Consultation on the explanatory note to GVP Module VII

10th industry stakeholder platform 3 February 2017

Agenda

- Introduction
- Points for discussion
  1. EU Product Information (PI)
  2. Provision of study reports: PASS or CSR from all studies
  3. Summaries of safety concerns
  4. New safety information
  5. Section overview of signals - close monitoring
  6. Section characterisation of risks
  7. Information regarding ongoing variations
  8. Effectiveness of risk minimisation
- Clarifications

1. EU Product Information (PI)

- In relation to the reference to QPPV oversight of the EU PI and provision of a statement accordingly, the explanatory note does not say that the MAHs' QPPV should only rely on the PSUR. However, experience gained with the PSUSA process so far is that several MAHs misunderstand the role of the RSI and do not make the bridge between the RSI and the PI in EU in order to maintain oversight of the European SmPC (as per IR)
- Regulators need to see implications of PSUR data for the EU PI not RSI
- PI is the only document PRAC gives recommendations of changes on
- Changes to the PI should be driven by PSUR data - the proposal to replace by "critical analysis of B/R" is not agreed as "PSUR data" is broader and may provide information that can also lead to regulatory outcomes
- Regarding changes to EU PI in the regional appendix, is our understanding correct that you agree to provide changes to the PI in this section with a cross reference in the body of the PSUR accordingly?

2. Provision of study reports

- Relevant safety information of part or the full study report can be submitted to support the sections 7 and 8 on safety findings from studies

- Exception: submission of final study reports for PASS that were finalised during the reporting interval is required as per the EU appendix (current GVP VII version)

- The above requirement regarding submission of PASS will be further revisited in the explanatory note and later on integrated in the revision of the GVP Module VII

3. Summaries of safety concerns

- This section of the explanatory note refers to products without RMP and will be revised to clarify the expectations for products with or without RMP

- MAHs will not be requested to develop a RMP if one does not exist. This would occur only in special situations but not by default

- In case a new RMP should be developed a request will be made on a case by case basis

4. New safety information (section 16.1)

- New data that became available during the period will not only be discussed if the signal threshold is reached

- The MAH is expected to discuss new data that became available during the period under review without duplication between the signal section and the risk section

- It is not necessary to include a detailed discussion of the information arising in the period covered by the PSUR that merely confirms the established safety profile or risk characterisation of the product

5. Section overview of signals

- Proposal for limiting the time period for close monitoring e.g. return to routine pharmacovigilance if 2 consecutive PSURs have not revealed a safety signal

- A fixed time limit could be restrictive, in particular in those cases where there is low exposure or the cases have been poorly documented

- Intention to maintain some flexibility on a case-by-case basis

6. Section characterisation of risks

- Industry proposal to remove statement that important identified, potential risks and missing information should be provided in this section, as current wording in explanatory note is not fully in line with GVP Module VII

- The sentence will be aligned with GVP Module VII as follows: "Focus should be given to those important identified/potential risks that are critical to the benefit/risk balance and may profit from further characterisation."

7. Information regarding ongoing variations

- Industry proposal for the explanatory note to justify why information regarding ongoing variations is required together with the level of detail needed in the PSUR

- The requirement for brief description of ongoing variations is included in the regional appendix

- The level of detail needed will be further elaborated in the final explanatory note and the revised GVP Module VII

8. Effectiveness of risk minimisation

- Proposal to clarify information on measuring of effectiveness of risk minimisation in the EU
- We understand the issue of the PSUR being an international document however, the wording proposed is not in line with GVP Module VII section VII.B.5.16.5 and also implementing regulation 32(3)
- However the explanatory note wording on this point will be rephrased to better clarify that even if the PSUR is a global document the EU relevant risk minimisation data should be provided in the regional appendix
- This will be clarified in the Q&A for assessors accordingly

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