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PHARM 723

PHARMACEUTICAL COMMITTEE
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Subject: **Overview of Member States biennial reports on audits of their pharmacovigilance systems (2015 reporting year)**

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This document is a Health and Food Safety Directorate General document for information purposes. It does not represent an official position of the Commission on this issue, nor does it anticipate such a position.

Contents

1. Introduction and background

All medicinal products for human use have to be authorised either at Member State or Union level before they can be placed on the EU market. They are subject to a strict testing and assessment of their quality, safety and efficacy before being authorised. Once placed on the market they continue to be monitored to assure that aspects which could impact the safety profile of a medicine are detected and assessed and that necessary measures are taken.

The legal framework of pharmacovigilance for medicines marketed within the EU is provided for in Regulation (EC) No 726/2004[1] with respect to centrally authorised medicinal products and in Directive 2001/83/EC[2] with respect to nationally authorised medicinal products (including those authorised through the mutual recognition and decentralised procedures).

The pharmacovigilance legislation places an obligation on Member States to operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in Union pharmacovigilance activities[3]. The legislation also obliges Member States to perform a regular audit of their pharmacovigilance system and report the results to the Commission every 2 years[4].

This report provides an overview of the audit activities reported by the national competent authorities of the Member States, in general covering the reporting period September 2013 to September 2015, based on the audits reports submitted them. The national competent authorities that submitted information on their audits activities is given in the Annex. The information provided by the national competent authorities is not presented in a harmonised way and is not directly comparable.

The first overview of the Member States audit activities[5] provided information on the general framework of the audit system in the Member States. This overview focuses on changes and updates of the activities between 2013 to 2015, it does not provide a detailed description of audit findings.

2. Pharmacovigilance Audit Facilitation Group

The Pharmacovigilance Audit Facilitation Group (PAFG) was set up by the Heads of Medicines Agencies (HMA) to foster a common approach to pharmacovigilance audits related to human medicines performed by national competent authorities and the European Medicines Agency (EMA).

The group is composed of experienced auditors and other experts (e.g. pharmacovigilance) from the national competent authorities, the Pharmacovigilance Risk Assessment Committee (PRAC) and the EMA. In the reporting period PAFG and PRAC continued to work to support the development of support common approaches among Member States for example with respect to risk ratings of pharmacovigilance process areas.

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

[3] Article 101(1) of the Directive 2001/83/EC

4 Article 101(2) of the Directive 2001/83/EC

[5] Overview of Member States biennial reports on audits of their pharmacovigilance systems (2013 reporting year) – PHARM 693, October 2015

3. Pharmacovigilance systems of the Member States

3.1. Overview of the pharmacovigilance systems of the Member States

According to the Member States' reports, national audit programmes continue to be elaborated on the basis of audit strategies adopted by the Head of Agency and senior managers in the competent authority.

3.2. Audit programmes

The development of each national competent authority's audit strategy takes account of past audits and on-going implementation of corrective actions, as well as the outcome of a risk assessment exercise. The strategies are generally reviewed within a rolling programme. During the reporting period around half the competent authorities reviewed their audit strategy.

A wide range of pharmacovigilance activities has been audited across the Member States. The findings are documented with different levels of detail, for example with respect to the audit scope, and findings description.

3.3. Organisation structure, responsibilities and resources

Organisational structures across the Member States have been described in different ways, varying from matrix to more vertical organisations. During the reporting period some Member States had noted organisational changes being implemented with the view to optimise the organisational orientation and personnel. One Member State indicated that there had been a reorganisation and restructuring of the governmental institutions. For others there had been some reorganisation of responsibilities within the national competent authority. The organograms and details of the organisational structures are published by some Member States. National scientific committees are part of the organisational structure in certain Member States. In some cases the audits found a need for improvement in organisation of work, these findings have or will be addressed in the follow up actions to the audit.

