official information (Summary of Product Characteristics for healthcare professionals and leaflet for the general public).

**Development of a central database**

The “Inspections” project plans to develop a common application for the inspection services, with the goal of providing a direct, central monitoring and reporting system.

**Development of digital transactions with external partners**

- KBO - BCE  
The DATALINK project is intended for the creation of a “customer” database that is common to all services and has a direct link with the KBO-BCE
- e-Health  
The common database created via the DATALINK project will also serve as the authentic source for the e-Health platform in the public health sector
- RIZIV - INAMI  
The synergy possibilities with RIZIV - INAMI in terms of the exchange of digital data and the consolidation of databases need to be investigated and implemented

**Compliance with the European directives on electronic submissions**

Compliance with the European directives requires a number of objectives to be achieved:

- Arriving at a functional vision of communication standards with EMEA and the Member States in partnership with the industry and in line with European legislation
- Standard project management, with important steps that are sponsored/supported by the Member States: first developing an IT infrastructure and then starting on a highly secure network followed by so-called “proofs of concept” in each field
- Success depends above all on the FAHMP’s proactive participation in the European telematics systems in order to improve the efficacy of the regular core business activities (production, medicine safety, clinical trials, application submission) with a view to protecting public health and economic growth in the Member States and ensuring more transparency and information for the general public

## Legal service

In 2007 the Legal service of the FAMHP was responsible for:

- Legislation
  - Achieving the policy objectives of the minister in charge
  - Compiling and overseeing legislation
  - Devising proposals for the improvement of current legislation
  - Monitoring the development of European regulations
  - Transposing European regulations into national law
- Coordination of international relations
- Legal advice and information
- Disputes
  - Legal cases and coordinating elements for the defence
  - Administrative fines
  - Requests for mercy

From 3 May to 20 December 2007 the government no longer had all its powers. As a consequence, during this period, apart from budgetary and very urgent provisions included in the laws of 21 December 2007, in principle, no legislative initiatives were taken. Nor were draft royal decrees signed by the Head of State. Draft texts that were prepared could therefore only be published and deliver results in 2008.

Despite this unusual regulatory situation in 2007, as far as possible the necessary regulatory texts relating to the practical establishment and functioning of the FAMHP were produced. Among other things, these included the royal decrees

determining the composition and functioning of the Scientific Committee, the Transparency Committee and the Consultative Committee established at the FAMHP and the various measures relating to the FAMHPS's personnel, such as determining linguistic ratios and pension arrangements. A large number of related draft texts continued to be prepared, such as those on the concrete composition of the above-mentioned three committees and the provisions relating to the organisational structure and functioning of the FAMHP.

Naturally, work was also done on other regulatory initiatives, such as the revision of the royal decree of 31 May 1885 on new provisions for doctors, pharmacists and druggists. This revision introduces important changes relating to the dispensing of medicines and medical devices. Thus the sale of non-prescription drugs over the Internet is regulated in it, "Good dispensing pharmaceutical practices" are stipulated and rules relating to the organisation of the night-duty service are established. This draft text will be finalised in 2008.

At European level, important texts were adopted such as Directive 2007/47/EC amending Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, and Regulation (EC) no. 1394/2007 on advanced therapy medicinal products. The FAMHP has cooperated intensively with the elaboration of this European legislation, and the necessary measures must be taken in 2008 to ensure their concrete application.

In 2007, 72 formal charges were also drawn up. 65 administrative fines were applied, of which 56 were paid, while 7 formal charges were sent to the Public Prosecutor for non-payment of administrative fines or for other reasons.

## Translation service

The FAMHP's Translation service was only started in mid-March 2007, with 1 FTE. On 1 June 2007 a second FTE arrived. The translators are responsible for translating texts, revising texts and providing linguistic advice.

### Some translated documents in 2007

- Minutes and reports
- MeSeA work records
- Internal and external communication (e.g. the FAMHP newsletters, press releases, service memos, circulars, letters, vacancy advertisements, job descriptions)
- Answers to parliamentary questions
- Draft regulations
- PowerPoint presentations
- Contracts and agreements

Most of the demand is for the translation of documents into French (50%) and Dutch (45%). To a lesser extent, there are also translation assignments into English (4%) and German (1%).

## Personnel & Organisation

The P&O service is responsible for HR management and organisational development within the FAMHP. Its main role is to strive for optimal efficiency and performance for each employee and the organisation as a whole.

In view of the transition from the DG Medicinal Products to the FAMHP, general personnel management for all FAMHP personnel members in 2007 was taken care of by the personnel service of the FPS Public Health via an SLA.

