

6 June 2019
EMA/875796/2016
Stakeholders and Communication Division

Strengthening collaboration between EMA and general practitioners/family physicians

Joint statement between the European Medicines Agency (EMA) and the European Union of General Practitioners (UEMO), the European Forum for Primary Care (EFPC), and the World Organisation of Family Doctors-Europe (WONCA Europe)

The Executive Director of the European Medicines Agency and representatives of the European Union of General Practitioners (UEMO), the European Forum for Primary Care (EFPC), and of the World Organisation of Family Doctors-Europe (WONCA Europe), met within the framework of EMA interaction with healthcare professionals and their organisations on 6 June 2019, Amsterdam, to sign the present joint statement.

Signatures

Guido Rasi
Executive Director
European Medicines
Agency (EMA)

Mary McCarthy
Vice-president
European Union of
General
Practitioners
(UEMO)

**Diederik
Aarendonk**
Forum Coordinator,
on behalf of Sally
Kendall, Chair
European Forum for
Primary Care
(EFPC)

Mehmet Ungan
President
World Organisation
of Family Doctors-
Europe (WONCA
Europe)

Common goals

The European Medicines Agency (EMA) and the two major organisations representing general practitioners/family physicians (GPs/FPs) in Europe – the European Union of General Practitioners (UEMO) and the World Organisation of Family Doctors-Europe (WONCA Europe) – and the major organisation representing primary care professionals in Europe – the European Forum for Primary Care (EFPC) – are committed to strengthen their interaction in order to:

- 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;
- facilitate the incorporation of views and input from GPs/FPs in the Agency's activities, recognising the pivotal role that they play in health and patient care;
- raise awareness amongst GPs/FPs of the role and activities of the EU medicines regulatory network.

Mutual benefit

For any collaboration to work, it is important to understand where the mutual benefits lie.

It is well recognised by EMA that GPs/FPs are a very large group of healthcare professionals whose clinical know-how and hands-on experience needs to be factored into the evaluation and monitoring of medicines.

In Europe, an immense number of health problems are 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 for data generation.

Conversely, personalised treatments involving innovative medicines will increasingly be initiated by different specialties in secondary and tertiary medical care, and will encompass 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 monitoring their safety and effectiveness, including their interactions with more routinely prescribed medicines.

EMA benefits from an existing [framework of interaction](#) with healthcare professionals, including physicians, pharmacists and nurses. However ad hoc interactions with GPs/FPs and feedback from primary care to EMA are limited at present and it is important to further strengthen interactions with this very large group of physicians.

GPs/FPs' areas of interest are mainly covered and represented in Europe by UEMO, EFPC and WONCA.

These organisations have their own mission and vision, but their individual fields of work are directly or indirectly impacted by EU policy and regulatory activity, including those areas where EMA plays a major role – the evaluation and supervision of medicines. GPs/FPs' involvement in high impact/targeted EMA activities will enable regulatory measures that can be more easily implemented in clinical practice. Thus, UEMO, EFPC and WONCA see an added value in working more closely with EMA. In return, they bring a collective expertise and outreach which are invaluable to EMA.

Notwithstanding the existing interactions between EMA and each of these organisations, there are areas where synergies can be explored together in order to bridge gaps between the regulatory and the real-life clinical practice worlds.

EMA and UEMO-EFPC-WONCA are coming together to achieve four main objectives

1. Involve GPs/FPs in EMA evaluation activities
2. Develop communication activities relevant to GPs/FPs
3. Explore options for further collaboration with existing research networks in primary care, with a focus on generation of real-world evidence
4. Identify opportunities for collaboration in regulatory training

By working together, EMA and UEMO-EFPC-WONCA will be able to i) identify areas that are relevant to them, ii) direct efforts into focused areas of collaboration and iii) use the findings emerging from such collaboration to drive improvements both in regulatory and clinical practice.

Joint effort

An action plan to 2020 has been developed in order to guide EMA and UEMO-EFPC-WONCA joint effort in the years to come (annex 1).

It is recognised that GPs/FPs' workload and limited resources require careful consideration when designing approaches for active involvement in EMA activities.

It is also important to acknowledge that during the period leading to 2020, EMA and the three organisations may face constraints that will impact the implementation of the proposed action plan. This is particularly relevant in the context of the UK withdrawal from the EU and any disruption of EMA activities which may occur due to its relocation to Amsterdam. Therefore no detailed timelines are specified at this point.

Progress will be monitored and discussed within the EMA GPs/FPs expert group and reported to the EMA healthcare professionals' working party (HCPWP). A dedicated focus group may be organised in 2019 to reflect on the future direction of travel.

European Medicines Agency (EMA)

EMA is a decentralised agency of the European Union (EU), created in 1995. Its mission is to protect human and animal health in the EU and to ensure access to medicines that are safe, effective and of good quality. EMA evaluates medicines for marketing approval throughout the EU and provides information on such medicines to healthcare professionals and patients. EMA also monitors the safety of all medicines authorised in the EU throughout their lifecycle and provides information on such medicines to healthcare professionals and patients.

