



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 June 2016  
EMA/281593/2016  
Stakeholders and Communication Division

## EMA collaboration with general practitioners/ family physicians (GPs/FPs): Report from a joint EMA workshop with EFPC, UEMO and WONCA-Europe organised on 19 April 2016

### Executive Summary

A workshop with EU representatives of general practitioners (GPs) and family physicians (FP) took place at the Agency on 19 April 2016, as part of the implementation of the EMA framework for interaction with healthcare professionals, which aims to reinforce and promote engagement with GPs and their representative organisations.

Twenty representatives from three major organisations – the European Forum for Primary Care (EFPC), the European Union of General Practitioners (GPs) / Family physicians (UEMO) and the World Organization of Family Doctors (WONCA) Europe - attended the workshop.

Participants discussed how general practice may be impacted by regulatory actions, and what type of input collected at primary care level would be most valuable/feasible to inform regulatory decision-making processes. Areas where collaboration would mutually benefit GPs/FPs and the EMA were also discussed. All participants agreed that strengthened interaction will:

- help EMA gain a better understanding of how medicines are being used in real life and the potential impact of specific regulatory actions on patient care;
- raise awareness amongst general practitioners on how they can inform regulatory discussions on the benefits and risk of medicines so that decisions take into account the reality of clinical practice.

The workshop led to the creation of an expert group of GPs/FPs initially composed of the 20 representatives who attended the meeting, who will in turn act as facilitators and communicate to their broader communities. These experts will be involved in a wide range of EMA activities whenever their specific feedback is needed. This includes participation in scientific advisory group meetings, input on feasibility and impact of risk minimisation measures and review of product information.

EMA and the three organisations will also develop a joint position paper outlining concrete areas of collaboration as well as long-term recommendations. One of the topics already suggested was the need for independent research to gain a better understanding of how medicines are used in real clinical practice.



## Background on the organisations

### European Forum for Primary Care (EFPC)

The aim of the Forum is to improve the health of the population by promoting strong primary care. This is done by advocating for primary care, by generating data and evidence on primary care and by exchanging information between its members. EFPC members include the three levels of academics, policy makers and practitioners of which the later all different primary care professionals are included like general practitioners, community pharmacists, primary care nurses, etc.

### European Union of General Practitioners / Family physicians (UEMO)

The association objectives are: a) to study and promote the highest standard of patient care, training, continuing medical education and continuing professional development, professional practice conditions within the field of the general practice / family medicine throughout Europe; b) to defend the role of general practitioners/ family physicians in the healthcare systems; c) to promote the ethical, scientific, professional, social and economic interests of European general practitioners / family physicians and to secure their freedom of practice in the interests of the patient; d) to be the medical organisation representing general practice/ family medicine in Europe; to be proactive in its representational role.

### World Organization of Family Doctors (WONCA) Europe

The society is the academic and scientific society for general practitioners in Europe. Its objective is to improve the quality of life of the peoples of the world through fostering and maintaining high standards of care in general practice/family medicine by providing a forum for exchange of knowledge and information; encouraging and supporting the development of academic organizations of general practitioners/family physicians; and representing the educational, research and service provision activities of general practitioners/family physicians before other world organizations and forums concerned with health and medical care.

## Working with healthcare professionals

The European Medicines Agency (EMA) has been interacting with European healthcare professionals in various areas of its work since it was founded in 1995.

Medicines are licensed on the basis of findings from clinical trials and pre-licensing studies carried out in a very controlled way, which do not reflect the real use of medicines. It is therefore important to bring real-life experience and clinical practice into the medicines evaluation. As prescribers and handlers of the medicines that the Agency evaluates, healthcare professionals are key stakeholders in the Agency's work and have specific knowledge and expertise to offer.

To this end, EMA has developed a specific framework of interaction with healthcare professionals.

The objective is to open up bidirectional avenues that can:

- on one hand, help EMA to gain a better understanding of how medicines are being used in real clinical practice and the potential impact of specific regulatory actions on patient care;
- on the other hand, support the creation of more awareness amongst healthcare professionals on how they can better inform regulatory discussions on benefit-risk evaluation of medicines and promote the alignment of regulatory decisions with the reality of clinical practice.