### Some focus points in 2007

#### Knowledge management

The P&O service wants to stimulate knowledge management within the organisation. In this context sessions were organised on a regular basis in 2007 at which trainees presented their work to interested parties within the organisation.

Work will continue in future years on knowledge management, with various initiatives.

#### eHR Twister

With a view to ensuring the complete autonomy of the P&O service, there was a need for an integrated IT solution for personnel management. In line with the rules on government contracts, a private company was asked to develop a special application tailored to FAMHP requirements. The system is specifically intended for the employees of the P&O service, and should make efficient personnel management possible.

The application includes various components such as personal details, deployment, current matters, skills and competencies, basic reporting and organisational development.

In the course of 2008 a second phase is planned, with more of a focus on tailored reporting.

### Some figures for 2007

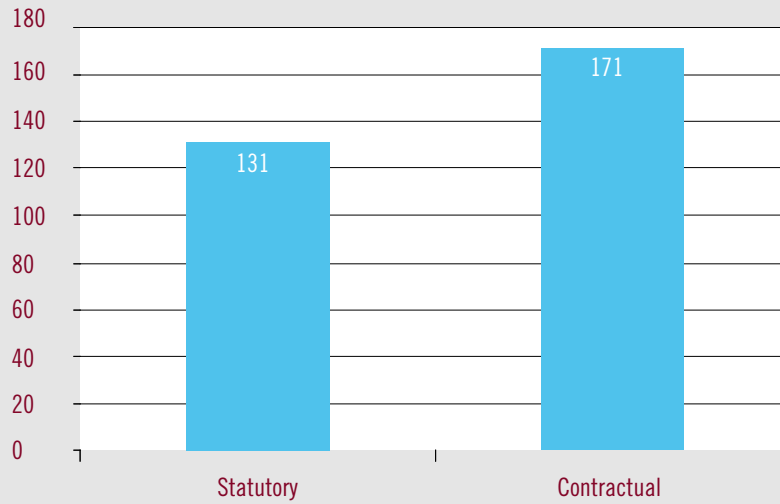
#### (situation on 30.11.2007)

302 personnel members were working at the FAMHP:

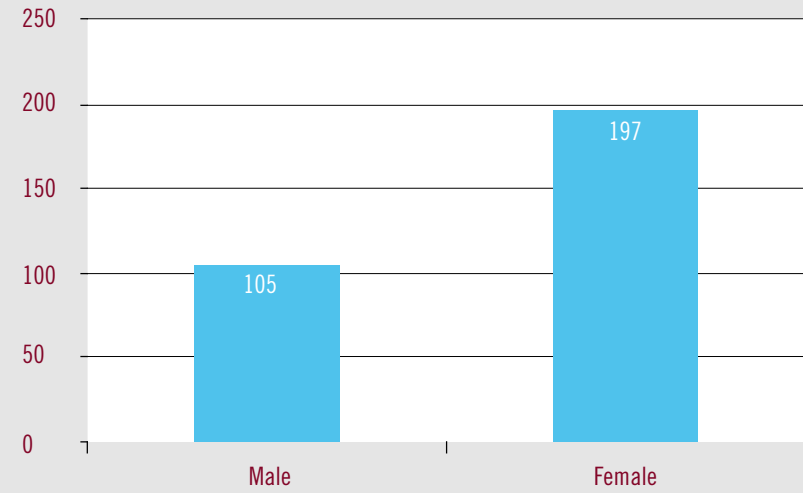
- 131 statutory, 171 contractual
- 105 male, 197 female
- 174 at level A, 24 at level B, 69 at level C, 35 at level D



