Federal agency for medicines and health products

PhD's : Shaping the future at National and European Competent Authorities

Greet Musch

The federal agency for medicines and health products (famhp)

The famhp is the Belgian **competent authority** in charge of ensuring the **quality**, **safety** and **efficacy** of **medicines** and **health products**, for human and veterinary use, in clinical development and on the market.

Mission

Ensuring, from development to use, the quality, safety and efficacy:

- of **medicines** for human and veterinary use, **including homeopathic medicines and herbal medicines**, pharmacy made and officinal **preparations**;
- of **health products**, including **medical devices** and accessories, and **raw materials** (active pharmaceutical ingredients) for the preparation and production of medicines.

Ensuring, from collection to use, the quality, safety and efficacy:

- of all **operations involving blood, cells and tissues**, which are also defined as health products.

Vision and ambition

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 divisions) within the organisation
- Realising and establishing a learning organisation culture

Values and role of the famhp

Values

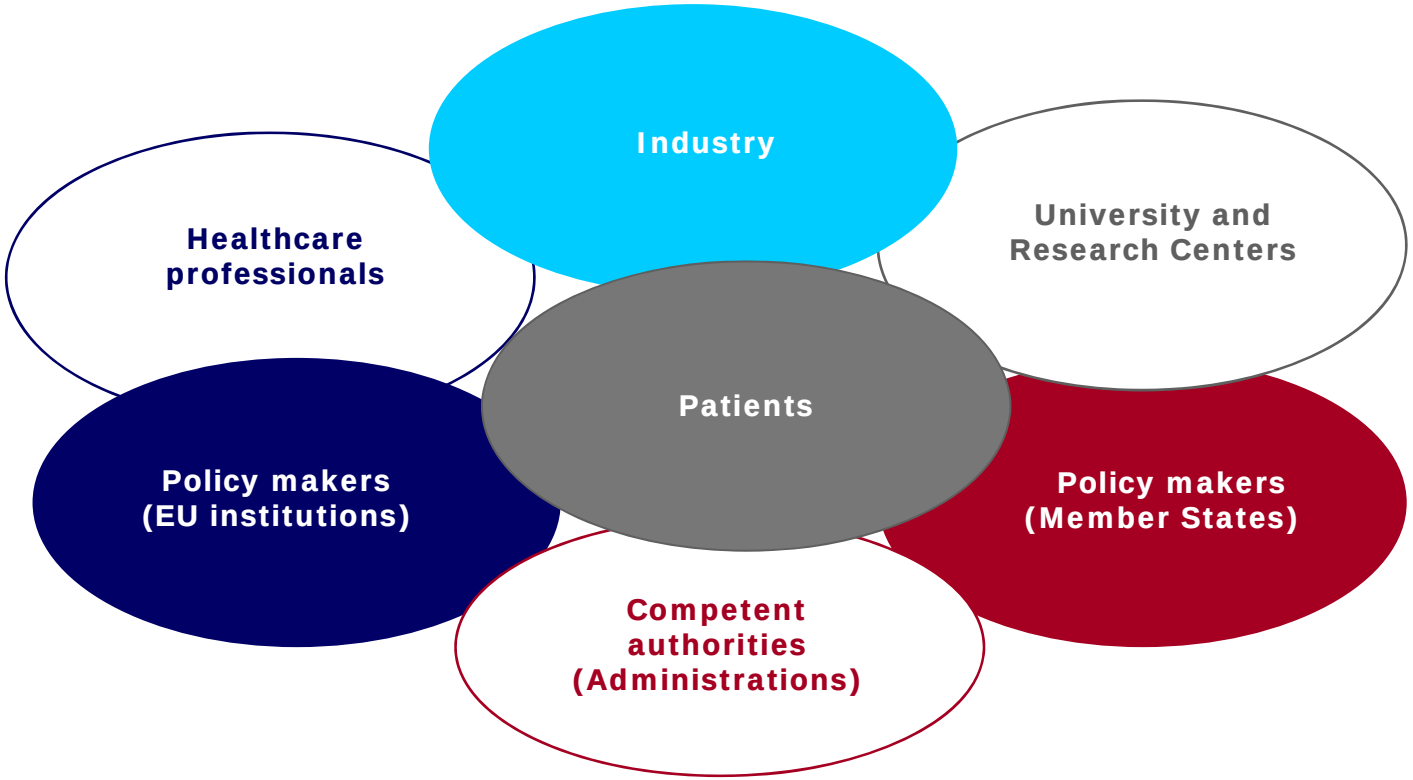
Within the famhp we carefully cultivate four core values, which we translate into our daily behaviour.

