Farmakovigilanční systém a jeho řízení

MUDr. Jana Hyánková
Head of QPPV Office, PV Quality & Compliance, EU/UK QPPV
iVigee

Agenda

Farmakovigilanční systém a jeho řízení (PV System & Quality Management)

- Udržování systému dle požadavků legislativy (Implementing Regulation 520/2012, nyní novela 2025/1466)
- Existence QPPV (Qualified Person Responsible for Pharmacovigilance)
- Vedení PSMF – Pharmacovigilance System Master File dle novely č. 2025/1466
- Reálný příklad SOP dokumentu

Udržování systému dle požadavků legislativy

Farmakovigilanční systém

MAH has to operate a **Pharmacovigilance (PV) System** for the fulfillment of his PV tasks.

(Directive 2001/83 EC as amended, Article 104 (1))

As part of the PV System, the MAH shall maintain and make available on request a pharmacovigilance system master file (PSMF) *(Directive 2001/83 EC as amended, Article 104 (3)(b))*

Základní dokument farmakovigilančního systému (PSMF)

PSMF - podrobný popis farmakovigilančního systému používaného držitelem rozhodnutí o registraci pro jeden nebo více registrovaných léčivých přípravků (PHV-6 verze 3)

Farmakovigilanční systém

MAH has to operate a **PV System** for the fulfillment of his PV tasks.
(Directive 2001/83 EC as amended, Article 104 (1))

As part of the PV System, the MAH shall:

- maintain and make available on request a pharmacovigilance system master file (PSMF) *(Directive 2001/83 EC as amended, Article 104 (3)(b))*
- PSMF is needed by all **MAHs and applicants** for MAs in the EU
- PSMF must be available during the authorisation process for new applications

Sídlo PSMF

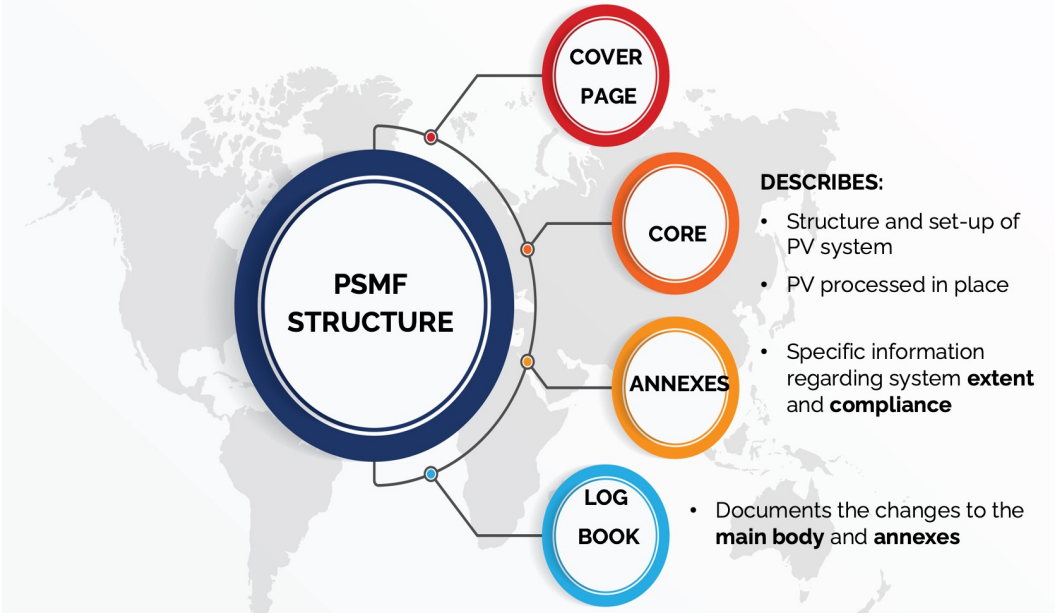
Location (within the EU + Norway, Iceland or Liechtenstein) where

- the EU QPPV resides and works
  OR
- main PV activities are conducted

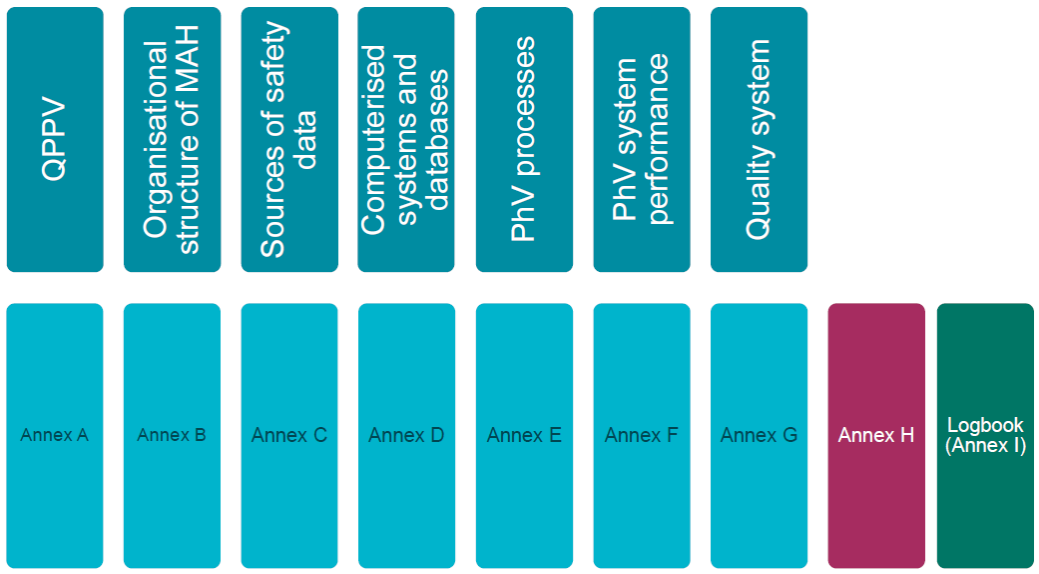
PSMF should be constantly updated → **living document**