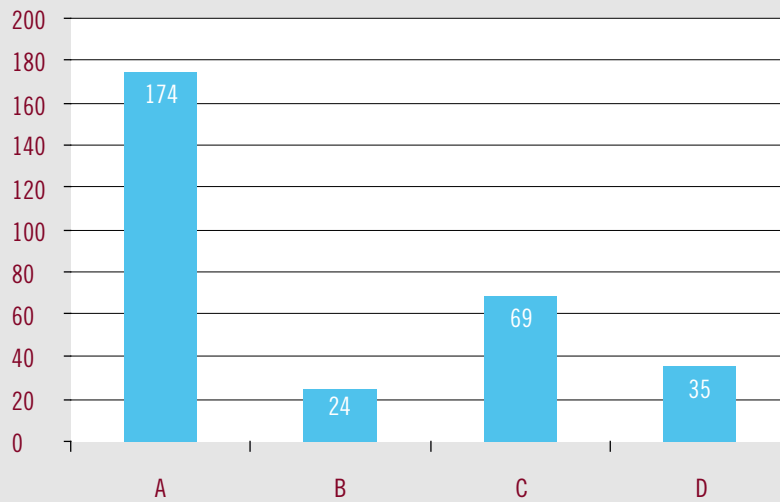
**Contractual-statutory distribution**



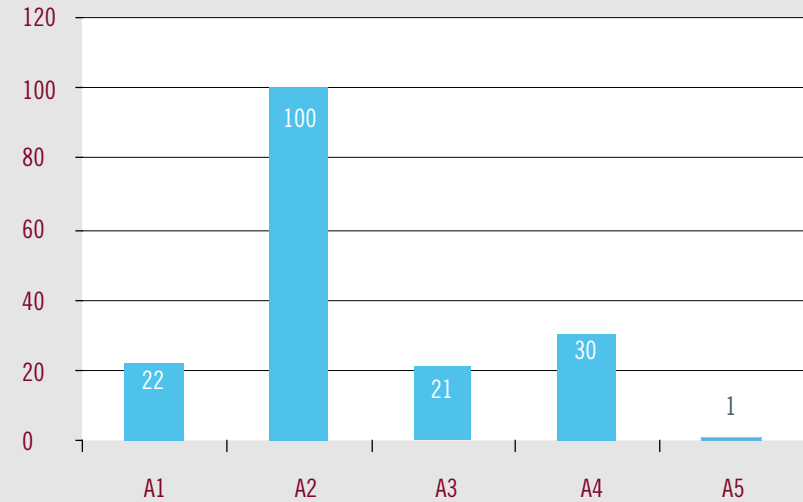
**Male-female distribution**



**Distribution between levels**



**Distribution within level A**







## “FAGG-AFMPS 2008” PROJECT

The FAMHP will, subject to the availability of the necessary resources, be developed into an innovative and highly effective organisation. The key elements of this ambition are, firstly, the provision of efficient and high-quality services and, secondly, compliance with all the legal requirements imposed on the FAMHP (taking account of the revised Belgian pharmaceutical legislation and the European Directives).

Under the guidance of two consultants and a Central Working Group, the “**FAGG-AFMPS 2008**” project started up in late June 2007 with the main goal of coming up with a design for the future organisation and implementing that design. The first results emerged in late September 2007, in the form of a clear proposal regarding the organisation’s core activities, a list of the key factors for effective functioning and a list of focus points.

### Central Working Group

To achieve the objectives of the “FAGG-AFMPS 2008” project, the Central Working Group was set up in such a way that its members represented all FAMHP departments and services.

At a first intensive workshop on 4 July 2007, consideration was given to ambitions to be achieved by 2012. This produced a first list of core elements for becoming a highly effective model organisation, and a number of powerful ideas emerged, such as the need for multidisciplinary and the value of forming “centres of excellence” or spearheads (see below) within the FAMHP.

At the end of August 2007, a second workshop was held with the aim of evaluating the discussions about the chosen spearheads, taking a more detailed look at the organisation’s competencies and starting the reflection exercise about the structure of the FAMHP.

The role of the Central Working Group is to take decisions together with the Chief Executive Officer regarding the development of the FAMHP and to set priorities.

## Levers, key factors and strategic objectives, PMO projects

### LEVERS

To achieve results as quickly as possible, a number of **levers** have been determined by the Central Working Group for the development of the new organisation. The chosen levers are resources or domains that will help with medium-term growth into a highly effective, smooth-running organisation.

The choice fell on:

- Communication
- Funding
- International coordination
- Learning organisation

For each of these levers, a working group has been set up for evaluation, further optimisation and the compilation of a concrete action plan. The working groups are composed of representatives from every department and service.

### KEY FACTORS AND STRATEGIC OBJECTIVES

In consultation with the Central Working Group, six **key factors** were determined that reflect the vision of the FAMHP. On the basis of the key factors, a number of concrete **strategic objectives** were then set for 2008.