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 academics, policy makers and practitioners, the latter group including all different primary care professionals such as general practitioners, community pharmacists and primary care nurses.

European Union of General Practitioners / Family physicians (UEMO)

The association's 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 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-Europe (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 organisations of general practitioners/family physicians; and representing the educational, research and service provision activities of general practitioners/family physicians before other world organisations and forums concerned with health and medical care.

Annex 1 – Action plan to 2020

1.1. Involve GPs/FPs in EMA evaluation activities

Proposed actions for EMA:

- Maintain and expand the operation of the EMA GPs/FPs expert group established in April 2016¹
 - Identify potential gaps in the composition of the group and discuss how to address them
- Identify activities for which the involvement of GPs/FPs would be relevant and clearly specify the type of input that would be required and how this should be collected. Activities should cover:
 - 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)
- Streamline involvement in activities by the EMA GPs/FPs expert group
 - Identify more specific areas of interest amongst members of the expert group to optimise interactions and ensure as much as possible a fair distribution of work
- Monitor participation in the following activities:
 - Ensure GPs/FPs are involved on EMA policy discussions, implementation of new legislation and new initiatives
 - Input in scientific advisory groups/ad-hoc expert group meetings
 - Review of labelling and other specific parts of product information
 - Review of public communications (e.g. EMA safety communications, direct healthcare professionals communications (DHPCs) and EMA communications on medication errors)
 - Input in consultations with scientific committees and working parties (standard of care; additional risk minimisation measures; product information)
 - Participation in EMA workshops
 - Participation in user-testing and technical groups supporting implementation of new legal requirements

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/06/WC500208964.pdf

Proposed actions for UEMO-EFPC-WONCA:

- Support the operation and expansion of the EMA GPs/FPs expert group:
 - Identify experts
 - Contribute to written consultations
 - Participate in dedicated meetings and conference calls
 - Identify relevant speakers for EMA conferences and workshops
- Systematically inform EMA of their position statements, guidelines, results of surveys or any other evidence gathered at European level, which may be relevant to medicines evaluation and monitoring (e.g. changes in clinical practice; constraints/ emerging concerns; new trends).

1.2. Develop communication activities relevant to GPs/FPs

Proposed actions for EMA:

- Identify topics where EMA can provide information of relevance to GPs/FPs, including information to support dialogue with patients (e.g. vaccines)
- Discuss whether existing content would need to be adapted to the primary care context
- Reflect on the feasibility of developing new content with the support of the EMA GPs/FPs expert group and/or other relevant UEMO-EFPC-WONCA members

Proposed actions for UEMO-EFPC-WONCA:

- Create an EMA news feed of newly approved medicines and safety communications relevant to GPs/FPs in their respective websites
 - Content and format to be discussed by the EMA GPs/FPs expert group
- Discuss EMA contribution to the European Journal of General Practice (EJGP)ⁱ
 - Identify topics that will benefit from better communication
- Disseminate information through GPs/FPs professional communication platforms

1.3. Explore options for further collaboration with existing research networks in primary care, with a focus on generation of real-world evidence

Proposed actions for EMA:

- Gain a better understanding of WONCA Europe networks and specialised interest groups, in particular the European GP Research Network (EGPRN)
 - Explore where interaction between EMA and EGPRN would bring synergy
- Stimulate organisations to become partners of ENCePP, as a means to strengthen the research base of GP/FM within pharmacovigilance and pharmacoepidemiology

- Explore the added value of a conference with ENCePP and the Primary Care research community
- Facilitate the establishment of channels of communication with existing European networks
 - Promote/facilitate reflection around the interface between regulatory science and public health research – what are the clinical outcomes to achieve; how to monitor them and how feasible are the actions; how to best communicate on corrective actions for an optimal use of medicines

Proposed actions for UEMO-EFPC-WONCA:

- Clarify what type of research and what contribution can be given by GPs
- Share best practices with EMA on the collection of data generated in clinical practice (eHealth records; registries; etc.)

1.4. Identify opportunities for collaboration in regulatory science training

Proposed actions for EMA:

- Participate in relevant UEMO-EFPC-WONCA Europe meetings
 - Develop content for an EMA generic info session for GPs to be conveyed in relevant European meetings
- Gain a better understanding of WONCA Europe networks and specialised interest groups, in particular of the European Academy of Teachers in General Practice (EURACT)
 - Explore EMA contribution to the EURACT Medical Education Conferences
- Explore possible synergies with the EU-NTC

Proposed actions for UEMO-EFPC-WONCA:

- List events for the upcoming years and identify opportunities for dedicated EMA sessions
- Use EMA material when developing educational resources, which can support GPs/FP and PC professionals on the safe and rational use of medicines
- Disseminate EMA resources targeted to healthcare professionals among their members

ⁱ de Vries, S.T., van der Sar, M.J.M., Cupelli, A. et al. Communication on Safety of Medicines in Europe: Current Practices and General Practitioners' Awareness and Preferences. *Drug Saf* (2017) 40: 729. <https://doi.org/10.1007/s40264-017-0535-0>