Presentation to the CAs → within **7 days upon request** (immediate access can be required)

Struktura PSMF



Struktura PSMF – Core vs Annexes



Existence QPPV

Zodpovědnosti držitele rozhodnutí o registraci (MAH)

- Shall operate a **PV system**
- Shall establish and use a **quality system** that is adequate and effective for performing its PV activities (structures and processes are in place)
- Shall have appropriate instructions on the processes to be used **in case of urgency**, including business continuity
- Shall have sufficient number of competent and appropriately **qualified and trained personnel**
- Shall have permanently and continuously at its disposal an appropriately **qualified person responsible for pharmacovigilance in the EU (EU QPPV)** including back-up person

MAH musí poskytnout EU QPPV následující:

- Infrastructure
- Access to data, particularly about:
  - New safety concerns
  - Ongoing and completed clinical trials
  - Contractual arrangements and data from partners
  - Procedures relevant to PV, used across the organization
  - PV databases
- Information about regular checks, audits, and Corrective and Preventive Actions
- Information about compliance

Kvalifikovaná osoba odpovědná za farmakovigilanci (QPPV)

QPPV - osoba jmenovaná držitelem rozhodnutí o registraci, je **zodpovědná za vytvoření a správu farmakovigilančního systému** držitele rozhodnutí o registraci

QPPV musí mít **bydliště** a **plnit své úkoly** v oblasti farmakovigilance **na území EU, Norska, Islandu nebo Lichtenštejnska**.

GVP Module I Pharmacovigilance systems and their quality systems, definuje požadavky, které má splňovat QPPV, aby mohla vykonávat svou činnost, tedy musí mít

- teoretické i praktické znalosti potřebné k výkonu farmakovigilančních činností,
- odborné znalosti a přístup k odborným znalostem v oblastech medicíny, farmacie, epidemiologie a biostatistiky,
- pokud QPPV nemá lékařské vzdělání, musí mít zajištěn přístup k medicínsky vzdělané osobě, toto musí být řádně zdokumentováno.

Zodpovědnosti EU QPPV (1)

- Is a natural person
- Shall be at MAH´s disposal permanently and continuously
- Assures back-up procedures in case of EU QPPV absence
- Shall be responsible for the establishment and maintenance of the MAH's PV system (PSMF)
- Shall have sufficient authority to influence the performance of the quality system and PV activities and to promote, maintain and improve compliance with legal requirements
- Having an overview of medicinal product safety profiles and any emerging safety concerns

Zodpovědnosti EU QPPV (2)

- Awareness of any conditions or obligations of MAH relating to safety or the safe use of the products
- Awareness of risk minimisation measures, having sufficient authority over the content of risk management plans
- Involved in the review and sign-off of protocols of Post-Authorisation Safety Studies, EU Risk Management Plan, Periodic Safety Update Report
- 24/7 contact point for the Competent Authorities and PV inspections
- Involved in the assessment of all safety concerns regarding medicinal products in the portfolio, incl. subsequent risk management
- Ensures the quality of all PV data posted to Competent Authorities, and responds their queries
- Participates on any other regulatory activities relevant to the risk-benefit evaluation

Vedení PSMF

Proces popsaný v proceduře

- Kdo – co – kdy – jak

- Časový rámec
  - Aktualizace – jak často
  - Jednotlivé kroky
  - Ad hoc aktualizace

Kick-off meeting – Vyžádání informací – Kompilace dokumentu – Kontrola kvality – Zapracování – Kontrola MAH a EU QPPV – Zapracování komentářů – Finalizace – Podpisy – Archivace (přístupová práva)

Změny dle novely č. 2025/1466

Dopad na následující procesy:

- Signal management process
- Subcontracted PV activities
- Audit Strategy
- Any **major or critical deviations** from the PV procedures, impact and management - documented in the PSMF

Reálný příklad SOP dokumentu

Struktura procedury (příklad)

- Cover page (approval)
- Purpose
- Scope
- General principles
- Procedure steps
- RACI
- Flowchart
- References
- Revision history
- Table of content
- Abbreviations and definitions


ivigee
Děkuji za pozornost.
Otázky?