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CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

A - PHARMACOVIGILANCE SYSTEM MASTER FILE

<u>Consultation n°1</u>:

No additional process or pharmacovigilance tasks should be covered in this document. Only the main processes should be described (management of ICSRs, PSURs, monitoring of product benefit risk profile, risk management activities, communication). The other processes will be documented in the procedures appended to the master file.

Comments:

Regarding point (3), contact person for pharmacovigilance where nomination at national level has been made, including contact details and a description of responsibilities.

Details on back up arrangement to apply in the absence of this person should also be included.

<u>Consultation n°2:</u>

A dedicated procedure could be implemented for the management of the master file. In this procedure, could be described process of changes to the content of the master file (when, how (version, copy, archiving).

In any case, the master file should be a versioned document, dated, and any variation of the document could be signed by the EUQPPV and the person responsible for AQ

<u>Consultation n°3:</u>

Normally, safety agreements will be sufficiently clear and precise to have all information regarding delegated activities (including for the co marketing of products).

Comments:

Regarding third parties, contact details and back up arrangement should be described.

<u>Consultation n° 4</u>

The audit report should be archived in the QA department. Nevertheless, the CAPA should be appended in the master file. As this document is available in the company, the CAPA will be more informative than the audit report. The aim of the master file is a concise and clear document which presents company's PV system. Therefore, it's more informative for the company but for the regulators to have findings and corrective actions.

<u>Consultation n°5</u>

I do agree with the requirements as regards the content and maintenance of the pharmacovigilance system.

Nevertheless,

- **a *<u>template</u>* of this document could be proposed by the Commission/regulators**
- **a *<u>list of required documents which should be appended to the master file</u>*.**

A template will allow avoiding national disparities during inspection/audit.

B – QUALITY SYSTEMS FOR THE PERFORMANCE OF PHARMACOVIGILANCE ACTIVITIES – COMMON OBLIGATIONS

C – QUALITY SYSTEMS FOR THE PERFORMANCE OF PHARMACOVIGILANCE ACTIVITIES BY MAH

Question regarding point 13 Resource Management

….”If the qualified person is not medically qualified, access to a medically qualified person should be available.”

In the guideline ICH E2D, medically qualified person could be a pharmacist, nurse, dentist, coroner or as otherwise specified by local regulations.

When the qualified person is a pharmacist, the backup can be a pharmacist? Medically qualified should be more precise due to different interpretations done by the regulators.

Consultation n° 6: No comment

Consultation n° 7: No comment

D - QUALITY SYSTEMS FOR THE PERFORMANCE OF PHARMACOVIGILANCE ACTIVITIES BY NATIONAL COMPETENT AUTHORITIES AND EMA.

Consultation n° 8: No comment

E – SIGNAL DETECTION AND RISK IDENTIFICATION

Consultation n° 9:

Work sharing process with a lead Member State is an excellent idea for the monitoring of medicinal products or active substances contained in several medicinal product.

Consultation n° 10: No comment

F – USE OF TERMINOLOGY

Consultation n° 11: No comment

Consultation n° 12: No comment

G – TRANSMISSIONS AND SUBMISSIONS REQUIREMENTS

Consultation n° 13: No comment

<u>Consultation n° 14:</u> No comment

<u>Consultation n° 15:</u> No comment

<u>Consultation n° 16:</u>

This new format contains numerous information regarding clinical trials and benefit evaluation. How the MAH will proceed with DSUR on the same periodicity and the PSUR? (cross reference?)

The template and/or the guideline ICHE2C R2 should be precise and clear on the pertinent findings on clinical trials which should include in the PSUR and the benefit evaluation

<u>Consultation n° 17:</u> No comment