Management of human resources is important as the implementation and operation of pharmacovigilance systems that comply with EU and national legislative requirements have had an impact on resource needs. Where possible, the effective implementation and operation have led to recruitment of additional personnel in various roles (e.g. pharmacovigilance assessors, administrative support, experts for technical committees). There has been an in increase in personnel in some pharmacovigilance departments in the Member States. Although, the shortfall in human resources has been flagged as an issue by some Member States.

3.4. Training

Overall, the organisation of activities related to training and personal development in the Member States follows a structured set of common principles. Some Member States indicated that during the reporting period special training of pharmacovigilance staff had been developed. The training can be a structured programme, exchange of experience through programmes or mentoring. In some cases the quality assurance of training of staff has been included in the quality management system.

3.5. Compliance management and record management

No major changes were noted regarding the systems for compliance management. Most Member States noted that they have in place procedures for the annual declaration of interests. In some cases audits had identified areas for improvement in work flows.

3.6. Monitoring of performance and effectiveness

National competent authorities have overall reported having adequate tools and mechanisms to monitor the performance and effectiveness of their pharmacovigilance systems. The system of monitoring can vary including peer review, business management reports. The key performance indicators might be included in the operational plans.

4. Overview of audits

Most competent authorities reported on their activities between September 2013 and September 2015. Two smaller Member States did not submit reports.

Where audit reports had been completed, the national competent authorities reported between 1 and 18 audits having been undertaken. The scope of the individual audits varied, in some Member States there were audits of their pharmacovigilance system overall whilst others had audited specific activities within the system. The template used for the biennial reporting provides for recording of the number of critical or major findings. Nearly half of the national competent authorities there were no major or critical findings. Where areas for improvement had been identified during the audit follow up action had already been taken or was in progress.

5. Summary

The Member States are obliged to submit reports on the results of the audits of their pharmacovigilance system every 2 years. This document provides an overview of the reports submitted for the reporting period September 2013 – September 2015.

The Member States plan the audit of their pharmacovigilance system according to a risk assessment of the various activities. Areas for improvement were identified in some audits. Where information was provided, follow up actions had been implemented or were in progress.

The continuous development and review of the pharmacovigilance system is noted in some reports. The Pharmacovigilance Audit Facilitation Group and other activities organised by the Member States, such as the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action, by the European Medicines Agency and training, support the national competent authorities in their own pharmacovigilance related activities.

ANNEX

The following designated competent authorities submitted information on their audit activities to the European Commission.

Member State	Competent Authorities
Belgium (BE)	Federal Agency for Medicines and Health Products
Czech Republic (CZ)	State Institute for Drug Control
Denmark (DK)	Danish Health and Medicines Authority
Germany (DE)	- Federal Institute for Drugs and Medical Devices - Paul-Ehrlich-Institute, Federal Institute for Vaccines and Biomedicines
Estonia (EE)	State Agency of Medicines
Ireland (IE)	Health Products Regulatory Authority
Greece (EL)	National Organization for Medicines
Spain (ES)	Spanish Agency for Medicines and Medical Devices
France (FR)	National Agency for the Safety of Medicines and Health Products
Croatia (HR)	Agency for Medicinal Products and Medical Devices of Croatia
Italy (IT)	Italian Medicines Agency
Cyprus (CY)	Pharmaceutical Services, Ministry of Health
Latvia (LV)	State Agency of Medicines
Lithuania (LT)	State Medicines Control Agency
Hungary (HU)	National Institute of Pharmacy and Nutrition
Malta (MT)	Medicines Authority
Netherlands (NL)	- Medicines Evaluation Board - Netherlands Pharmacovigilance Centre Lareb
Austria (AT)	Austrian Medicines and Medical Devices Agency
Poland (PL)	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Portugal (PT)	National Authority of Medicines and Health Products
Romania (RO)	National Agency for Medicines and Medical Devices
Slovenia (SI)	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
Slovak Republic (SK)	State Institute for Drug Control
Finland (FI)	Finnish Medicines Agency
Sweden (SE)	Medical Products Agency
United Kingdom (UK)	Medicines and Healthcare products Regulatory Agency

In addition the Icelandic Medicines Agency (IC) submitted a report on its pharmacovigilance audits.