EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency starts infringement procedure to investigate Roche's alleged non-compliance with pharmacovigilance obligations

The European Medicines Agency has started an infringement procedure against Roche Registration Ltd, following a request of the European Commission, to investigate allegations that the company has failed to comply with pharmacovigilance obligations in relation to its 19 centrally authorised medicines.

The initiation of the infringement procedure follows a pharmacovigilance inspection carried out in 2012 by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which identified serious shortcomings of Roche's pharmacovigilance processes.

The start of this procedure means that the Agency will further investigate the allegations against Roche within the legal framework of Regulation (EC) No 658/2007. It does not prejudge the outcome of the investigation.

The Agency will report the outcome of its investigation to the European Commission who may impose fines or periodic penalty payments under the Regulation mentioned above if it finds that Roche has committed an infringement of its obligations.

The Agency continues to assess the overall public health impact of the inspection.

The Agency has informed Roche, the European Commission and the Member States' national competent authorities that it has started an infringement procedure in this case.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A press release from June 2012 with information on the inspection findings and the Agency's actions is available on the Agency's website, together with a question and answer document.
3. The legal base for the Agency's opening of formal proceedings is Article 5 of Commission Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations

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in connection with marketing authorisations granted under Regulation (EC) No 726/2004, the 'penalties regulation'.

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

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