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Press Office

Press release

EMA Management Board: highlights of June 2015 meeting

Green light for central repository for safety reports, positive assessment of 2014 operations, and support to PRAC expertise

Central repository for periodic safety reports: one year to go before mandatory use

The European Medicines Agency (EMA) Management Board gave its green light for the central repository for periodic safety update reports (PSURs) for medicines authorised in the European Union (EU). In one year's time, on 13 June 2016, the central repository will become the single, central platform for these reports to be used by all regulatory authorities and pharmaceutical companies in the EU to exchange information on the safety of medicines. This decision by the Board follows an independent audit of the repository that evaluated whether it meets the agreed functional specifications. For further information, please see separate news announcement.

Positive assessment of EMA 2014 operations

The Board gave a positive assessment of EMA's operations in 2014, and of its management and internal control system.

Areas of work highlighted by the Board included: the Agency's effort to support early access to medicines through its adaptive pathways project; the creation of an expert group (ADVENT) to support the development of innovative medicines for animals; the strengthened interaction with health technology assessment bodies to facilitate patients' access to medicines; EMA's coordinating role during the Ebola outbreak within the European medicines regulatory network and with the World Health Organization; and the coordinated initiatives undertaken in the fields of both human and veterinary medicine to combat the risk of antimicrobial resistance.

EMA's Financial Regulation requires that the Management Board analyses and assesses annually the Executive Director's report on the performance of his duties and the implementation of the agreed work programme in the previous year.

Recognition of PRAC expertise

The Board confirmed that the competencies and expertise of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) members are both broad and specialised enough to cover all aspects of

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the safety monitoring and risk management of human medicines and ensure the highest levels of patient health protection.

This includes core expertise in areas such as the identification, assessment, management, minimisation and communication of risks, and also additional expertise in clinical pharmacology, pharmacoepidemiology, vaccine and biologicals pharmacovigilance, pharmacovigilance in specific populations such as older people and children, medications errors and the misuse and abuse of medicines.

The PRAC was created three years ago following the entry into force of the European pharmacovigilance legislation. As required by this legislation, EMA's Management Board reviews the composition of the PRAC every three years to ensure that the composition of the committee covers the scientific areas relevant to its tasks.

Notes

1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course. This press release is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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