#### Key factor 1

##### Recognition at national, European and international level

- Ensuring a strong, recognised identity, internally and externally
- Implementing the spearheads
- Ensuring proper coordination at European and international level

#### Key factor 2

##### Informing the public optimally

- Publicising the FAMHP (Formation - Organisation - Contact)
- Providing information about the legal context and procedures
- Providing information about medicines and health products

#### Key factor 3

##### Developing transversality within the organisation

- Ensuring optimal coordination between the three pillars (PRE, POST and INSPECTION)
- Integrating the spearheads across the organisation

Transversally integrating and coordinating the operational departments and other services

**Key factor 4****Developing partnerships with the healthcare sector**

- Determining common objectives and priorities with the sector (e.g. professional associations and industry)
- Determining common objectives and priorities with patients' associations and members of the public

**Key factor 5****Realising and establishing a learning organisation culture**

- HRM policy
- Organisational culture
- IT tools
- Knowledge management

**Key factor 6****Performing basic tasks in a professional manner**

- Optimising and simplifying procedures
- Ensuring the necessary expertise
- Ensuring market control

**PMO PROJECTS**

In order to achieve the strategic objectives, some 70 **PMO projects** (e.g. self-inspection, risk management) have been defined. The PMO unit will undertake the coordination of these projects starting in 2008, supported by the PMO Working Group.

## Spearheads and other focus points

### SPEARHEADS

Within the FAMHP's new structure, in addition to the effective performance of the basic tasks, special attention will also be focused on a number of "centres of excellence" or spearheads.

Spearheads are fields in which the FAMHP wishes to excel and which can be regarded as the FAMHP's visiting card. In a European context, it is important for the FAMHP to stand out in a number of areas from the medicines authorities in other Member States.

The FAMHP wants:

- To emerge as a point of reference for scientific advice
- To attract clinical trials
- To act as rapporteur or RMS in the evaluation of registration applications for important products
- Where relevant, to be a point of reference for specific inspection tasks
- To define a clear programme of communication with other Member States, stakeholders and citizens
- To play an active role in international commissions, committees, working groups, seminars and conferences
- To be a point of reference for legal affairs

In the course of 2007 the Central Working Group analysed possible spearheads for the FAMHP. A list of potential substantive (vertical) and process-related (horizontal) spearheads was drawn up and a number of criteria were determined by which the different areas could be compared with one another. These were: industrial fabric in Belgium, research and expertise in Belgium, expertise within the FAMHP, development potential, differentiating potential and speed with which expertise can be developed. "Importance for public health" was not selected as a criterion for the selection of the spearheads, given that the protection of public health is the fundamental role of the FAMHP and is obviously important for all proposed areas.

On the basis of this analysis, four spearheads (two substantive and two process-based) were chosen at the end of 2007:

- Vaccines
- Oncology (with special attention for cancer pain and paediatric oncology)
- Early phase development
- Proactive vigilance policy

### FOCUS POINTS

During the numerous discussions, a number of focus points were listed by the Central Working Group:

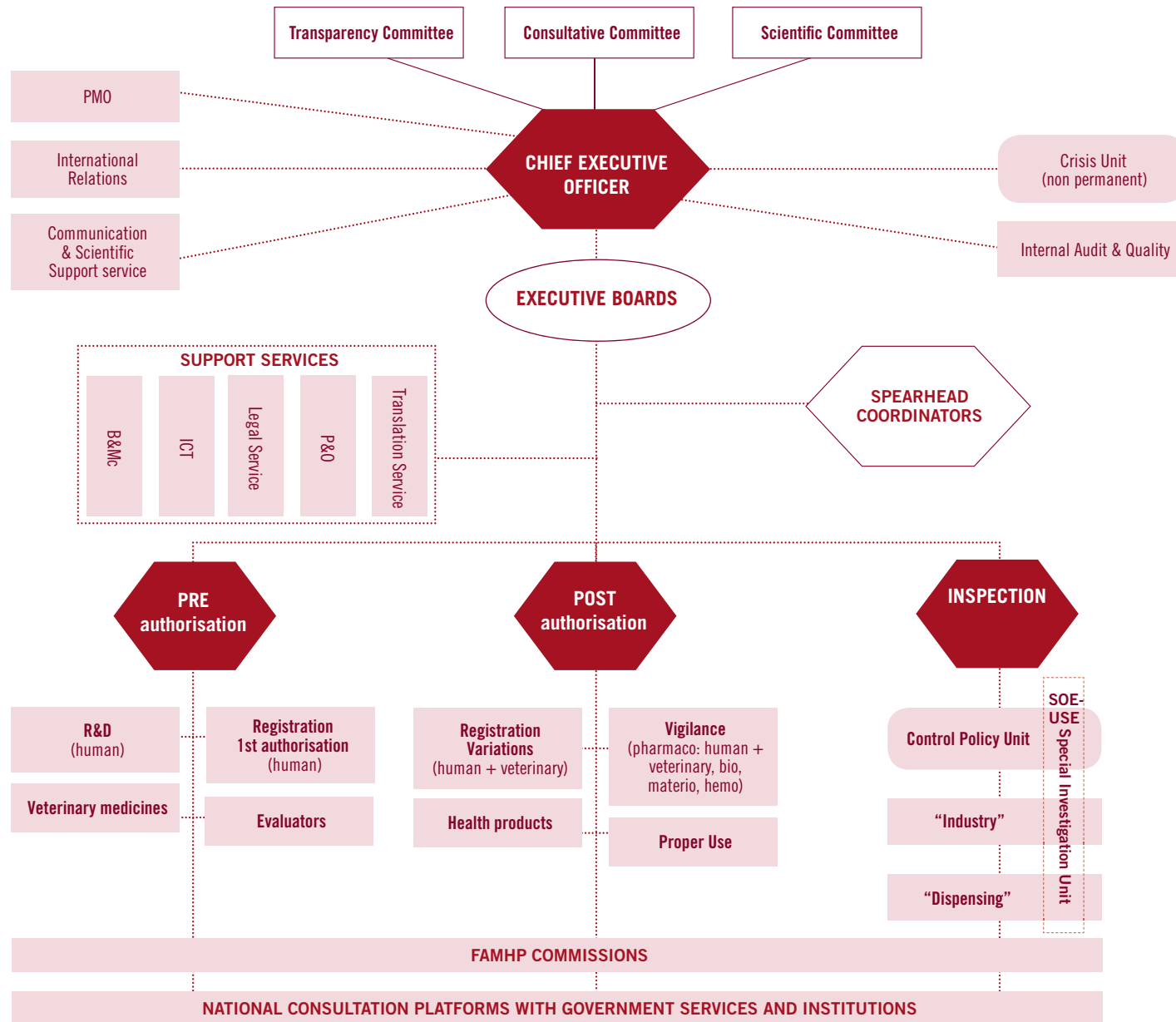
- Backlogs (in registration applications for medicines for human use and veterinary medicines, raw materials (active ingredients) for pharmacists, establishment of retail pharmacies, medical devices)
- Management of possible crisis situations
- Coordination of the (inter)national representation of the FAMHP
- The difference between the roles of "Communication" versus "Information"
- Points of entry for applications submitted to the FAMHP
- MeSeA
- Rapid Alerts (concerning quality problems, clinical trials and vigilance)