- Integrity
- Commitment
- Adaptability
- Cohesion

Role

In the interest of Public Health, the famhp ensures the quality, safety and efficacy of medicines and health products in clinical development and on the market.

‘Stakeholders’ or partners



Our partners are: patients, healthcare professionals, the academic world, the pharmaceutical industry and the other industries concerned, other national, European and worldwide authorities, as well as policy makers.

Our core business (1/3)

Our main activities concentrate on all medicines and health products for human and veterinary use and can be divided into four main domains:

Advising all our partners, starting from our expertise:

- national, European and worldwide authorities;
- policy makers such as the parliament and the minister in charge;
- the academic world;
- the industry;
- healthcare professionals;
- the press;
- patients and citizens who require further information.

Our core business (2/3)

Delivering official documents such as authorisations, approvals, certificates, ...:

- **clinical trial** approval;
- **marketing authorization** (MA);
- authorisation for **parallel import**;
- **standardisation** of pharmacy made preparations and monograph approval;
- authorisation of **raw material** for pharmacy made preparations;
- **notification** number or **export certificate**;
- **approval of advertising** to the general public and visas for scientific events.

Our core business (3/3)

Watching over the quality, safety and efficacy:

- ensuring **follow-up of assumed adverse reaction and incident notifications** with medicines and health products, evaluating these notifications and taking the necessary corrective actions;
- organizing **surveys**;
- carrying out **inspections** and **controls**;
- **ensuring follow-up of the quality problem notification** system for medicines.

Imposing sanctions such as:

- imposing an administrative **penalty**;
- **withdrawing** or **adapting** official **documents**;
- taking **health protecting measures**;
- imposing a **ban**.

