Protecting public health and patients in member states: priorities, constraints and opportunities

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European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

famhp

The famhp: role and core business

We are the Belgian competent authority in charge of ensuring

- the quality
- the safety
- the efficacy

→ of **medicines** and **health products:**

- medical devices and accessories
- raw materials
- blood and blood products of human origin
- human tissue material

→ for **human** and **veterinary** use

→ **from development to availability on the market**.

The famhp: role and core business

- Providing advice, based on our expertise;
- Issuing official documents;
- Monitoring the quality, safety and efficacy of all medicines and health products;
- Imposing sanctions within our legal context.

And also....

Providing permanent access to objective, correct, complete and transparent information so that medicines and health products are used in a proper way by patients and healthcare professionals.

Priorities

Highlights for 2014-2018 – Management Plan of the famhp

Through our strategic objectives, our aim is:

- to consolidate previous achievements;
- to be prepared to provide stakeholders with the necessary support to tackle new challenges.

With special attention for two aspects:

- meet public health needs in terms of medicines and health products;
- confirm the central place of the patient.

Priorities

Meet public health needs in terms of medicines and health products

- by having the appropriate medicines and health products on the market;
- as soon as possible;
- in the most efficient way;
- while working together with all healthcare professionals;

Priorities

Meet public health needs in terms of medicines and health products

- by monitoring adverse reactions events and incidents (vigilance);
- by inspecting all actors in the sector and imposing sanctions if needed;
- **by cooperating with other competent authorities at national, European and international level.**

Priorities

Meet public health needs in terms of medicines and health products

Recent realisations:

1. Unmet Medical Need;
2. Taskforce on (non)-availability of medicines and its central reporting point;
3. Dispensing medicines adapted to patient's needs.

1. Unmet Medical Need

- Responding to patient's expectations with life threatening or seriously debilitating conditions without adequate treatment;
- Balance between early access and having all data on the quality, safety and efficacy of a medicine;
- Enhancing the landscape for development, licensing and procurement of innovative medicines;
- New national regulation on early temporary authorisation and early uptake in the health insurance system;

Unmet Medical Need

- Designation of unmet medical need status;
- Evaluation of positive risk/benefit balance;
- Positive opinion of ethics committee;
- Commitment to introduce an application for marketing authorisation within the upcoming 6 months by the applicant;

Entry into force from 1st of July 2014 – 5 applications received so far.

2. Taskforce on non-availability of medicines

- ✓ Creation of central reporting point for all information regarding the marketing status of medicines at our Agency;
- ✓ Alignment with other competent authorities of the information needed (reasons for non-availability, expected duration, measures taken etc...) ;
- ✓ Public database with situation on the Belgian market updated on a daily basis;
- ✓ Evaluation of the essential character of the unavailable medicine;
- ✓ Information on possible alternative treatments.

3. Dispensing medicines adapted to patient's needs

- Individual medication preparation for patient's living in community settings:
  - Prevent medication errors.
- Specific 'compounding' autorisation:
  - Medication preparation (reconstitution) in the most qualitative conditions (GMP adapted);
  - Hospital settings

Priorities

Confirm the central place of the patient

- A patient-centred approach in all of our activities: from development to the availability on the market;

- Maintain a dialogue with patients by their representation in:
  - Consultative Committee, who advises the agency on its current and future policy;
  - Patient platform (specific, since 2010).

Constraints and opportunities

Confirm the central place of the patient

Ongoing reflexions:

- Patient representation in the evaluation commissions for authorisation procedures.
- How to increase patient reporting of suspected adverse reactions (17% of all reports are from patients) – collaboration with the patient and consumer representations.
- Debate with patient organisations to further establish their expectations in terms of information and what the famhp can do to fulfil them.

Constraints and opportunities

- An aging population and polypharmacy.
- The socio-economic situation. Do better and more with less.
- Globalised context (international incidents and their national impact).
- Misleading information on the internet.
- Improve the visibility of our agency to the general public.
- National Competent Authorities have to work together and use the same language and standards → Enhance global mutual recognition and international collaboration.
- Shortages of essential medicinal products, falsification etc....

Constraints and opportunities

Changes in the way we think and act:

> "Making sure we are **doing the things right** (in regards to our mission) but even more **doing the right things** (in regards to the patient)".

