Member States pharmacovigilance systems audits

Pharmaceutical Committee
21 October 2015

Health and Food Safety Directorate General

Health and Food Safety

Legal background

- Obligation on Member States (MS) to operate a pharmacovigilance system (Article 101(1) of Directive 2001/83/EC)

- Obligation to perform regular audit of the system and report to the Commission by 21 September 2013 and every 2 years (Article 101(3) of Directive 2001/83/EC)

Reports submitted

- All Member States and Norway submitted information on the audits

- Most MS reported on activities between July 2012 and September 2013, 7 MS covered audits prior to July 2012

Format of reports

- Template prepared by Pharmacovigilance Audit Facilitation Group
- Findings documented to different levels of detail
- Information provided by the MS is not directly comparable

Audit programmes

- Audit strategy adopted by Head of Agency
- Take account of risk assessment
- Conducted by internal or external auditors independent from pharmacovigilance activities

Reported activities

- Organisation
- Training
- Facilities and equipment
- Compliance management
- Record management
- Documentation of the quality system
- Business continuity arrangements
- Monitoring of performance and effectiveness

Overview

- 26 MS and Norway reported completing audits
- Between 1 to 18 audits had been completed by individual MS
- Not possible to compare audits and their outcomes
- Scope of audits varied
- Areas for improvement were identified in some audits – most addressed in the reporting period