Directorate-General for Health & Consumers

Public consultation on a concept paper on implementing measures for the performance of pharmacovigilance activities

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EUROPEAN COMMISSION

Directorate-General for Health & Consumers

New Pharmacovigilance legislation

- Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance

Implementing measures

(a) The content and maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;

(b) The minimum requirements for the quality system for the performance of pharmacovigilance activities by the national competent authorities, the European Medicines Agency (EMA) and the marketing authorisation holder;

(c) The use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;

Implementing measures

(d) The minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new risks or whether risks have changed;

(e) The format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder;

(f) The format and content of electronic periodic safety update reports and risk management plans;

(g) The format of protocols, abstracts and final study reports for the postauthorisation safety studies.

Implementing measures

Public consultation: Concept paper

- 8 September 2011
- http://ec.europa.eu/health/human-use/pharmacovigilance/developments/index_en.htm

- harmonise the performance of the new PhV activities
- supplement essential details of the new PhV system providing technical details
- that have to be observed by MAHs, NCAs and the EMA in the daily practice of applying the new provisions
- balance between safeguard of public health and general internal market requirements

About the consultation

- With the public consultation the European Commission intends to describe the scope and content of the implementing measure which it is currently considering and seeks views and feedback from stakeholders on those issues.

About the consultation

- The period of consultation ends on 7 November 2011
- All citizens and organisations (public and private) are welcome to contribute to this consultation
- Received contributions will be published on the internet
- The suggestions contained in this document do not prejudge the form and content of any future proposal by the European Commission.

Consultation topics

A. Pharmacovigilance system master file
B. Quality systems for the performance of PhV – Common obligations
C. Quality systems for the performance of PhV activities by MAHs
D. Quality systems for the performance of PhV activities by NCAs and EMA
E. Signal detection and risk identification
F. Use of terminology
G. Transmission and Submission requirements

Consultation topics

- Annex I – Electronic submissions of suspected adverse reactions
- Annex II – Risk management plans
- Annex III – Electronic periodic safety update reports
- Annex IV – Protocols, abstracts and final study reports for the post-authorisation safety studies

PhV MF

- Should additional processes and pharmacovigilance tasks be covered?
- The aim of the pharmacovigilance master file is two-fold: to concentrate information in one global document and to facilitate maintenance by uncoupling it from the marketing authorisation. Therefore changes to the content of the master file will be no longer subject to variation obligations.

Would it be nevertheless appropriate to require the marketing authorisation holder to notify significant changes/modifications to the master file to the competent authorities in order to facilitate supervision tasks?

If so, how should this be done?

Should the master file contain a date when it was last reviewed?

PhV MF

- Is it necessary to be more precise on potential delegation, e.g. In the case of co-marketing of products? Please comment.
- Should a copy of the audit report be retained in the master file?

Would it be appropriate to require documentation of audit schedules?

- Overall, do you agree with the requirements as regards the content and maintenance of the pharmacovigilance master file?

QS

- Is there a need for additional quality procedures, e.g. in relation to study reporting in accordance with Article 107p of the Directive, in relation to communication on pharmacovigilance between the marketing authorisation holder and patients/health professionals; in relation to processes for taking corrective and improvement actions or in relation to the detection of duplicates of suspected adverse reaction reports in the Eudravigilance database?
- Do you agree with the requirements... ?

Signal detection and risk identification

- For efficiency reasons a ‘work sharing’ procedure could be appropriate for the monitoring of medicinal products or active substances contained in several medicinal product. However, do you see a risk in cumulating all tasks (for the authorisation, PSUR scrutiny and Eudravigilance monitoring) in one Member State, as thereby the benefits of parallel monitoring may be lost (“peer review” system)?
- Additionally, it may be envisaged to extend ‘work sharing’ to all medicinal products (including all centrally approved products) and to appoint a lead Member State in addition to EMA (Article 28a(1)(c) of Regulation (EC) No 726/2004). Please comment.

Signal detection and risk identification

- In the Commission's view the aim of this part is to establish common triggers for signal detection; to clarify the respective monitoring roles of marketing authorisation holders, national competent authorities and EMA; and to identify how signals are picked up? Are the proposed provision sufficiently clear and transparent or should they be more detailed? If so, which aspects require additional considerations and what should be required?

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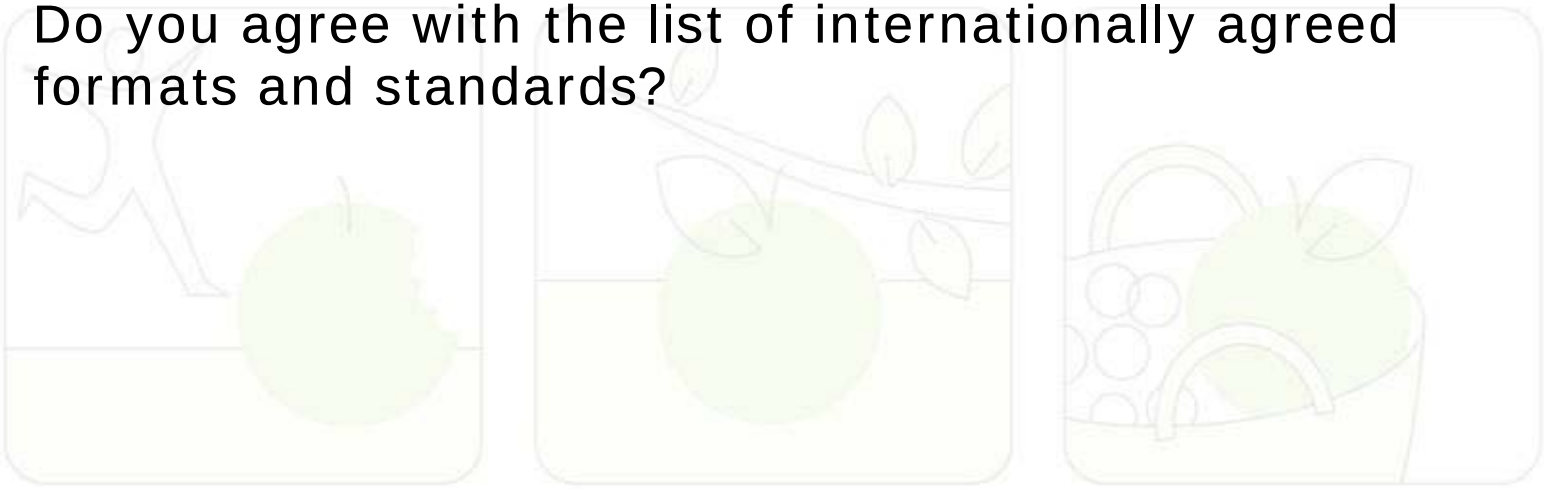
Use of terminology

- Do you agree with the proposed terminology?
- Do you agree with the list of internationally agreed formats and standards?



Transmission and sublission requirements

- Is there additionally a need for transitional provisions as regards certain aspects of this implementing measure, especially in relation to the specifications on format and content?

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Thank you