Industry Stakeholder platform - Operation of EU pharmacovigilance legislation

12 June 2015

CMDh subgroup on RMP, for same active substances
CMDh RMP Webpage/Cover Note /List of safety concerns per approved Risk Management Plan (RMP) of active substances per product

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Content presentation

- Actions CMDh as of January 2015
  - Extension PSUR WS WP into WP on PPWS
  - List of safety concerns published by CMDh
- Meeting CMDh subgroup on RMP for same active substance with industry
- Future issues for discussion: WS RMP assessment/proactive preparation key elements RMPs?

Actions CMDh as of January 2015 - WP on PPWS

Extension mandate of PSUR WS Working Party (WP) to also discuss issues regarding RMPs and to manage list of active substances. New name Working Party:
Working Party on Pharmacovigilance Procedures Work Sharing (PPWS WP)

Actions CMDh as of January 2015 - WP on PPWS

Press release CMDh February 2015:
The CMDh has adopted a revised mandate of the working party including a new name. The mandate has been changed to capture the changed responsibilities of the working party, including the development of procedures for RMPs, particularly for generics. The new name reflects the broadened mandate. The revised mandate will be published on the CMDh website under “CMD Working Parties/Working Groups, Working Party on Pharmacovigilance Procedures Work-Sharing”.

Actions CMDh as of January 2015 - List of safety concerns per active substance published by CMDh in April 2015

- List published under Pharmacovigilance/RMP (http://www.hma.eu/464.html)
- Published list:
  - a **starting** point to get information on safety concerns in public domain
  - list is not complete yet: **“growing list”** to be further populated by NCAs and later (if necessary) by MAHs
  - CMDh PPWS WP responsible for maintenance of the list

Actions CMDh as of January 2015 – Cover note/List of safety concerns per active substance published by CMDh in April 2015

Purpose of this list:

- By publishing the safety concerns of agreed RMPs, Members States and companies can base their assessment/prepare their RMP on safety concerns of already approved RMPs for the active substance, which will lead to more harmonised outcomes.
- In due time the Working Party on Pharmacovigilance Procedures Work Sharing will discuss based on the information included in the list how full harmonisation (where applicable) of RMPs for the same active substances may be achieved.

CMDh subgroup on RMP for same active substance with industry

Composition CMDh subgroup on RMP for same active substance:

- ✓ some members of CMDh PPWS WP
- ✓ representatives of several trade associations

First meeting on **22 June 2015**

Possible issues for this subgroup:

- ➢ Published List of safety concerns
  - ✓ How to optimise/complete the list
  - ✓ How to harmonise the different approved RMPs included in the list for one active substance e.g. via worksharing procedures
  - ✓ Further discussions on possible inclusion of e.g. links to (E)PARs/published educational materials etc.

CMDh subgroup on RMP for same active substance with industry

Possible issues for this subgroup (continued):

- Possibility for worksharing of assessment of RMPs (see also proposal EGA/EFPIA).
  NB: WS of assessment of RMPs not comparable with (former) informal WS of PSUR assessment

- Possibility of proactive drafting by industry of key elements for RMPs for future generics of “new products” to be assessed by a NCA –lead Member State (appointed in CMDh?) - together with PRAC?

- Any other issues …

Thank you!!