The ultimate mutual goal is to protect public health by promoting the rational and safe use of medicines.

In the context of the implementation of this framework, the Agency interacts with specialised doctors from different medical fields, including GPs/FPs, as well as with pharmacists and nurses.

Despite ad hoc interactions with GPs/FPs, feedback from primary care to EMA is limited and the specific need to further strengthen interaction with this very large group of physicians has been recognised.

## **A special interest in general practitioners**

The European definition of general practice / family medicine<sup>1</sup> (GP/FM) reflects the broad and complex role of general practitioners. They play a key role in patient care; often have the first contact with the patient and accompany them throughout the life of their condition; deal with all health problems regardless of the age, sex, or any other characteristic of the person concerned; work to maintain good health in healthy individuals; manage simultaneously acute and chronic health problems in an individual patient whilst having a specific responsibility for the health of the community; manage illness which presents in an undifferentiated way at an early stage of development; coordinate care with other professionals in primary care and manage the interface with other specialities.

In several European countries, the vast majority of all care problems are being resolved at Primary Care level and thus GPs/FPs are responsible for the largest percentage of all medicines prescribed. Their unique position in the healthcare system allows them to have contact with the vast majority of the population and puts them in a leading role of data generation. They can provide early indicators of health population changes and variations in medicine utilisation patterns. These are particularly relevant in light of ongoing demographic transformations, such as the increasing older patient population with prevalent multi-morbidity and poli-pharmacy, the rising numbers in frail patients with prevalent complex and/or chronic-degenerative diseases, and the growing migrant movements with associated emergent public health issues.

This is a contrasting reality with the controlled environment of clinical trials and with the hospital care setting where focus is given to specific conditions, highly specialised therapies and surgical procedures, and considerably smaller patient sub-population groups over a particular period of time.

Conversely, an increasing number of innovative medicines available for personalised treatments will be initiated by different specialties in secondary and tertiary medical care, encompassing ever more complex and sophisticated risk management plans. These are likely to require complementary follow up measures at the level of ambulatory/primary care. GPs/FPs will therefore be involved in the follow up of patients treated with these innovative medicines and in a position to monitor their safety and effectiveness.

Fast-paced technical and scientific developments also pose a number of challenges and opportunities to GPs/FPs and all healthcare providers in general. Gaining a better understanding of the extent of those challenges and opportunities is necessary to ensure regulatory decisions are feasible and proportionate.

These are the reasons why the EMA wants to engage more GPs/FPs in its activities as their knowledge and experience on how a medicine is used and addresses patient needs in real life can greatly inform regulatory decision-making.

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<sup>1</sup> <http://www.woncaeurope.org/sites/default/files/documents/Definition%203rd%20ed%202011%20with%20revised%20wonca%20tree.pdf>

## Shared goals in a diverse Europe

The workshop brought together general practitioners from 13 different EU countries who shared a common interest in gaining a better understanding of what EMA is about and how they can inform regulatory discussions on the benefits and risk of medicines, so that decisions take into account the reality of clinical practice.

They pointed out however that common interests would need to be taken in the context of very diverse realities across the EU in relation to national healthcare systems' organisation, available resources and culture. The role of a GP/FP can vary significantly between countries. In some healthcare systems general practitioners work in primary care centres where they play a central role in the healthcare team, while in other models of care they work in a more isolated manner.

In some countries, general practice and primary care are not necessarily synonymous. In some European countries first-contact care is provided by specialists whilst in the UK and in Italy, for example, general practitioners are at the base of their healthcare system pyramid and access to specialists is essentially guided by a GP referral. The majority of recent scientific publications emphasise the importance of a gate-keeping system in order to control costs and quality of the health care system<sup>2</sup>.

Some countries have access to a broader therapeutic armamentarium than others. There are also different approaches in relation to diagnosing controls and prescribing protocols.

