5th Stakeholder Forum – 25 May

Implementation of the pharmacovigilance legislation

Update from the European Commission

When does it start?

- **For CAPs: 2 July 2012**
- **For NAPs: 21 July 2012**

…but it is not a revolution, but an evolution with a progressive switch to the new legal and regulatory framework

… some features of the new pharmacovigilance legislation will only be fully functional in some years (Eudravigilance)

Commission Implementing Regulation

Implementing regulation on the performance of pharmacovigilance activities – recent developments

- **March 2012: Notification under the TBT-Agreement (G/TBT/N/EU/29) – Standstill period until end of April**
- **April/May 2012: Translation of the draft**
- **29 May 2012: Vote in the Standing Committee on medicinal products for human use (Member States)**
- **June 2012: Adoption by the Commission**

Commission Implementing Regulation II

Implementing regulation on the performance of pharmacovigilance activities – structure

- **Pharmacovigilance system master file**
- **Quality systems**
- **Signal detection/Monitoring of Eudravigilance**
- **Use of terminology, format and standards**
- **Transmission of suspected adverse reactions**
- **Risk management plans**
- **Periodic safety update reports**
- **Post-authorisation safety studies**
- **Final provisions including transitional provisions**
- **Annexes on specific formats**

Commission Implementing Regulation III

Implementing regulation on the performance of pharmacovigilance activities – key elements

- **Pharmacovigilance system master file: core content + annexes**
- **Quality systems: human resources/compliance management/record management**
- **Signal detection/Monitoring of Eudravigilance: detection of new signals by marketing authorisation holders**
- **Use of terminology, format and standards: move to EN/ISO standards**
- **Periodic safety update reports: integration of new ICH format**
- **Transitional provisions: Phasing-in period of 6 months**

Commission Implementing Regulation IV

Implementing regulation on the performance of pharmacovigilance activities

- **Availability of the final draft**
  - Within 1-2 weeks after the positive vote the final draft as voted will be available in the Comitology Register in all EU languages (http://ec.europa.eu/transparency/regcomitology/index.cfm)
- **Availability of the adopted regulation**
  - Once adopted by the Commission the Regulation will be published in the Official Journal of the European Union

Commission delegated act

- **Article 10b: "In order to determine the situations in which post-authorisation efficacy studies may be required (…), the Commission may adopt (…) delegated acts".**
- **Commission is currently considering possible ways ahead**
- **Later this year the publication of a concept paper on post-authorisation efficacy studies (situations in which they may be required) is likely**

Appointment of members to the Pharmacovigilance Risk Assessment Committee

- **Independent scientific experts**
  - Appointment process is ongoing
  - Expert appointment close to finalisation
- **Patient and healthcare professional representatives**
  - The recent consultation of the European Parliament resulted in the request of the Parliament to the Commission to re-launch the call for the expression of interest in view of the low number of applications and to apply a strict Conflict of Interest scrutiny of the proposed candidates
  - A re-launch of the call means that the appointment of patient and healthcare professional representatives is delayed for an indefinite period

Any questions?

Thank you

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