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Media and Public Relations

Press release

Infringement procedure against Roche – EMA update

The European Medicines Agency (EMA) has concluded its second inquiry within the framework of its infringement procedure against Roche.

The infringement procedure was started by EMA 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 Roche failed to comply with its pharmacovigilance obligations in relation to 19 of its centrally authorised products.

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

The initial EMA investigation report was finalised on 14 April 2014 and forwarded, in accordance with Article 10 of the Penalties Regulation, to Roche, the Member States and the European Commission.

Upon transmission of the investigation report, the procedure continued at European Commission level. However, in July 2015 the European Commission returned the file to EMA for a new period of inquiry and for further examination of certain points of fact.

The Agency has now concluded its second inquiry and sent, on 1 July 2016, the final updated report to the European Commission summarising its findings in light of the inquiries carried out in accordance with the Penalties Regulation.

The report will form the basis for the European Commission's decision on whether or not 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.

No new safety concerns identified

Within the framework of the public health review, Roche has continued to provide additional data as part of their obligatory follow-up and considered these data in their routine pharmacovigilance activities, including the periodic cumulative reviews of the benefits and risks of these medicines.

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The assessment by the Agency of the impact of the additional data provided by Roche on the medicines concerned has not identified any important new safety concerns. These reviews have not led to any changes in the terms of the marketing authorisations of these medicines. The balance of benefits and risks of these medicines has not been affected and there is no new advice regarding their use. Patients should continue to take these medicines as advised.

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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