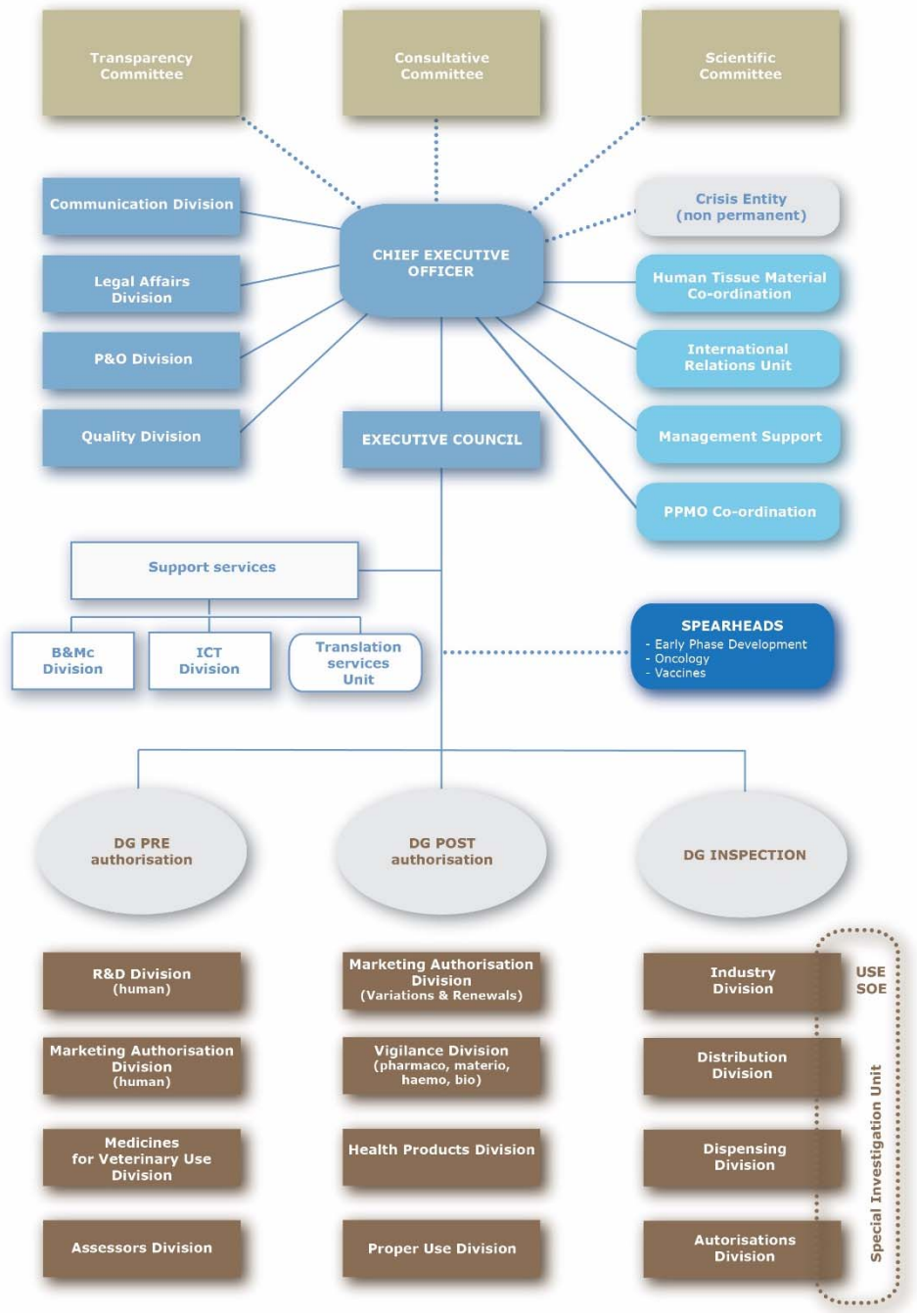
Organisation chart of the famhp

- **Three Directorate-Generals's**
  - DG PRE authorisation
    or all activities prior to approval of the first marketing authorisation for a medicine or health product.
  - DG POST authorisation
    or all activities after approval of the first marketing authorisation for a medicine or health product.
  - DG INSPECTION
    or all inspection and control activities

- **Administrator-General's services**
  Communication Division, Crisis Entity (non-permanent), Human Tissue Material Co-ordination, International Relations Unit, Legal Affairs Division, Management Support, P&O Division, PPMO Co-ordination, Quality Division

- **Support services**
  Budget & Management Control Division, ICT Division, Translation Division

Organisation chart



Supporting innovation in drug development : Current challenges in accelerating medicines development and patient access