Empowered patient and his active role in the decisions made about his own health.

Access to information.

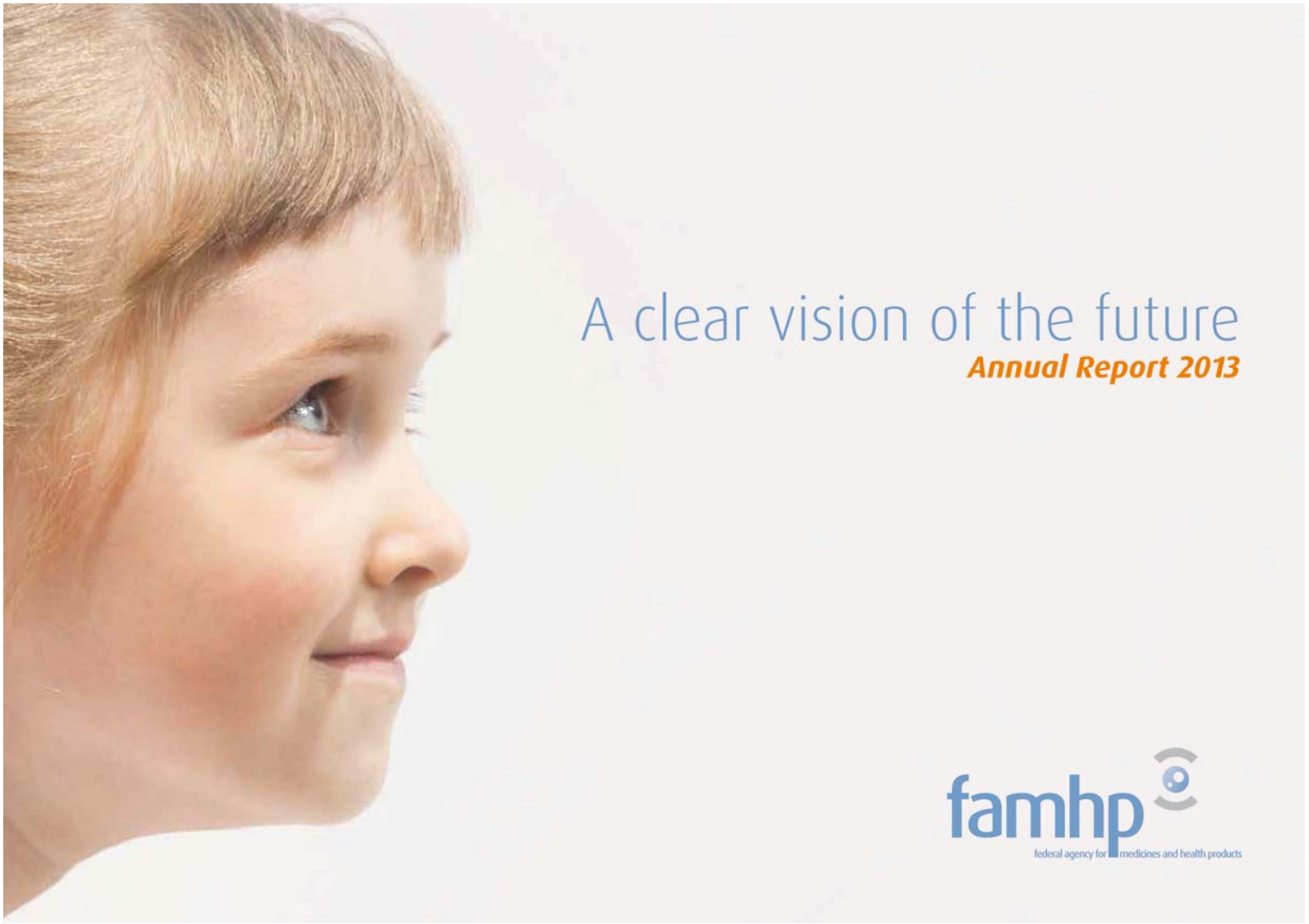
Cooperation

With other Competent authorities at European and international level:

European Union, Council of Europe/EDQM, WHO

- Common goals: high quality standards for medicines (European Pharmacopeia), prevent falsification (Medicrime convention), ensure quality and safety in blood transfusion…..
- Reach the patient

Your medicines and health products, our concern.



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