## Generation, collection and analysis of clinical practice data

The type of medicines that will be authorised in the future is changing. This will impact on how evidence will need to be generated and collected to support the assessment of their benefit/risk balance against overall performance in real life and consequent decisions on pricing and reimbursement. The EMA, as other stakeholders in healthcare, has to evolve and adapt to this changing environment.

Regulators, industry, payers and HTA bodies have all recognised that evidence generation must be planned as early as possible in the development phase to know what questions will have to be answered after the release of a new medicine; that planning should be done with the input from patients and healthcare professionals. From the start (endpoints, comparators) to the end (cost, safety) EMA decisions are crucial for primary healthcare and the whole European population. The role for general practitioners will thus become essential not only in the post-marketing phase, where their natural role is well established, but also at a much earlier phase in the regulatory pathway.

The example of dabigatran (indicated for the prevention and treatment of thromboembolic events) was used to illustrate a case where it would be essential to involve GPs/FPs in the design of risk management plans due to their contact with patients over extended periods of their lives, alongside with the input from cardiologists. Regulators could benefit more from bringing GPs/FPs' perspective of long-term use of medicines in a given target population as well as their views of the place of a new medicine in overall therapy.

The example of finasteride (indicated for prostatic hypertrophy) and associated gynecomastia was provided to illustrate how the GP/FP will have to consider and manage the patient circumstances over

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<sup>2</sup> Improving quality primary care: from measurement to improvement: a roadmap  
Report Primary Health Care Improvement, Global Stakeholder Meeting in Geneva at WHO Headquarters, 6-8 April 2016.  
[http://www.euprimarycare.org/sites/default/files/primary\\_health\\_care\\_-\\_from\\_measurement\\_to\\_improvement.pdf](http://www.euprimarycare.org/sites/default/files/primary_health_care_-_from_measurement_to_improvement.pdf)

time and their wish to discontinue treatment, even though not recommended by standard practice. The challenge remains in documenting such intervention.

Many medicines for which additional risk minimisation measures have been imposed are initially prescribed by a specialist and then transferred to GPs/FPs. There is usually a shared care agreement whereby both specialist and general practitioner agree (e.g. once the patient is stabilised and handed over to the general practitioner there are instructions on what time interval parameters should be checked). As for the previous example, practice cannot solely rely on algorithms. GPs/FPs need to consider the overall clinical situation of the patient over time, as well as their values, preferences, expectations and living conditions. These interventions are not part of the shared care contract, risk management plan or therapeutic guideline and reflection is needed around how easy it is to document them to generate evidence that may allow the review of existing recommendations, particularly where some 'pay per performance' models focus on prescribing a specific medicine.

Collection of data cannot in itself become the sole activity of the GP/FP, risking the de-humanisation of the provision of care. There is a need to support practitioners with appropriate planning and tools.

## **Where should the focus be?**

During the workshop, break-out sessions of smaller groups were used for participants to reflect further and to identify more concrete areas of collaboration and priorities. The main points emerging from the breakout session are summarised under the three headings below.

### ***Support the Agency to gain a better understanding of how medicines are used in real clinical practice and how to promote appropriate use***

- Involve GPs/FPs in EMA evaluation and communication activities focusing on:
  - medicines used for conditions treated by GPs/FPs (e.g. chronic: cardiovascular, diabetes, asthma/COPD; acute: pain; inflammation; infection);
  - medicines initiated by a specialist but for which GPs/FPs follow up on interactions and side effects (e.g. psychotropic drugs; antineoplastic agents);
- Provide input on standard of care; improve wording of indications; support identification of patients at highest risk; advise on drug regimens on the basis of data captured across health records; provide guidance on complexity and availability of approaches in the primary care setting; discuss specific controls for age groups; inform on different national healthcare realities (e.g. off-label use).
- Identify existing information (through eHealth records; registries; etc.) prior to defining new/reviewed risk minimisation measures with an impact in GM/FM and involve GPs/FPs in early design of risk management plans.
- Consult on risk minimisation measures, including review of core messages to be included in educational materials and safety communications.

