



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Questions and answers on the assessment of the deficiencies in the safety reporting system at Roche Registration Ltd

The European Medicines Agency (EMA) and the national regulatory agencies in the European Union (EU) are currently assessing deficiencies in the medicines safety reporting system of Roche Registration Ltd and evaluating whether these impact on the overall benefit-risk profile for any of the medicines concerned. The assessment affects nineteen centrally authorised medicines as well as various medicines that have been nationally authorised.<sup>1</sup>

### Why is the assessment being carried out?

The assessment follows a routine inspection by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) which identified several deficiencies in the safety reporting systems at Roche Registration Ltd. The inspection showed that case reports for medicines marketed by Roche collected from a US Patient Support Programme (PSP)<sup>2</sup> had not been evaluated to determine whether or not they were suspected adverse reactions which would need to be reported to the competent authorities in the EU. Other deficiencies identified related to the evaluation and reporting to national medicines agencies of suspected adverse reactions from their reporting systems and clinical trials.

### What has happened so far?

Following the inspection, the company was requested to take corrective actions to ensure the correct processing of reports of suspected adverse drug reactions. In addition, the company was requested to report any missing cases of suspected adverse drug reactions to the appropriate EU authorities in accordance with the current legislation.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is currently reviewing data provided by Roche, which include previously missing case reports and corrections to previously processed data.

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<sup>1</sup> Centrally authorised medicines: Avastin, Bondenza, Bondronat, Bonviva, Cellcept, Fuzeon, Herceptin, Invirase, Mabthera, Mircera, Neorecormon, Pegasys, Roactemra, Tamiflu, Tarceva, Viracept, Xeloda, Xenical and Zelboraf

Nationally authorised medicines contain the following active substances: allopurinol, benzerapide/levodopa, bromazepam, calcitriol, carvedilol, ceftriaxone, cilazapril/cilazapril hydrochlorothiazide, clodronate, clonazepam, diazepam, dornase alfa, flumazenil, flunitrazepam, ganciclovir, glibenclamide, granisetron, interferon alfa-2a, isotretinoin, ketorolac tromethamine, lactulose, mefloquine, midazolam, naproxen, phytomenadione, pyrimethamine/sulfadoxine, ribavirin, tretinoin, trimethoprim/sulfamethoxazole, and valganciclovir

<sup>2</sup> Patient support programmes provide patients and healthcare providers with coverage and reimbursement support as well as assistance for patients who are uninsured. In the course of their business PSPs may also receive reports of adverse reactions from patients and healthcare professionals.



As part of the assessment, the PRAC is evaluating whether these deficiencies may have an impact on the overall risk-benefit balance for any of the medicines involved.

### **What are the recommendations?**

So far, there is no indication of a negative impact on the benefit-risk balance of the medicines affected.

For the time being all medicines remain authorised without changes to the treatment advice for patients and healthcare professionals.

The review of individual medicines is expected to finalise by March 2013. The EMA will issue further updates as appropriate.