These focus points will be further analysed and evaluated so that avenues for improvement or clarification can be proposed in the short term.





# ORGANISATION CHART



FAMHP COMMISSIONS<sup>3</sup>

- |   |   |  |
|---|---|--|
| <ul style="list-style-type: none"> <li>● Evaluation commission for active implantable medical devices</li> <li>● Evaluation commission for homeopathic medicines</li> <li>● Evaluation commission for medical devices</li> <li>● Evaluation commission for medicines for human use</li> <li>● Evaluation commission for medicines for veterinary use</li> <li>● Evaluation commission for traditional herbal medicines</li> <li>● Pharmacopoeia commission</li> </ul> | <ul style="list-style-type: none"> <li>● Evaluation commission for active implantable medical devices</li> <li>● Evaluation commission for homeopathic medicines</li> <li>● Evaluation commission for medical devices</li> <li>● Evaluation commission for medicines for human use</li> <li>● Evaluation commission for medicines for veterinary use</li> <li>● Evaluation commission for traditional herbal medicines</li> </ul> | <ul style="list-style-type: none"> <li>● Advisory commission that is consulted e.g. in cases of non-availability of medicines</li> <li>● Commission for the approval of institutions assigning preliminary approvals for scientific events</li> <li>● Commission for the establishment of retail pharmacies and chambers of appeal (French-speaking chamber and Dutch-speaking chamber)</li> <li>● Commission for the recognition of pharmacists-clinical biologists</li> <li>● Commission for the supervision of advertising for medicines for human use</li> </ul> |
|---|---|--|