### ***Initiatives to measure how EU regulatory decisions impact GPs practice***

- Need to create more awareness amongst GPs/FPs of EU regulatory decisions and how these are reached.

- As EMA recommendations are filtered through national bodies, a reflection needs to take place on what could be collected at primary care level that could be of value to measure impact such as:
  - how to measure feasibility and effectiveness of risk minimisation measures;
  - how to capture the time gap between introduction of a new medicine in the market in the different countries;
  - implementation of new recommendations (changes in conditions of use) for medicines already available on the market;
  - analysis of how recommendations are translated into clinical guidelines.
- Make the most of existing capacity – explore links to the European General Practice Research Network (EGPRN) to foster and coordinate multinational studies, to exchange experiences and to develop a validated scientific basis for GP/FM.

### ***How the Agency can best communicate with healthcare professionals to support their role in the safe and rational use of medicines***

- Manage expectations by creating a better understanding of the EMA remit; whilst primary care covers a broad spectrum of healthcare, the EMA focus is on medicines and not on health education and lifestyles.
- Disseminate EMA communications to GPs/FPs (and their patients) through their national communication channels (email groups; newsletters; bulletins and journals).
- Information needs to be put in national context – as do guidelines for chronic diseases; focus on peer groups that can influence behaviour.
- Focus communication effort on new medicines and new information on indications and safety concerns; medical review should be inbuilt into such communication; brief pieces of information are more useful than pages of detail.
- EMA should provide more information on medicines in relation to their place in therapy.

### **Emerging opportunities for further collaboration**

- Explore involvement of GPs/FPs in HTA assessments to support discussions on best place in therapy.
- Reflect on how to establish sentinels for long time cancer survivors to study impact on medicines use.
- Discuss how to use existing resources to strengthen training of medical students and young doctors in the field of medicines regulation and how to contribute to regulatory decision-making.
- Maximise the potential of primary care epidemiology<sup>3</sup> as an evolving clinical research discipline to respond to specific research questions of direct interest to EMA. A very clear message was conveyed by the workshop participants to investigate ways to promote independent research

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<sup>3</sup> Editorial: Philip C Hannaford, Blair H Smith, and Alison M Elliott  
 Primary care epidemiology: its scope and purpose *Family Practice (February 2006) 23 (1): 1-7* first published online December 6, 2005 doi: 10.1093/fampra/ami102  
<http://fampra.oxfordjournals.org/content/23/1/1.full>

through the creation, for example, of an independent fund, and have a database of independent research available.

## Next steps

EMA, UEMO, EFPC, and WONCA concluded that the way forward would include:

- Developing a set of recommendations in a position statement EMA/UEMO/EFPC/WONCA:
  - What can be implemented now (areas of focus at EMA level);
  - What need a long-term approach (emergent fields for collaboration);
- Involving GPs/FPs on concrete activities, through the creation of a specific expert group, initially composed of the workshop participants; each expert will also act as contact person at national level; entire group or individual experts to be involved in virtual and/or physical meetings depending on the issues – these could be organised by population groups or therapeutic area:
  - Input in scientific advisory groups/ad-hoc expert group meetings;
  - Review of labelling aspects and additional risk minimisation measures including implementation;
  - Review of safety communications and direct healthcare professionals communications (DHPCs), including prevention of medication errors;
  - Collection of data generated in clinical practice (eHealth records; registries; etc.);
  - Scientific committees and working parties consultations (standard of care; risk minimisation measures; product information);
  - Participation in EMA workshops;
  - Participation in user tests and technical groups supporting implementation of new legal requirements.

It was highlighted that although there is room to expand to other primary care healthcare professionals at a later stage, EMA needs to keep focus on its remit, field of expertise and area of influence. The EFPC, representing a broad range of primary care professionals, will make sure that their members from professional groups other than GP's/FM's will be invited to join when their involvement is relevant to EMA's remit.

On the basis of the workshop outcome, the Agency will continue to work with all three organisations to implement the agreed areas and format of interaction between EMA and GPs/FPs. Progress will be regularly monitored and a follow up workshop may be organised in the future.