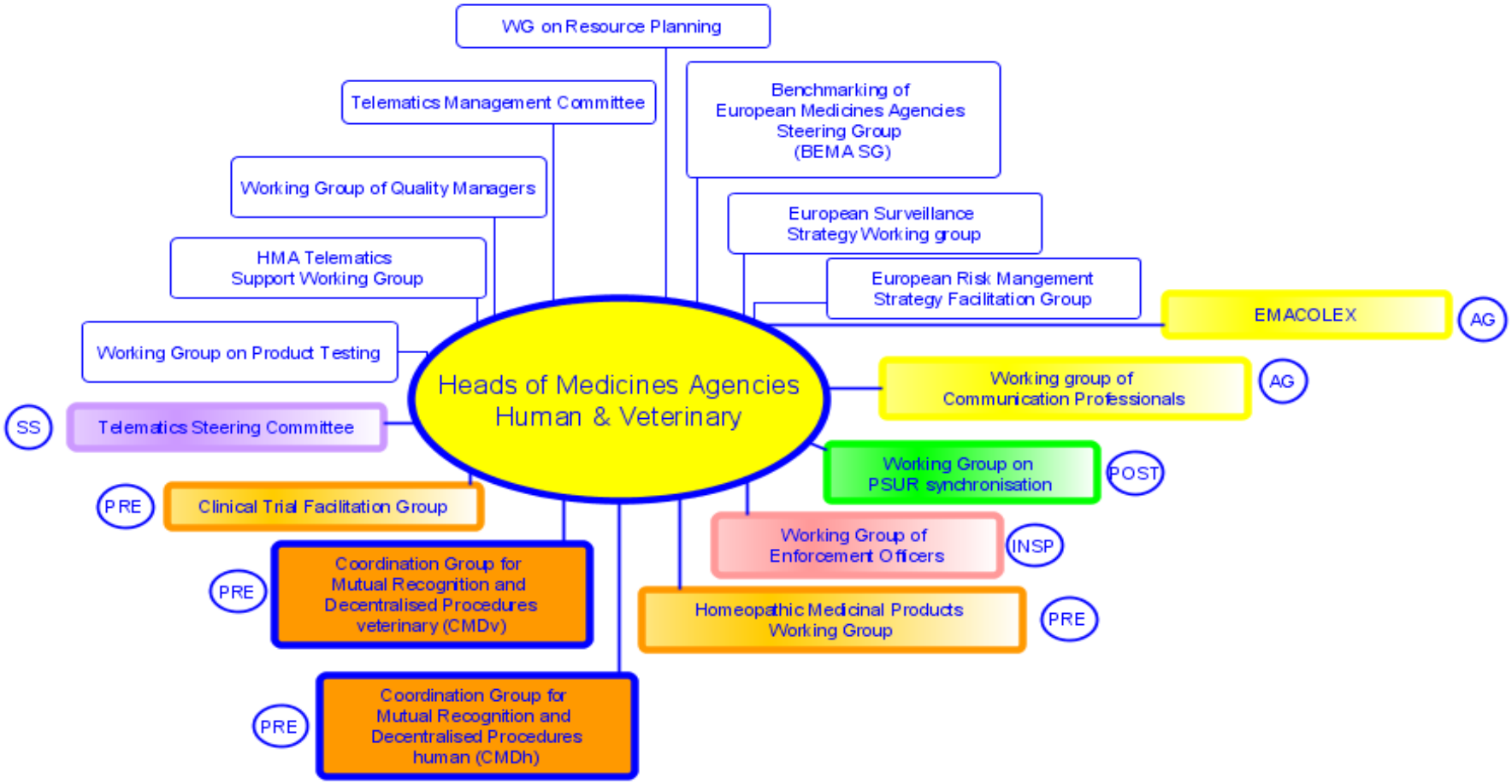
Mission of famhp as part of the EU regulatory network :

Facilitating the translation of innovative scientific advances into medicinal products meeting adequate standards and accelerate patients' access to promising therapies fulfilling unmet medical needs.

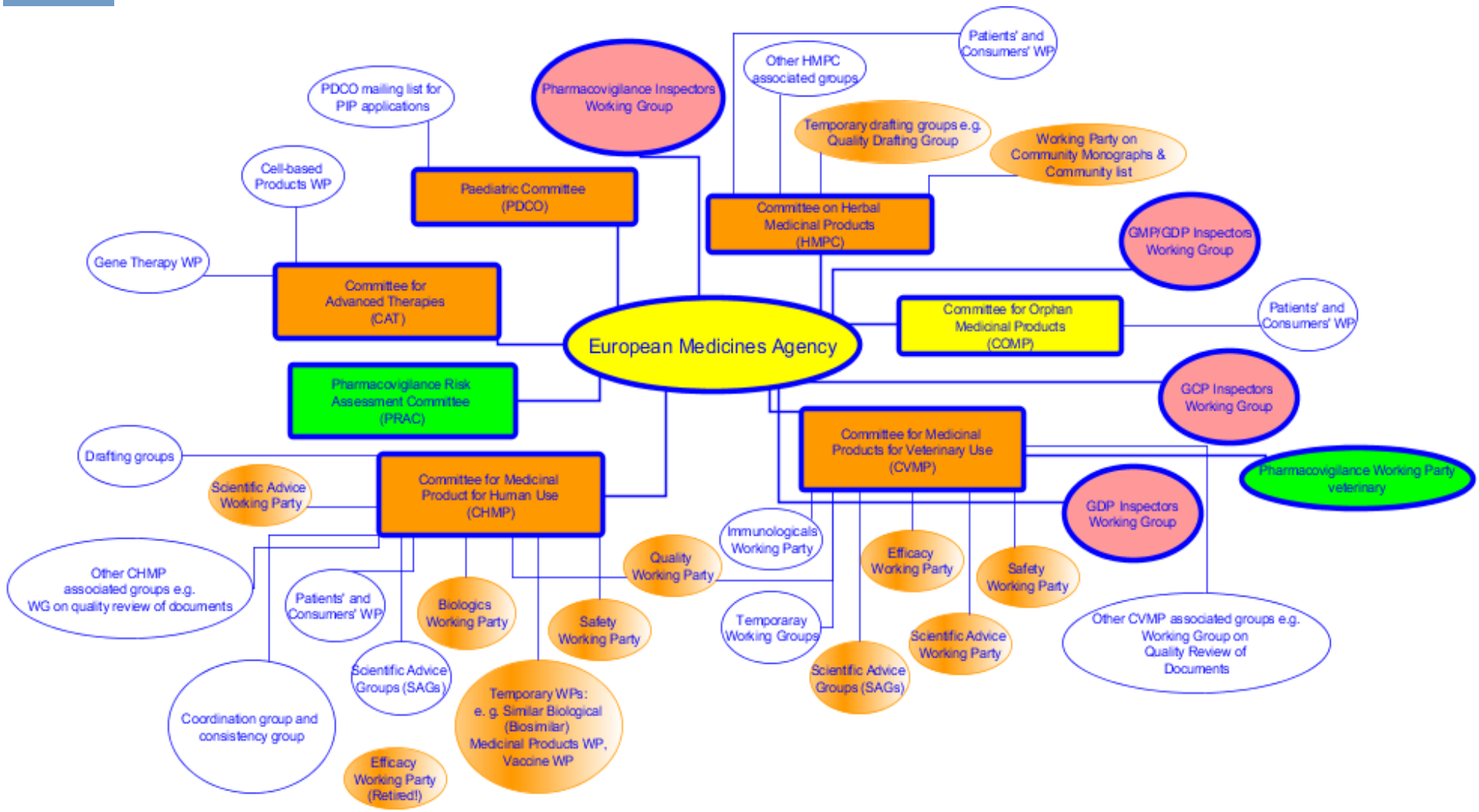
1: Current key activities : State of the art and cartography in Belgium

