EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guidance on transitional measures for the Pharmacovigilance Legislation

Stakeholders meeting on 20 October 2011

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Outline

- Scope of the ‘transitional’ exercise
- Legislation on transitional periods
- Gap analysis
- Guidance
- Objectives

Scope of the 'transitional' exercise

- Transitional period foreseen in the legislation
- Gap analysis to identify additional transitional aspects

- To identify changes impacting on :
  - future MA applications
  - ongoing MA applications
  - existing MAs

  at the time of entry into force of the new legislation

Legislation

- Transitional periods set out for:
  - Pharmacovigilance System Master File (PSMF) for 'old' products:
    - at renewal or from 2/21 July 2015
  - Post-Authorisation Safety Study (PASS) being a condition to the marketing authorisation (MA)
    - For PASS to commence after 2/21 July 2012
  - Reporting of Adverse Drug Reactions until Eudravigilance is fully functional
    - Reporting to MSs and Agency until upgrade of Eudravigilance
  - PSUR submission until the repository is fully functional
    - To submit PSURs to all MSs until availability of the repository

Key-changes from the Gap analysis

- Renewal
- Referral
- RMP
- Product Information (black symbol / HCP-patient reporting)

- PhV System Master File (PSMF)
- PASS being condition to the MA
- PSUR

- New Requirements
- Modifications of existing requirements
- New procedures and decision making process

New Requirements

→ How to introduce ?

- Black symbol and statements in SmPC and PL for authorised products subject to additional monitoring
- Standard text encouraging HCPs and patients reporting in SmPC and PL for authorised products
- PSUR frequency as condition to the MA

Modification of existing requirements

→ When to apply?

- RMP
  - Systematic RMP and summary for MAs authorised after July 2012
  - New format and content
- PSMF on site and PSMF summary in the MA
  - PSMF summary for MAs authorised after July 2012
  - Introduction of PSMF summary for authorised products before renewal or July 2015
  - New format and content
- Renewal
  - New submission deadline (from 6 to 9 months before expiry of the MA)
  - Updated content of the renewal application

New procedures and decision making process

- Involvement of PRAC
  - Safety related referrals
  - PSUR
  - RMP
  - PASS (condition to the MA) - for study to 'commence' after July 2012

    ('commence' = start of data collection – *Impl. Measures*)

→'old' versus 'new' legal framework?

- New decision making process (binding)

  For Referrals / PSUR / PASS
  - CAP only -> CHMP / EC
  - NAP only -> CMDh (by consensus) / EC (if no consensus)
  - Mix CAP/NAP -> CHMP / EC

CAP: Centrally authorised products

NAP: Nationally authorised products

Development of transitional measures guidance

- A joint exercise between EC / EMA / MS

- Where to be published?
  - Implementing measures
  - Legal and operational guidance on transitional measures

    →will be published on EC/EMA/HMA websites

Objectives of the guidance

- To operate in a consistent and harmonised way the entry into force of the new legislation across the Member States, the Agency and MAHs/applicants

- To provide timely guidance to Marketing Authorisation Applicants / Holders

Thank you for your attention

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