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Press Office

Press release

New pharmacovigilance legislation comes into operation

Better protection of public health through strengthened EU system for medicines safety

The European Medicines Agency welcomes the start of new European Union (EU) legislation on pharmacovigilance. This new piece of legislation aims to promote and protect public health by strengthening the existing Europe-wide system for monitoring the safety and benefit-risk balance of medicines.

“The progress made in healthcare would not have been possible without medicines and the research and development community behind them. But we need smart regulation for the system to be able to continue to deliver safe and effective medicines,” said the Agency’s Executive Director Guido Rasi. “The new pharmacovigilance legislation will help us to make the system more robust for public health and more transparent. It gives regulators a range of new or improved tools to ensure that patients are not exposed to unnecessary risks when taking medicines. It also increases the efficiency of medicines regulation for the benefit of all stakeholders.”

The new legislation was proposed by the European Commission in 2008 and adopted by the European Parliament and the Member States in December 2010. Highlights of the new legislation include:

- Establishment of a new scientific committee, the Pharmacovigilance Risk Assessment Committee (PRAC).
- Clarification of the roles and responsibilities of all actors involved in the monitoring of the safety and efficacy of medicines in Europe and strengthened coordination, leading to more robust and rapid EU decision-making.
- Engagement of patients and healthcare professionals in the regulatory process, including direct consumer reporting of suspected adverse drug events.
- Improved collection of key information on medicines, e.g. through risk-proportionate, mandatory post-authorisation safety and efficacy studies.
- More transparency and better communication, including publication of agendas and minutes of the PRAC and the possibility to hold public hearings.

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The Agency is ready for the first meeting of the PRAC on 19 and 20 July 2012. 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.

Information about the roles and the functioning of the PRAC has been published today and can be found on the Agency's website, together with more information about the new pharmacovigilance legislation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the new pharmacovigilance legislation is available here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000491.jsp&mid=WC0b01ac058033e8ac .
3. The status report 'Countdown to July 2012: the Establishment and Functioning of the PRAC' is available on the Agency's website.
4. The new pharmacovigilance legislation is comprised of Directive 2010/84/EU and Regulation (EU) No 1235/2010.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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