14th Industry stakeholder platform – operation of EU pharmacovigilance 28 September 2018

Issues and update from the CMDh

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1. Update on HaRP project

HaRP = **Ha**rmonisation of **R**M**P**s

Aim of the project:

to harmonise the Risk Management Plans of the same active substances for which marketing authorisations have already been granted with different RMPs in place

HaRP - Project proposal: 2 domains

Domain 1

Developing up-to-date RMPs for the innovator product for active substances for which the data exclusivity of the reference product will expire soon (prospective approach)

Domain 2

Clean-up of the Excel List of safety concerns as published on the CMDh website

(first step for substances with no reference product or with reference product without an RMP in place)

RMP Peerreview group (RMP PRG) (1/2)

- RMP PRG set up for (initially) especially domain 2
- Chaired by NL
- Already 27 volunteers (CMDh members/assessors and PRAC members) appointed!
- Since April 2018 4 meetings via TC

RMP Peerreview group (RMP PRG) (2/2)

What has been done so far:

- selection of a first set of active substances to start a pilot
- methodology/algorithm agreed
- template suitable for the assessment procedure agreed
- ARs/proposals for harmonised safety concerns finalised for 24 substances, resulting in:
  - ✓ 21 substances “empty” RMP (no remaining safety concerns)
  - ✓ 3 substances with 1 or 2 remaining safety concerns only

Next steps (draft)

Once harmonised RMP agreed by the PRG, the proposals is sent to:

- Pharmaceutical Industry (one Lead contact MAH) (to be further discussed with the Interested Parties)
- all MSs
- PRAC, in case of CAP innovator product or disagreement

- Final adoption by CMDh and agreed harmonised RMP published on the CMDh website, similarly to SmARs in the PSUR work sharing procedure
- Proposed draft procedure/methodology shared with members on behalf of MAHs of small ad hoc CMDh working group on RMPs
- Meeting/TC with Trade associations (MAHs) with small ad hoc CMDh working group on RMPs needed in Q4 2018 to discuss comments received

2. PSUFU (**PSU**SA **F**ollow **U**p procedure)

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

http://www.hma.eu/314.html

June 2018
CMDh/367/2017, Rev. 1

CMDh Guidance on the Informal Work-Sharing procedure for follow-up for PSUSA for NAPs

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Message to MAHs

MAHs **cannot ask for PSUFU** but should respond to RSI sent to MAH on day 60

In case the question/RSI is not clear please ask EMA/LMS for further explanation

See also the comments received during the public consultation on PSUFU guidance and the published CMDh's responses

3. Worksharing variations: safety updates of product information

Message to MAHs

September 2018 CMDh press release

Use of variation worksharing procedures

The CMDh strongly encourages MAHs to use variation worksharing procedures for MRP/DCP and purely nationally authorised products, whenever possible.

The use of variation WS improves efficiency for both industry and regulators and will ensure harmonisation of the assessment outcome, hence improving public health across the EU.

THANKS FOR YOUR ATTENTION