21 June 2012
EMA/405725/2012
Press Office

Press release

European Medicines Agency acts on deficiencies in Roche medicines-safety reporting

Medicines authorities focus on any possible impact on patients

The European Medicines Agency is working with national medicines agencies to investigate deficiencies in the medicine-safety reporting system of Roche. This includes looking at whether the deficiencies have an impact on the overall benefit-risk profile for any of the products involved.

There is at present no evidence of a negative impact for patients and while the investigations are being conducted there is no need for patients or healthcare professionals to take any action.

The deficiencies are identified in a May 2012 report from the UK medicines regulatory agency (MHRA) following an inspection at Roche. This was part of a coordinated European programme of routine inspection of safety reporting systems.

At the time of the inspection the company identified some 80,000 reports for medicines marketed by Roche in the USA that had been collected through a Roche-sponsored patient support programme, but which had not been evaluated to determine whether or not they should be reported as suspected adverse reactions to the EU authorities. These included 15,161 reports of death of patients and it is not known whether the deaths were due to natural progression of the disease or had a causal link to the medicine. More recent information from the company indicates a smaller number of reports, but this information needs to be verified by the authorities.

It remains unclear whether any of the reports have already been submitted to the EU authorities through other channels, for example by the treating healthcare professionals.

Other deficiencies identified related to the evaluation and reporting to national medicines agencies of suspected adverse reactions from their reporting systems (around 23,000) and clinical trials (around 600).

The Agency's Committee for Medicinal Products for Human Use (CHMP), CHMP Pharmacovigilance Working Party and the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh) discussed the issues arising from the inspection at their meetings in May and June 2012.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Specific actions include:

- Roche to ensure that all known reportable events are immediately reported to the appropriate EU authorities in accordance with their existing legal obligations. The company must confirm to the Agency that this has been done, both for products in clinical trials and for marketed products.
- Roche to submit a revised comprehensive action plan by 27 June 2012 for the evaluation and reporting of all outstanding cases and plans for corrective measures to ensure the correct processing of reports on suspected adverse drug reactions in the future. This includes evaluation of each of the 80,000-plus reports received by the patient support programme in the USA and appropriate follow-up.

The EMA continues to work closely with the national medicines agencies and the US FDA and other international partners to assess the overall public health impact of the findings, including any consequences for the overall benefit-risk balance of the concerned medicines.

Updates will be made on the EMA website as appropriate.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. 'Patient support programmes' (PSP) provide patients and healthcare providers in the USA with coverage and reimbursement support as well as assistance for patients who are uninsured. In the course of their business the PSP may also receive reports of adverse reactions from patients and healthcare professionals. The PSP records deaths occurring in participating patients regardless of the cause, as one of the purposes of the PSP is to manage insurance reimbursement and shipment of medicines.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu