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MONTHLY REPORT
PHARMACOVIGILANCE WORKING PARTY (PHVWP)
DECEMBER 2009 PLENARY MEETING

The CHMP Pharmacovigilance Working Party (PhVWP) held its December 2009 plenary meeting on 14-16 December 2009.

PhVWP DISCUSSIONS ON SAFETY CONCERNS

Below is a summary of the discussions regarding non-centrally authorised medicinal products in accordance with the PhVWP publication policy (see under http://www.ema.europa.eu/htms/human/phv/reports.htm). Positions agreed by the PhVWP for non-centrally authorised products are recommendations to Member States.

For safety updates concerning centrally authorised products and products subject to ongoing CHMP procedures, readers are referred to the CHMP Monthly Report (see under http://www.ema.europa.eu/pressoffice/presshome.htm). The PhVWP provides advice on these products to the Committee of Medicinal Products for Human Use (CHMP) upon its request.

Epoetins - Risk of pure red cell aplasia

Record name of epoetin product (trade name or scientific name with name of manufacturer) in patient file

Epoetins are modified copies of the natural substance erythropoietin, a hormone that is produced by the kidneys and stimulates the production of red blood cells from the bone marrow. Epoetins are used to treat anaemia (low red blood cell counts) in cancer patients receiving chemotherapy and in patients with chronic kidney disease. Pure red cell aplasia (PRCA, a severe type of anaemia where the red blood cell count is decreased) is a known risk of epoetins due to the possible

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development of neutralising anti-erythropoietin antibodies. PRCA is a very rare event and usually only develops after months of epoetin treatment.

In June 2009, a clinical trial to evaluate the safety and immunogenicity of a biosimilar epoetin product in the treatment of anaemia associated with chronic renal insufficiency in predialysis patients was stopped because of the occurrence of PRCA cases. While investigations on the cause of PRCA in these cases are still ongoing, the PhVWP considered it important that accurate medication histories are maintained for patients treated with epoetins, i.e. recording the trade name or the scientific name with the name of the manufacturer in the patient file. The identification and traceability of epoetin products used in patients will help to assess if PRCA cases and other reported cases of adverse reactions are related to any quality specifications of a certain epoetin product. The PhVWP recommended that the product information of all epoetins includes a request to maintain patient medication records.

This recommendation was transmitted to France as the Reference Member State for the product EPREX© and to the CHMP for all other epoetin products, which are subject to a central marketing authorisation in the EU. For updates on the product information of centrally authorised epoetins, readers are referred to the website of the European Medicines Agency (http://www.ema.europa.eu/).

GUIDELINES AND GENERAL MATTERS

Below readers will find a summary of the principal discussions on guidelines and other general matters of organisational, regulatory or methodological nature.

Pharmacovigilance for medicinal products used against novel Influenza A (H1N1) virus

Medicines used to treat or prevent influenza belong to the groups of antivirals and vaccines. The European Medicines Agency is engaged, in close co-operation with European and international partners, in ensuring the availability and surveillance of medicines effective against the pandemic A (H1N1) influenza. The PhVWP supports the activities undertaken by the Agency in this respect. In particular, the PhVWP contributes to the Agency's newly established Pandemic Pharmacovigilance Rapid Response Group (PREG) which provides advice on any emerging safety data on influenza vaccines. Updates on the activities undertaken and on product information of influenza medicines are reported to the public via the Agency's website http://www.ema.europa.eu/.

REGULATORY ABBREVIATIONS

CHMP – Committee of Medicinal Products for Human Use
CMD(h) – Co-ordination Group for Mutual Recognition and Decentralised Procedures for Human Medicines
EU – European Union
HMA – Heads of Medicines Agencies
PhVWP – CHMP Pharmacovigilance Working Party
PASS – Post-Authorisation Safety Study
PL – Package Leaflet
PSUR – Period Safety Update Report
RMP – Risk Management Plan
SmPC – Summary of Product Characteristics