NATIONAL CONSULTATION PLATFORMS WITH GOVERNMENT SERVICES AND INSTITUTIONS<sup>4</sup>

- |   |   |   |
|---|---|---|
| <ul style="list-style-type: none"> <li>● BAPCOC (with FPS Public Health)</li> <li>● Board for biosafety (with WIV - ISP and the Biosafety and Biotechnology Service)</li> <li>● Consultation platform with FAVV - AFSCA, FPS Public Health and Public Health Minister's Office</li> <li>● "Grey area" consultation platform (with FPS Public Health and FAVV - AFSCA)</li> <li>● Professional Ethics Committee (with FPS Public Health - DG Animals - Plants - Foodstuffs)</li> <li>● Strategic unit/RIZIV - INAMI</li> </ul> | <ul style="list-style-type: none"> <li>● BAPCOC (with FPS Public Health)</li> <li>● Consultation platform with FAVV - AFSCA, FPS Public Health and Public Health Minister's Office</li> <li>● e-MED (electronic prescription of medicines) (with FPS Public Health and RIZIV - INAMI)</li> <li>● "Grey area" consultation platform (with FPS Public Health and FAVV - AFSCA)</li> <li>● Guidance committee of the network of medical-pharmaceutical committees</li> <li>● Interdepartmental committee of experts on blood, organs, cells, tissues and embryos (with FPS Public Health, KCE, RIZIV - INAMI and WIV - ISP)</li> <li>● Interdepartmental network on "information society services" (with FPS Economy)</li> <li>● Strategic unit/RIZIV - INAMI</li> <li>● Unavailability of medicines (with RIZIV - INAMI)</li> <li>● Working group on blood of the Belgian Federal Supreme Health Council</li> <li>● Working group on cells, tissues and organs of the Belgian Federal Supreme Health Council</li> </ul> | <ul style="list-style-type: none"> <li>● Consultation platform with FAVV - AFSCA, FPS Public Health and Public Health Minister's Office</li> <li>● DGO - SCM guidance committee (with APB and OPHACO)</li> <li>● e-MED (electronic prescription of medicines) (with FPS Public Health and RIZIV - INAMI)</li> <li>● "Grey area" consultation platform (with FPS Public Health and FAVV - AFSCA)</li> <li>● Guidance committee of the network of medical-pharmaceutical committees</li> <li>● ICVV - CICSA</li> <li>● Influenza (in cooperation with external partners)</li> <li>● Interdepartmental committee of experts on blood, organs, cells, tissues and embryos (with FPS Public Health, KCE, RIZIV - INAMI and WIV - ISP)</li> <li>● Inter DG drugs (with FPS Public Health)</li> <li>● Mdeon board of management</li> <li>● Potassium iodide tablets campaign (with FPS Interior Affairs)</li> <li>● Provincial medical commissions (with FPS Public Health)</li> <li>● Strategic unit/RIZIV - INAMI</li> <li>● Unavailability of medicines (with RIZIV - INAMI)</li> </ul> |
|---|---|---|

3 and 4 Free translations and explanations - see also list of abbreviations and definitions

## CONTACT

### SOME USEFUL CONTACT DETAILS

#### Reception (general)

tel. 00 32 2 524 80 00

fax 00 32 2 524 80 01

#### Registration call centre

tel. 00 32 2 524 80 04

e-mail [DGG\\_CallCenter\\_DGM@fagg-afmps.be](mailto:DGG_CallCenter_DGM@fagg-afmps.be)

#### Media contacts and external communication actions

tel. 00 32 2 524 80 12

gsm 00 32 495 23 71 69

fax 00 32 2 524 80 03

e-mail [comm@fagg-afmps.be](mailto:comm@fagg-afmps.be)

#### Information about medicines and health products

e-mail [info.FAGG\\_AFMPS@fagg-afmps.be](mailto:info.FAGG_AFMPS@fagg-afmps.be)

#### Information about sample availability

e-mail [ech\\_staal@fagg-afmps.be](mailto:ech_staal@fagg-afmps.be)

#### Information about the marketing of medicines (sunset clause)

e-mail [fagg-afmps.sunsetclause@fagg-afmps.be](mailto:fagg-afmps.sunsetclause@fagg-afmps.be)

## “A MEDICINES AGENCY UNDER CONSTRUCTION”

### ANNUAL REPORT 2007 AND NOW ...

The first year of the FAMHP and this first annual report present an opportunity to pause for reflection and look back over the progress that we have made so far, despite very difficult circumstances.

Over the past year I have taken the time to meet as many people as possible, not just colleagues but also the many stakeholders, to discuss a specific subject or a specific case during a meeting or a chance encounter.

I want to encourage these instructive exchanges further in the future, and would like to emphasise how pleased I am to have encountered so many motivated people who take their job and their responsibilities seriously, despite the difficulties inherent in starting up a new organisation and despite IT applications that are not yet fully developed.

Right from my appointment in May, following the interim period under the leadership of Piet Vanthemsche, I announced that 2007 was a transitional year, the first phase towards a properly organised and structured FAMHP.

The expectations that our stakeholders and our fellow-citizens rightly had of the FAMHP may not have been completely satisfied as yet, but the many new projects started up in past months will soon produce a number of effective services.

In short, we are working to gain your confidence, to help us oversee the safety, quality and efficacy of the available medicines and health products. We thank you for the support we have received during the creation of the FAMHP and are convinced that the FAMHP will be able to present a markedly better summary after its second year.

