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EMBARGOED: Do not publish until after signing of joint statement on 6 June 2019

Key messages

Strengthening collaboration between EMA and general practitioners

Key messages for EMA/UEMO/WONCA Europe and EFPC

- EMA and the two major organisations representing general practitioners/family physicians in Europe – the European Union of General Practitioners (UEMO) and the European section of the World Organization of Family Doctors (WONCA) – and the major organisation representing primary care professionals in Europe, the European Forum for Primary Care (EFPC) signed a joint statement of collaboration on Thursday, 6 June 2019 committing to strengthening interaction.
- The aim of this strengthened interaction is 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/family physicians into EMA's activities recognising the pivotal role that they play on the front line of health and patient care;
 - raise awareness among GPs of the role and activities of the EU medicines regulatory network.

Importance of GPs and family physicians

- General practitioners and family physicians play a key role in patient care;
- They usually have the first contact with the patient and provide continuity of care regarding acute and chronic disease to all the members of the family, often over many decades, which puts them in a unique position;
- They have important clinical 'know-how' and hands-on experience that is of great value in the development, evaluation and monitoring of medicine:



- They are currently responsible for most medicines prescribed;
- They follow-up patients treated with innovative medicines and monitor drug interactions with routinely-prescribed medicines and therefore play a leading role in data generation once a medicine is on the market.
- The knowledge and experience of GPs and family physicians on how a medicine is used and addresses patient needs in real life can greatly inform EMA's decision-making.

Concrete action plan to 2020

- The statement includes a concrete action plan to 2020 to guide EMA and UEMO, EFPC and WONCA in their work on this topic. Specific areas of involvement include:
 - Involving GPs and family physicians in EMA evaluation activities
 - Developing communication activities relevant to GPs and family doctors
 - Exploring options for further collaboration with existing research networks in primary care, with a focus on generation of real-world evidence
 - o Identifying opportunities for collaboration in regulatory science training

Background on EMA interaction with GPs

- The development of the joint statement between EMA and the three organisations follows a
 workshop which took place in 2016 with representatives of general practitioners and family
 physicians in order to explore new ways to engage with these providers of primary care in EU
 Member States and further involve them in EMA activities;
- The formalisation of this interaction marks an important step in EMA's engagement with healthcare professionals and falls under EMA's overall framework for interaction with healthcare professionals including physicians, pharmacists and nurses;
- However, ad hoc interactions with GPs 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.