5th Industry stakeholder platform - operation of EU pharmacovigilance legislation

15 September 2015

Risk Management summary publication
Review of experience – update CMDh activities since 12 June 2015

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Content presentation

- Actions CMDh after Stakeholders meeting held on 12 June 2015
  - Meeting CMDh ad hoc group to discuss RMP initiatives with industry
  - Q&A on same RMP in different procedures (published by CMDh)
  - Further CMDh initiatives agreed by CMDh in July 2015

CMDh ad hoc group to discuss RMP initiatives with industry

Composition CMDh ad hoc group:

- some members of CMDh Pharmacovigilance Procedures Work Sharing WP
- representatives of several trade associations

First meeting took place on **22 June 2015**/issues discussed
Several issues discussed like:

- List of safety concerns published by CMDh
  - ✓ Updates list how visible
  - ✓ Possibility for MAHs to provide information for the list
  - ✓ Inclusion of educational material?
  - ✓ Use list to identify areas for need for harmonisation
  - ✓ Include in list information on safety concerns from PSUSA ARs?

- Possibilities for work sharing of assessment of RMPs

Q&A on same RMP in different procedures (published by CMDh)

Question 9 (on Pharmacovigilance Legislation)
How can I achieve identical RMPs in different procedures?

Answer:
For different ongoing procedures:
You should not attempt to achieve identical RMPs without informing the RMS/NCA.
If you have applied for products in the same substance class via different procedures, the need for separate RMPs should be discussed with the RMS/NCA and they may request a RMP that only includes the product in question for their procedure.

For different already authorised products:
Should you wish to achieve one identical RMP covering multiple different authorisations, it is recommended to submit a worksharing variation to update the RMP.

Initiatives agreed by CMDh in July 2015

CMDh agreed with following proposals:

- MAHs to be able to provide information to update the CMDh list of safety concerns in approved RMPs – proposal/template will be discussed in CMDh September 2015
- Further development of the list by gathering information from PSUSA assessments – e.g. in separate file to distinguish from approved RMPs
- Further investigation and development of process for peer review of RMPs containing the same substance by e.g. lead MS PSUSA or RMS reference product
- Further development of procedure for review and publication of the innovator RMP at the 5-year renewal or near expiry of data exclusivity.

Thank you!!