Because

*“Your medicines  
and health products  
are our concern”*

Xavier De Cuyper  
and all employees of the FAMHP

## LEGAL CONTEXT

The following is a selection of the regulations governing the organisation, functioning and activities of the FAMHP (see also [www.fagg.be](http://www.fagg.be)):

- Law of 20 July 2006 on the establishment and functioning of the Federal Agency for Medicines and Health Products
- Royal decrees of 25 February 2007 on the composition and working method of the committees of the Federal Agency for Medicines and Health Products
- Royal decree of 20 December 2007 determining the date of establishment of the Scientific Committee, namely 1 February 2008
- Royal decree of 28 January 2008 on the concrete composition of the Consultative Committee
- Ministerial decree of 11 January 2007 on the composition and appointment of the members of the executive board of the Federal Agency for Medicines and Health Products
- Law of 25 March 1964 on Medicines – revision of 1 May 2006 and its implementing decree of 14 December 2006 on medicines for human and veterinary use (the so-called “mammoth decree”)
- Law of 24 February 1921 on trading in poisons, soporifics and narcotics, psychotropic substances, disinfectants and antiseptics and substances that can be used for the illegal production of narcotics and psychotropic substances and its implementing decrees of 31 December 1930 governing soporifics and narcotics and concerning risk limitation and therapeutic advice and of 22 January 1998 governing certain psychotropic substances and concerning risk limitation and therapeutic advice and of 12 April 1974 containing certain provisions relating to substances with hormonal, antihormonal, anabolic, beta-adrenergic, anti-infectious, antiparasitic and anti-inflammatory action
- Law of 15 July 1985 on the use in animals of substances with hormonal, anti-hormonal, beta-adrenergic or production stimulating action
- Law of 13 June 1986 on the removal and transplanting of organs, with regard to cells and tissues
- Law of 28 August 1991 on the practice of veterinary medicine, regarding the provision of medicines to animal carers
- Law of 5 July 1994 on blood and blood derivatives of human origin
- Law of 7 May 2004 on experiments on the human person
- Royal decree of 31 May 1885 approving new instructions for physicians, pharmacists and druggists
- Royal decree of 22 September 1966 on the conditions and arrangements for the recognition of laboratories for the analysis and checking of medicines
- Royal decree of 6 June 1960 on the production, preparation and wholesale distribution and delivery of medicines
- Royal decree no. 78 of 10 November 1967 on the practice of the healthcare professions regarding the dispensing of medicines to the public and Royal decree of 25 September

- 1974 on the opening, transfer and merger of retail pharmacies
- Royal decree of 9 July 1984 on the provision of information and advertising relating to medicines
  - Royal decree of 11 January 1993 determining the conditions under which medicines for human use may be supplied in sample form
  - Royal decree of 7 April 1995 on the provision of information and advertising relating to medicines for human use
  - Royal decree of 15 July 1997 on active implantable medical devices, transposing Directive 90/385 EEC (AIMD)
  - Royal decree of 19 December 1997 on the control and analysis of the raw materials used by dispensing chemists
  - Royal decree of 18 March 1999 on medical devices, transposing Directive 93/42/EEC of 14 June 1993 (MDD)
  - Royal decree of 11 July 2003 determining the conditions under which medicines for veterinary use may be supplied in sample form
  - Law of 16 December 2004 modifying the regulations on combating abuses in the promotion of medicines
  - Royal decree of 10 June 2006 establishing the report point referred to in Article 10, § 5, of the law of 25 March 1964 on medicines
  - Royal decree of 23 November 2006 implementing Article 10, § 3, of the law of 25 March 1964 on medicines
  - Royal decree of 25 February 2007 recognising the institutions referred to in Article 10 § 3 of the law of 25 March 1964 on medicines

## PUBLICATION INFORMATION

This report "A medicines agency under construction. Annual report 2007" originated as a trainee's report by Ann Eeckhout, head of the Communication & Scientific Support service, with the valuable cooperation of colleagues from the FAMHP.

