

Pharma investigations: Commission closes infringement procedure against Roche without penalty

Today, 15 December 2017, the Commission sent an explanatory statement to Roche Registration Ltd and its parent company Roche Holding AG, informing them about the closure of the infringement procedure¹ taken against them for failure to meet certain obligations related to their marketing authorisations. This is the first case initiated under the Penalty Regulation, whereby the Commission may impose financial penalties on marketing authorisation holders if deemed necessary. However, in this case, after considering all the available evidence and being satisfied with the company's remedial actions, the Commission decided not to notify a statement of objections to Roche Registration Ltd and Roche Holding AG and to close the case.

In a written statement submitted to the Commission Roche said:

"Roche accepted all the inspection findings. It took them extremely seriously and fully understands the EMA's and Commission's concerns. It has worked diligently to remediate the deficiencies as quickly as possible and also to enhance the company's medical compliance and PV systems to prevent any recurrence. While it has come a long way, the company knows that its efforts to enhance its systems and to maintain the trust of all stakeholders must continue. It is committed to working with the authorities to ensure it becomes, and then remains, a leader in the field."

Overview of the infringement procedure

Following results of a routine inspection of Roche's pharmacovigilance system carried out in 2012 the Commission requested the European Medicines Agency (EMA) to investigate allegations that Roche had failed to meet their pharmacovigilance obligations for 19 centrally authorised medicines. This inspection identified shortcomings, in particular concerning pharmacovigilance information stemming from market research and patient support programs within and outside the EU. An infringement procedure was initiated in October 2012, and the EMA submitted its final report to the Commission in July 2016. In consideration of this final report, and taking into account all available evidence, the Commission decided not to notify a statement of objections to Roche Registration Limited and Roche Holding AG and to close the case.

The objective of the Penalty Regulation is to ensure the enforcement of certain obligations connected with marketing authorisations for centrally authorised products. Pharmacovigilance activities are a core part of the activities of a marketing authorisation holder to monitor the continuous safety of medicinal products that have been placed on the market. In the course of the present infringement procedure Roche fully and explicitly recognised the findings of the 2012 and 2013 inspections of its pharmacovigilance system and the significant deficiencies. As a consequence, Roche remedied the deficiencies and provided a long-term commitment to further enhance its pharmacovigilance activities in full compliance with the applicable rules. The measures that Roche have already implemented appear to address the findings of the inspections and of the Agency's report,

¹ In accordance with [Article 11\(2\) of Commission Regulation \(EC\) No 658/2007 \("Penalty Regulation"\)](#)

and to provide sufficient assurances that the inspection findings should not occur again in the future due to the overall strengthening of the companies' pharmacovigilance system.

Moreover, all benefit-risk assessments of Roche's products concerned by the present proceeding taking into account the previously unassessed information have been completed. All Periodic Safety Update Reports submitted by Roche between 23 May 2013 and 31 January 2016 have been assessed by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and that evaluation by PRAC did not lead to any change to the terms of the marketing authorisations for the products concerned. The main issue identified in the EMA Final Report therefore appears to be remedied and it appears that the previously unassessed information did not have any impact on the benefit-risk profiles of the products concerned. There is hence no actual risk to public health or patient safety.

It is essential that marketing authorisation holders comply with pharmacovigilance obligations and have a functioning pharmacovigilance system in place in order to assume responsibility for their products and to ensure that appropriate action is taken when necessary.

For more information:

- [European Medicines Agency \(EMA\) website](#)

Follow us on Twitter: [@EU_Health](#)