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Press Office

Press release

Update on infringement procedure against Roche Registration Ltd.

The European Medicines Agency has concluded its inquiry into alleged non-compliance with pharmacovigilance obligations of Roche Registration Ltd and sent its report on the inquiry to the European Commission for the next steps.

The inquiry is part of the infringement procedure against Roche Registration Ltd. It was started by the Agency on 23 October 2012 at the request of the European Commission in the framework of Commission Regulation (EC) No 658/2007, the so-called Penalties Regulation. The aim of the inquiry was to investigate allegations that the company had failed to comply with pharmacovigilance obligations in relation to its 19 centrally authorised medicines.

This followed a pharmacovigilance inspection carried out in 2012 by the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), which identified serious shortcomings in Roche's pharmacovigilance processes.

The report summarises the Agency's findings in relation to the inquiry. On the basis of the report the European Commission will decide whether the matter should be pursued and financial penalties should be imposed.

In accordance with Article 23(1) of the Penalties Regulation, an infringement procedure is carried out subject to the principles of confidentiality and professional secrecy. Any information that is part of the infringement procedure is considered confidential.

Notes

1. This press release, together with all related documents, 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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