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Patient Health Protection

PhVWP Monthly report on safety concerns, guidelines and general matters

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The CHMP Pharmacovigilance Working Party (PhVWP) held its June 2012 plenary meeting on 18-20 June 2012.

Safety concerns

Discussions on non-centrally authorised medicinal products are summarised below in accordance with the PhVWP publication policy. The positions agreed by the PhVWP for non-centrally authorised products form recommendations to Member States. For the publication policy, readers are referred to http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/10/WC500006181.pdf.

The PhVWP also provides advice to the Committee for Medicinal Products for Human Use (CHMP) on centrally authorised products and products subject to ongoing CHMP procedures at the request of the CHMP. For safety updates concerning these products, readers are referred to the meeting highlights from the CHMP published under http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/news_and_events.jsp&mid=.

None of the ongoing discussions on non-centrally authorised medicinal products were finalised this month.

European Medicines Agency
7 Westferry Circus ● Canary Wharf
London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

HMA Management Group
Kevin O'Malley House ● Earlsfort Centre
Earlsfort Terrace ● Dublin 2 ● Ireland
Telephone +353 1 634 3453 **Facsimile** +353 1 661 4764
E-mail hma-ps@imb.ie **Website** www.hma.eu

Guidelines and general matters

Below is a summary of the main discussions on guidelines and other general matters of an organisational, regulatory or methodological nature.

Good Pharmacovigilance Practices (GVP) for the EU

The PhVWP noted that the first seven modules of good pharmacovigilance practices (GVP) were in the process of finalisation for publication on 25 June and that two further draft modules would be released for public consultation on 27 June 2012.

The first seven modules provide guidance on pharmacovigilance systems and their quality systems, the pharmacovigilance system master file, risk management systems, reporting of adverse reaction cases, periodic safety update reports, post-authorisation safety studies and signal management. They will come into force on 2 July 2012. Interested readers and those wanting to participate in the public consultation of the two new draft modules on pharmacovigilance inspections and the additional monitoring process are referred to the EMA website (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac05804fcdb1).

GVP is a set of guidelines for the conduct of pharmacovigilance in the EU, drawn up by the European Medicines Agency in cooperation with the competent authorities in Member States and interested parties based on Article 108a of Directive 2001/83/EC as amended by the new pharmacovigilance legislation (see PhVWP Monthly Reports 1101 and 1202). GVP applies to marketing authorisation holders in the EU, the Agency and competent authorities in Member States. Experts from the PhVWP contribute to its development, and the PhVWP has been consulted on all modules drafted and finalised so far as part of the development process.

Deficiencies in Roche's adverse reaction reporting

The PhVWP was involved in the discussion relating to the investigation of deficiencies in the reporting of adverse reactions by the marketing authorisation holder Roche. Interested readers are referred to the Agency's press release accessible under http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/06/news_detail_001539.jsp&mid=WC0b01ac058004d5c1.

Regulatory abbreviations

CHMP – Committee for Medicinal Products for Human Use

CMDh – Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

EU – European Union

HMA – Heads of Medicines Agencies

PASS – post-authorisation safety study

PhVWP – CHMP Pharmacovigilance Working Party

PL – package leaflet

PSUR – periodic safety update report

RMP – risk management plan

SmPC – summary of product characteristics