European Medicines Agency

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# Publication Policy for the Monthly Reports of the CHMP Pharmacovigilance Working Party

## The CHMP Pharmacovigilance Working Party (PhVWP)

The PhVWP is an expert working group which meets every month (except for August) at the European Medicines Agency (EMEA) in London, holding discussions on the safety surveillance of medicines (pharmacovigilance) in the European Union (EU)[1].

### *Mission and Responsibilities of the PhVWP*

It is the mission of the PhVWP to provide advice on the safety of medicinal products authorised in the EU and to investigate adverse reactions to enable effective identification, assessment and management of risk, at any phase in the product life cycle. On the basis of such advice, the PhVWP will provide, where applicable, recommendations for regulatory action to the Committee for Medicinal Products for Human Use (CHMP)/EMEA and to the Competent Authorities of the Member States. This should enable effective management and subsequent communication of risk. The key responsibilities of the PhVWP are:

- Evaluation of potential signals arising from spontaneous reporting, including those identified from the EudraVigilance database, and all other sources, including epidemiological databases, studies and published literature;
- Provision of advice on confirmation and quantification of risk and on regulatory options;
- Risk management by advising on risk management plans;
- Monitoring regulatory action and the outcomes of such action;
- Setting standards for procedures and methodologies to promote good vigilance practice;
- Promotion of communication and exchange of information between the EMEA and Competent Authorities of the Member States; and
- International cooperation.

### *PhVWP Recommendations*

As outcome of their assessments and discussions on medicinal products, the PhVWP may recommend regulatory action, such as a change to the dosing instructions or advice to monitor patients for certain signs which may indicate that a patient does not tolerate the medicine well and may be at risk to experience an adverse effect. By means of regulatory action, the product information, namely the Package Leaflet (PL) for the patients and the Summary of Product Characteristics (SPC) for healthcare professionals, will be updated accordingly.

The PhVWP transmits its recommendations to
- the CHMP for products subject to CHMP procedures; and
- the Competent Authorities of the Member States for nationally authorised products.

[1] Details on the membership, tasks and rules of procedure of the PhVWP are provided in the PhVWP Mandate (EMEA/CHMP/PhVWP/88786/04) on the EMEA website: www.emea.europa.eu.

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Medicinal products subject to CHMP procedures are
- products authorised centrally by the European Commission for the whole EU;
- products authorised nationally but referred for decision-making at EU level (mainly for reasons of public health relevant for all Member States).

The CHMP is the scientific committee at the EMEA for medicines to be used in humans. They take into account recommendations from all their expert working groups, including the PhVWP, for finalising CHMP Opinions. Such Opinions are transmitted to the European Commission as the Competent Authority for the preparation of legally binding Commission Decisions. The outcomes of CHMP discussions are published by the EMEA in the CHMP Monthly Reports[2].

All medicines which are not centrally authorised are subject to marketing authorisations issued by the Member States of the EU.

For such nationally authorised products, recommendations from the PhVWP are addressed to the Competent Authorities in the Member States. The National Competent Authorities will consider them for decision-making and take implementing action in line with their legislation as they consider it appropriate.

Rarely, if the newly identified risks are considered to outweigh the benefits of a medicine, regulatory action may be necessary to temporarily suspend or definitely withdraw a product from the market, and in such cases CHMP procedures will be initiated.

## The PhVWP Monthly Reports

In order to increase the transparency of the PhVWP towards the public, PhVWP Monthly Reports are published after each meeting as of September 2009. This initiative was agreed with Heads of Medicines Agencies at their meeting in July 2009.

### *Contents of the PhVWP Monthly Reports*

In these PhVWP Monthly Reports, the following outcomes are included:

- PhVWP recommendations to the Competent Authorities of the Member States for nationally authorised products (unless subject to a CHMP procedure);
- Information, on a case-by-case basis, on the status of discussions for which PhVWP recommendations have not yet been finalised, where the safety concern is already in the public domain, depending on the need for transparency;
- Final Guidelines on pharmacovigilance;
- Draft Guidelines on pharmacovigilance and related documents for public consultation;
- Information, on a case-by-case basis, on topics where the PhVWP contributes to publicly announced meetings or public consultations;
- General matters, e.g. on organisational issues of the EU regulatory network, policies and methods, on a case-by-case basis, depending on their interest for the public.

For product-related PhVWP recommendations to the National Competent Authorities for changes to the product information, Member States will initiate national procedures to implement them as appropriate. Frequently, the Co-ordination Group for Mutual Recognition and Decentralised Procedures for human medicines (CMD(h)) will be involved as they facilitate marketing authorisations and implement updates to product information for medicines available in more than one Member State[3]. Readers will be referred to the CMD(h) section of the HMA website for advice on the implementation of the PhVWP recommendations, including final wordings for SPCs and PLs.

[2] More information on the CHMP is available on the EMEA website: http://www.emea.europa.eu.
[3] More information on the CMD(h) is available on the HMA website: http://www.hma.eu.

Guidelines developed by the PhVWP set standards for the good conduct of pharmacovigilance and are agreed with the CHMP. They are released for public consultation by either the EMEA or the European Commission, and the comments received through this consultation are taken into account when finalising the guidance document.

***Not Included***

In the PhVWP Monthly Reports, recommendations from the PhVWP for products subject to a CHMP procedure will not be included as these are transmitted to the CHMP for consideration and the outcome of the CHMP discussion will be included in the CHMP Monthly Report[4].

Further, the PhVWP does not publish information on ongoing discussions in order not to undermine the conclusion processes at the level of the PhVWP (unless on a case-by-case basis where the safety concern is already in the public domain, see above).

Information received from regulatory authorities outside the EU will be treated in accordance with the Confidentiality Arrangements in place between the EMEA and the respective authority.

## Publication of the PhVWP Monthly Reports

The PhVWP Monthly Reports are published on the Thursday in the week following the PhVWP, at the same time as the CHMP Monthly Report, on the EMEA website under http://www.emea.europa.eu/whatsnewp.htm (for the archive including the latest report, see http://www.emea.europa.eu/htms/human/phv/reports.htm).

A link from the website of the Heads of Medicines Agencies to the EMEA website will be provided (see under http://www.hma.eu/cmdh.html).

## Index

A cumulative index will be kept up-to-date on the EMEA website, indicating the items in alphabetical order with the relevant issue number(s) for each item.

## Copyright



## Contact Points

Any questions from the media relating to this policy should be addressed to the EMEA Press Office (press@emea.europa.eu). Other members of the public may direct questions to info@emea.europa.eu. Contact points in Member States for medicinal products authorised nationally can be found under http://www.hma.eu/human.html.

[4] The CHMP Monthly Reports are published under http://www.emea.europa.eu/pressoffice/chmp.htm.