Preparation of amendments to COM Implementing Regulation 520/2012 on the performance of pharmacovigilance activities (draft)

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Pharmaceutical Strategy for Europe 2020

- As part of the Pharmaceutical Strategy for Europe, the Commission is not only committed to evaluate and review the general pharmaceutical legislation, but also to update and optimise existing implementing measures

- => revision of COM Implementing Regulation No 520/2012

Legal background on pharmacovigilance

- Chapter IX ‘Pharmacovigilance’ in Directive 2001/83/EC => also chapter IX in the proposal for a pharma Directive
- Chapter VIII ’Pharmacovigilance’ in Regulation 726/2004 => Chapter XVIII in the proposal for a pharma Regulation
- Reform of the EU pharmaceutical legislation - European Commission (europa.eu)
- but also other articles and other legal acts such as Commission Regulation (EC) No 507/2006 on the conditional marketing authorization
- Commission Implementing Regulation 520/2012 on 19 June 2012 on the performance of pharmacovigilance activities, in force since 10 July 2012 (‘IR 520/2012’)
- Draft Commission Implementing Regulation amending IR 520/2012 (‘draft IR’)

Policy background

- Targeted stakeholder consultation on the amendments to Commission Implementing Regulation (EU) 520/2012 on pharmacovigilance activities - European Commission (europa.eu) from 31 August to 15 October 2021

- EMA's Concept Paper for the EC on Safety and Pharmacovigilance 24 Feb 2022

- Pilot on signal detection by marketing authorisation holder (MAH) in Eudravigilance: 22 February 2018 – end 2024 + transitional arrangements

Signal management | European Medicines Agency (europa.eu)

Main identified issues + possible solutions

The overall experience with the IR is good, but the need for some targeted amendments

SUBCONTRACTING MAH-THIRD PARTIES => *content of subcontracts should include provisions on compliance controls of third parties (subcontractors); third parties should be obliged to submit themselves to audits and inspections;*
Now: no provisions
Purpose: strengthening the MAH's oversight regarding compliance controls of third parties; enabling audits and inspections

EUDRAVIGILANCE MONITORING =>*MAH should use the Eudravigilance as an additional source of information (no continuous monitoring and related obligations). Only EMA and the national authorities should have the obligation of continuous monitoring Eudravigilance*
Now: MAH obligations: continuous monitoring of Eudravigilance, signal validation and information to the Agency and the national competent authorities BUT transitional arrangements (Pilot) in place until end 2024 – continuous monitoring only for certain substances and not applicable to simplified reporting and management of individual case safety reports
Purpose: clarifying tasks; taking into account the experience from the Pilot

Main identified issues + possible solutions

TERMINOLOGY/STANDARDS => *updating*

TRANSMISSION OF SUSPECTED ADVERSE REACTIONS => *minimum requirements for all individual safety reports*
Now: minimum requirements only for expedited reporting: a reporter, patient, suspected adverse reaction and medicinal product concerned
Purpose: quality of information
=> *Digital Object Identifier (DOI)*
Purpose: to improve literature referencing

POST-AUTHORISATION SAFETY STUDIES => *obligation to register post-authorisation safety studies in the electronic register maintained by the Agency*
Now: EU PAS Register maintained by EMA (voluntary)
Purpose: transparency

Timeline

Inter-service consultations

Feedback mechanism – publication of the draft for comments – Have your say website – 4 weeks
Have your say - Public Consultations and Feedback (europa.eu)

Examination procedure – vote in the Committee by a qualified majority

We aim for adoption at the end of **Q2/2024**

Thank you