- Clinical trials (medicinal products)
- Clinical investigations and evaluations (medical devices)
- Compassionate use and Medical Need Programs
- Scientific Regulatory advice at national level
- Scientific advice at EU level (SAWP at EMA)
- Marketing authorisations at EU level Rapporteurships (CHMP at EMA)

EU activities: within the HMA



EU activities: within the EMA



Working with the famhp

Working for a federal agency is something that appeals to you?

- **Focus on innovation** in the different domains of competence
- **Global thinking** (at national and international level)
- Increased need for **multidisciplinarity**
- **Convergency** of drugs and health products within a fast changing therapeutic area / public health environment

Working with the famhp

Working for a federal agency is something that appeals to you?

Famhp offers you the possibility to gain experience **before** :

- during master/PhD studies , post doc studies
- via graduate programs
- others

Via **welcome@fagg-afmps.be or greet.musch @fagg.be**

Working with the famhp

Working for a federal agency is something that appeals to you?

Famhp welcomes you as a **new collegue** :

Take part in our recruitment procedures and join our organization.

The most researched profiles today are:

- Medico-pharmaceutical profiles (PhD's incl) such as physicians , veterinarians , pharmacists , biotechnoligists , chemists , biologists …
- Biomedical engeneers , engeneers specialised in data technology (PhD's incl)

as :

- Scientific experts (assesors , inspectors)
- Regulatory scientists
- Project managers , managers

Working with the famhp

A flavour of our job opportunities , currently available :

- CHMP member Vaccines (human use)
- Clinical assessor medical devices
- Project manager Zero Based Budgetting
- Project manager Clinical trial regulation

Upcoming :

- Project manager national Innovation office
- Scientific profiles in view of the Pacts Pharma and BeMedtech and the Minister of Public health and in view of the mobile health project

Working with the famhp

How to apply?

As we are a federal organization, most of our selection procedures are conducted by **Selor**.

If you wish to apply, you should react to the job ad that will be published on their website (www.selor.be) or contact our HR Director , Mrs Wittevrongel : lien.wittevrongel@fagg.be

Specific profiles are also recruited via **WIV-ISP** :

http://wiv-isp.hr-technologies.com/content/jobpage.asp or contact Mr Stefaan Vernaeve **(Stefaan.Vernaeve@wiv-isp.be**) and Dr Wim Penninckx **(wim.penninckx@fagg.be)**

Thank you for your attention

Your medicines and health products, our concern

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