EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on GVP Module P.II. Biologicals

Feed-back from public consultation

7th Industry stakeholder platform operation of the EU pharmacovigilance legislation

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In this presentation:

Overview of main general comments received during the public consultation, with note for clarification

Proposals for text amendments are being reviewed; no response on specific proposals.

Content of presentation

- General comments
- Comments regarding scope
- Comments regarding batch traceability
- Comment regarding PSURs
- Comments regarding risk management plans
- Relevant comments beyond the scope of GVP Module P.II
- Next steps

General comment

- Draft GVP Module supported and considered useful, with agreement on aims and approaches
- Appreciation that many of the pharmaceutical industry comments to the 2014 biological concept paper have been taken into account
- Relevant comments received in response to the recent public consultation on the *Guideline on Immunogenicity assessment of biotechnology-derived therapeutic proteins* to be taken into account.

Comments on scope

- Pharmacovigilance processes similar for all biologicals; biosimilars and related biological medicinal products should not be singled out
  - *Note: there was a need for guidance on certain pharmacovigilance aspects of biosimilars and related biological medicinal products, e.g. update of risk management plans where changes were made to the reference product RMP.*
- GVP Module P.II should also apply to ATMPs
  - *Note: Current guidance on ATMPs will be amended and address the specific challenges of pharmacovigilance and patient traceability for ATMPs.*

Comments on batch traceability

- Practical challenge of obtaining batch numbers for biologicals where reporters may not be aware of the batch number; need for better training of HCPs
  - ➢ *Note: acknowledged but GVP needs to establish principles for best practice, not to describe the actual situation*
- Feasibility to collect batch numbers in biologics registers in rheumatology where data are collected every sixth months; batch-related risks cannot be compared within a registry and should be detected by spontaneous reporting; workload
  - ➢ *Note: Guidance related to studies with primary data collection in GVP Module VI; analyses not done at registry level but globally*
- Separation between activities falling under MS' and MAHs' responsibility
  - ➢ *Note: Specific activities presented in Module P.II.C. – will be reviewed*

Comment on PSURs

•In the absence of a safety signal, batch numbers should not routinely be included in the PSUR/PBRER as such information is not collected via routine PhV; this information is not required by GVP Module VII.

- *Note 1: Module VII.B.5.5.2 states that "An overall estimation of patient exposure should be provided. In addition, the data should be routinely presented by sex, age, indication, dose, formulation and region, where applicable. Depending upon the product, other variables may be relevant, such as number of vaccination courses, route(s) of administration, and duration of treatment."*
- *Note 2: Focus is on signal detection of batch-related safety issues; many batches will no longer be in circulation at the time of PSUR production.*

Text to be reviewed and amended as necessary.

Comments on Risk management plan

- Immunogenicity not to be included as a safety concern unless it is associated with a clinical outcome.
  - *Note: this was the intention; text to be reviewed and amended if necessary*

- No automatic update of a RMP based on safety findings with another product in absence of confirmation of safety finding for the concerned product
  - *Note: need to update RMP is based on an assessment of the specific safety findings and concerned products; text to be reviewed and amended if necessary*

Relevant comments beyond the scope of GVP Module P.II (1)

- Measures should be adopted at national level to encourage prescribing biologicals by brand/invented name and/or preventing inappropriate switch.
- Art. 26 of Delegated Regulation (EU) 2016/61 on rules for safety features appearing on the packaging of medicinal products for human use: MS can exempt healthcare institutions (incl. hospitals, in- and out-patient clinics,…) from the obligation to verify safety features on the packaging, incl. the unique identifier – traceability will depend upon the way each MS implements the act.
- Practicalities and logistics of collaborations between MAHs for sharing RMP documents, safety specifications, risk minimisation tools, results of signal assessments, regulatory actions – proposal to create a "safe harbour" hosted by EMA.
- Regulators to define a strategy to improve collaboration between EMA/NCAs and MAHs and between different MAHs.

Relevant comments beyond the scope of GVP Module P.II (2)

- 2012 pharmacovigilance obligation not completely implemented – key priority is to closely monitor, support and stimulate implementation by MS of Art. 102(e) of Directive 2001/83/EC (identification of biologicals) incl. exchange of best practices among MS, education platform for patients and HCPs, limitation of product information/labelling changes, improvement of ADR reporting systems

- Implementation of the WHO proposal on the Biological Qualifier (BQ): divergent positions between respondents

- General support to unique identifier introduced with the Falsified Medicines Directive

Next steps

- Revision of draft GVP Module P.II based on comments
- Consultation of relevant committees (BWP, BMWP, PRAC, CHMP,…)
- Finalisation
- Approval by PRAC
- Publication

Thank you for your attention

Further information

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