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Press Office

Press release

European Medicines Agency holds first meeting of the Pharmacovigilance Risk Assessment Committee (PRAC)

Establishment of new European committee marks start of new era for public health protection and transparency of medicines safety in Europe

The European Medicines Agency is holding the first meeting of its newly formed Pharmacovigilance Risk Assessment Committee (PRAC) today and tomorrow.

The new Committee will play a major role in overseeing the safety of medicines in the European Union. Its establishment is one of the main deliverables of the new pharmacovigilance legislation that came into operation on 1 July 2012. The legislation aims to save lives by strengthening the Europe-wide system for monitoring the safety of medicines.

In addition to its role in the protection of public health, the PRAC will operate under unprecedented levels of transparency. There will be much more proactive publication of information on safety issues, the PRAC will have the possibility of holding public hearings, and agendas and minutes of its meetings will be published.

“Medicines such as antibiotics, vaccines, treatments for heart disease, diabetes or cancers have had an enormous impact on individuals’ health”, said Guido Rasi, the Executive Director of the European Medicines Agency. “But we all know that no medicine is without risk, and our role as regulators is to ensure that over the lifecycle of a medicine its benefits for patients are greater than the potential harm through side effects. The establishment of the PRAC will make the existing system even more robust, as we will now have a dedicated committee responsible for assessing and monitoring safety issues for human medicines.”

The agenda for the inaugural meeting can be found on the Agency’s website. The items on the agenda concern mainly organisational aspects, so that the PRAC is ready to start discussion on medicines-related issues at its September 2012 meeting.

The composition of the PRAC can also be found on the Agency’s website. All Member States have nominated their members. The European Commission has appointed six independent scientific experts who will also serve as members. The nomination of PRAC members representing patients and healthcare professionals will follow a new public call for expressions of interest.

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Notes

1. This press release, together with all related documents, is available on the Agency's website at

2. Information about the roles and the functioning of the PRAC can be found on the Agency's website, together with more information about the new pharmacovigilance legislation: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000456.jsp&mid=WC0b01ac05801ae8fb

3. The agenda of the PRAC can be found on the Agency's website: http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2012/07/WC500130053.pdf

4. The inaugural meeting of the PRAC is being held in Brussels, in accordance with the Agency's planning for the 2012 Olympics in London. For more information please see the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000511.jsp&mid=WC0b01ac058046d779

5. The Agency has produced a video with an introduction to the new pharmacovigilance legislation by Dr Peter Arlett, Head of Pharmacovigilance and Risk Management. The video can be found here: http://www.youtube.com/user/emainfo/featured

6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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