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Press Office

Press release

Better protection of public health: European Medicines Agency counts down to introduction of new pharmacovigilance legislation

Agency and European Member States prepare for fundamental changes in pharmaceutical legislation

The European Medicines Agency, together with the European Member States and the European Commission, is preparing for the introduction of the new pharmacovigilance legislation in July this year, which will bring the biggest change to the legal framework since the establishment of the Agency in 1995. Over the next five months, the Agency will finalise its preparations for the inaugural meeting of the new Pharmacovigilance Risk Assessment Committee (PRAC), planned for 19 July 2012.

The Agency will continue to inform stakeholders of the ongoing implementation process through its website and stakeholder meetings. This will include consultation and guidance on new or revised processes, information on transitional arrangements for the pharmaceutical industry, and information on how patients and healthcare professionals can be involved in the detection and management of safety issues in European Member States. This information will complement the implementing measures being finalised by the European Commission.

In addition to the establishment of the PRAC, the mandate of the existing Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) has been revised to strengthen its role in pharmacovigilance. This group will begin meeting based on its new responsibilities from September 2012.

The Agency will begin to operate the new urgent Union procedure for safety issues concerning nationally and centrally authorised medicines in 2012. The Agency will implement the procedure for protocol approval of post-marketing safety studies and results management initially only for centrally authorised medicines, and will develop a revised process for the coordination of pharmacovigilance inspections during the year. The revised process for signal detection for centrally authorised medicines will start as of July 2012, with additional data support being provided to the European Member States for nationally authorised products.

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With the new legislation, any patient in European Member States will be able to report suspected adverse drug reactions to his or her national medicines authority. This right already exists in some Member States. The Agency will cooperate with the Member States on providing information to patients on direct reporting during 2012.

The new pharmacovigilance legislation will significantly increase the transparency of all pharmacovigilance activities of the Agency and the European Member States. The Agency will increase the transparency of its processes and procedures by publishing the agendas, recommendations, opinions and minutes from its scientific committees, including the PRAC, the CMDh and the Committee for Medicinal Products for Human Use (CHMP). At the request of the PRAC, the Agency will organise public hearings allowing the public to engage with the Agency on safety issues, and will strengthen its current role in ensuring coherent and consistent messages on safety issues across Europe.

Following consultation with European industry associations at a workshop held on 30 January 2012, the Agency will publish information on the revised implementation of the electronic submission of information on all medicines for human use authorised or registered in the European Union (also known as Article 57 requirements) in February 2012.

Also in February, the Agency will publish its concept paper on the structure of good pharmacovigilance practice (GVP) and release the first wave of GVP modules for public consultation.

The Agency has today published a new implementation plan detailing the activities of the new pharmacovigilance legislation scheduled for implementation in 2012 and those activities which will be the focus beyond 2012. Activities contributing to public health are given the highest priority, followed by activities increasing transparency and improving communication, and then those that simplify processes.

From February, the Agency will be communicating closely with its stakeholders on developments related to the implementation of the new legislation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The document detailing the plan for implementation of the new pharmacovigilance legislation is available on the Agency's website.
3. The term European Member States used in this press release refers to the European Economic Area (EEA). In addition to the 27 Member States of the European Union, the EEA also includes Iceland, Liechtenstein and Norway.
4. The draft implementing measures are available on the European Commission’s website.
5. More information on the new pharmacovigilance legislation is available on the Agency’s website in the special topics and regulatory sections.
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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