### Person responsible for the publication

X. De Cuyper, Chief Executive Officer

### Coordination

Communication & Scientific Support service

### Graphic design and production



#### ● CIBE vzw

CIBE vzw, public sector tailored communication  
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[www.cibecommunicatie.be](http://www.cibecommunicatie.be)

### This report exists in Dutch, French and English

The electronic version of this annual report 2007 is available on the FAMHP's website

[www.fagg.be](http://www.fagg.be) - [www.afmps.be](http://www.afmps.be) / Medicines / FAGG

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<b>ICVV - CICSA</b>	Interdepartementale Coördinatiefceel voor de controle van de Voedselveiligheid - Cellule de Coordination Interdépartmentale pour le Contrôle de la Sécurité Alimentaire : <i>interdepartmental coordination unit for the control of food security</i>
<b>i.e.</b>	id est - that is to say
<b>IMP</b>	Investigational Medicinal Products
<b>INCB</b>	International Narcotics Control Board
<b>IT</b>	Information Technology
<b>KBO - BCE</b>	Kruispuntbank voor Ondernemingen - Banque-Carrefour des Entreprises : <i>crossroads bank for enterprises</i>
<b>KCE</b>	Federaal Kenniscentrum voor de Gezondheidszorg - Centre Fédéral d'Expertise des Soins de Santé : <i>Belgian health care knowledge centre</i>
<b>KPI</b>	Key Performance Indicator
<b>MA</b>	Marketing authorisation
<b>MDD</b>	Medical Device Directive
<b>MDeon</b>	Mdeon is the common professional ethics platform created for the associations of doctors, pharmacists, the pharmaceutical industry and the medical devices industry
<b>MeSeA</b>	Medicines electronic Submission and electronic Approval
<b>MRP</b>	Mutual Recognition Procedure
<b>NAT</b>	Nucleic Acid Testing
<b>NP</b>	National Procedure
<b>no.</b>	Number
<b>OPHACO</b>	Vereniging der Coöperatieve apotheken van België - Office des Pharmacies Cooperatives de Belgique : <i>Belgian professional association of cooperative retail pharmacies</i>
<b>P&amp;D</b>	Production and distribution
<b>P&amp;O</b>	Personnel and organisation
<b>PDCO</b>	Paediatric Committee
<b>PEN</b>	Pre Export Notification
<b>PMO</b>	Program Management Office
<b>PROJECT PRISM</b>	International initiative set up by the INCB which monitors the five main precursors of amphetamine type stimulants, the equipment used for illegal production of such products and the inappropriate use of the Internet to divert products from legal to illegal channels
<b>PSUR</b>	Periodic Safety Update Report
<b>R&amp;D</b>	Research and development
<b>RAS</b>	Rapid Alert System
<b>RASH</b>	Regulatory Affairs Society for Homeopaths
<b>RD</b>	Royal decree

<b>RIZIV - INAMI</b>	Rijksinstituut voor ziekte- en invaliditeitsverzekering - Institut national d'assurance maladie-invalidité : <i>national institute for sickness and invalidity insurance</i>
<b>RMS</b>	Reference Member State
<b>RQ</b>	Renouvellement quinquinal : <i>five-yearly renewal</i>
<b>SAWP</b>	Scientific Advice Working Party
<b>SLA</b>	Service Level Agreement
<b>SMALS</b>	Smals supports and guides the social sector and federal government services with their information management (non-profit association)
<b>SmPC</b>	Summary of Product Characteristics
<b>SOE - USE</b>	Speciale Onderzoekseenheid - Unité Spéciale d'Enquête : <i>special investigation unit</i>
<b>TGV - ATU</b>	Tijdelijke Gebruiksvergunning - Autorisation Temporaire d'Utilisation : <i>temporary use autorisation</i>
<b>TCM</b>	Traditional Chinese Medicines
<b>TFR - CTP</b>	Technisch Farmaceutische Raad - Conseil Technique Pharmaceutique : <i>technical pharmaceutical council</i>
<b>TMF- FTM</b>	Therapeutic Magistral Formularium
<b>TDR</b>	Technisch Overleg Registratie - concertation technique en matière d'enregistrement : <i>technical consultation platform for registration</i>
<b>TSE</b>	Creutzfeldt-Jakob's Disease - Transmissible Spongiform Encephalopathy
<b>TU</b>	Traditional Use
<b>UNAMEC</b>	Professional association for companies producing, importing and/or distributing medical devices
<b>V-amazone</b>	<i>Consultation platform on veterinary medicines</i>
<b>VAR</b>	Veterinary and Agrochemical Research Centre
<b>Vit@</b>	Internal electronic newsletter of the FAMHP
<b>Vit@ Express</b>	Internal electronic newsletter of the FAMHP for urgent notices
<b>Vzw - asbl</b>	Vereniging zonder winstoogmerk - association sans but lucrative : <i>non-profit association</i>
<b>WHO</b>	World Health Organisation
<b>WIV - ISP</b>	Wetenschappelijk Instituut Volksgezondheid - Institut Scientifique de Santé Publique : <i>scientific institute of public health</i>

*This document contains free translations and explanations of e.g. official bodies, commissions and organisations that are only denominated in Dutch and French.*



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