An Introduction to the Pharmacovigilance System Master File

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TransPerfect – Life Sciences
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Pharmacovigilance exists to ensure the safety of development for medicinal products.

AGENDA

- Overview - Guidelines on Good Pharmacovigilance Practices (GVP)
- Overview - Module II - Pharmacovigilance System Master File (PSMF)
- Moving Forward

GUIDELINES ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)

Regulation 1235/2013 Directive 2010/84EC	• Published December 2010 • **Implantation July 2012** • Legally enforceable legislation
Implementing Regulation 520/2012	• Published June 2012 • Legally enforceable legislation
Good Pharmacovigilance Practices (GVP)	• Consultation & Publication 2012 & 2013 • Detailed operation guidance (day to day) • Not legally enforceable

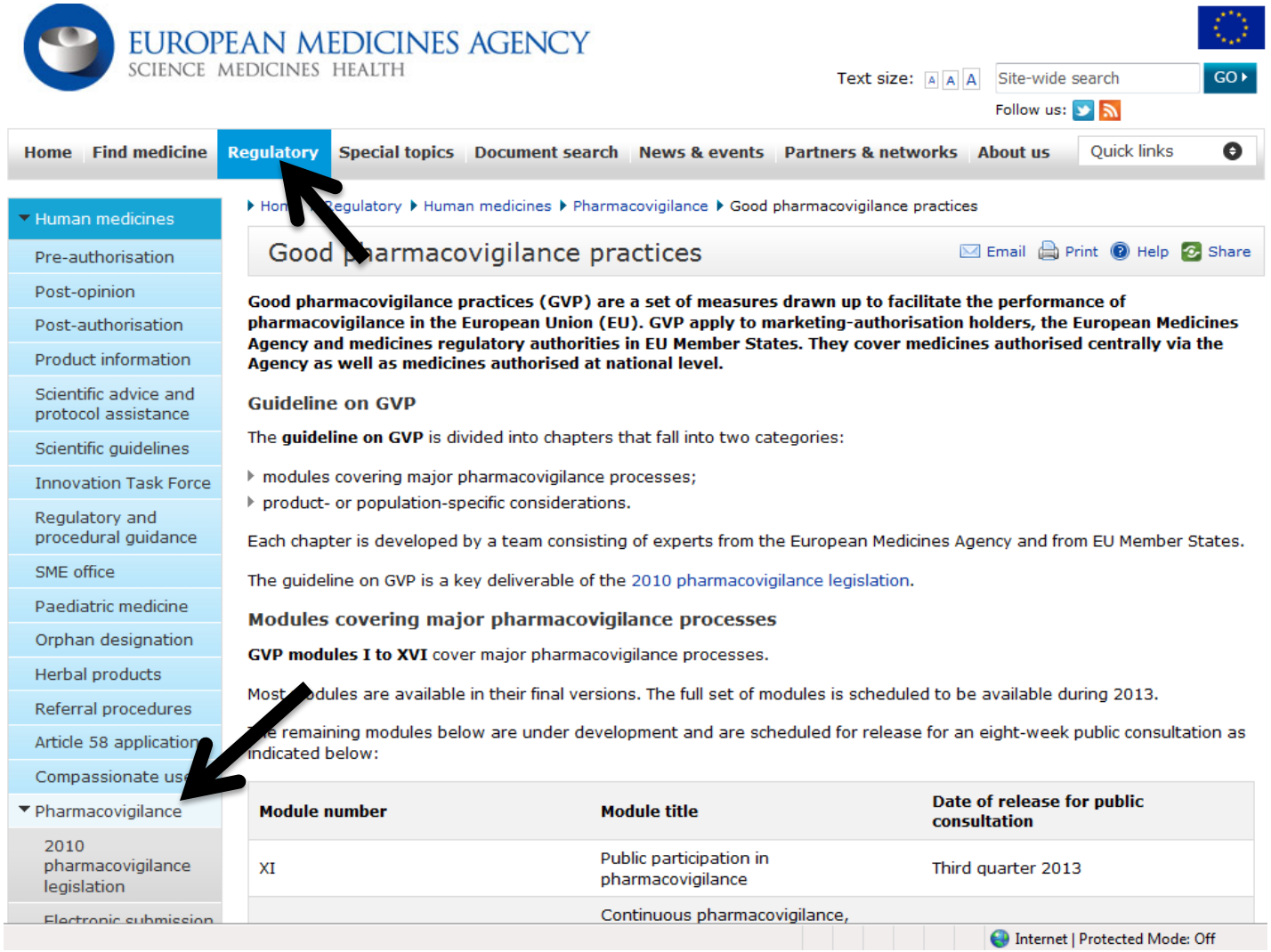
Transitional Provisions: Implementation 2012 - 2016

IMPACT

European Economic Area (EEA)

- European Union (28 Countries)
- European Free Trade Association (3 Countries)

GUIDELINES ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)



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GUIDELINES ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)

EEA GVP Modules

I Pharmacovigilance Systems and their Quality Systems Published 22-Jun-2012

II Pharmacovigilance System Master File Published 22-Jun-2012 **Update** 09-Apr-2013

III Pharmacovigilance Inspections Published 12-Dec-2012

IV Pharmacovigilance Audits Published 12-Dec-2012

V Risk Managements Systems Published 22-Jun-2012

VI Management & Reporting of Adverse Reactions to Medicinal Products Published 22-Jun-2012

VII Periodic Safety Update Report Published 22-Jun-2013 Consultation Rev 1 19-Apr-2013

VIII Post-Authorisation Safety Studies Published 22-Jun-2013 Update 19-Apr-2013

IX Signal Management Published 22-Jun-2013

X Additional Monitoring Published 19-Apr-2013

XI Public Participation in Pharmacovigilance Consultation Q3 2013

XII Continuous Pharmacovigilance, Ongoing Benefit-Risk Evaluation, Regulatory Action and Planning of Public Communication Consultation Q3 2013

XIII Void

XIV International Coorperation Consultation Q3 2013

XV Safety Communication Published 22-Jan-2013

XVI Risk-Minimisation Measures: Selection of Tools & Effectiveness Indicators Consultation Q2 2013

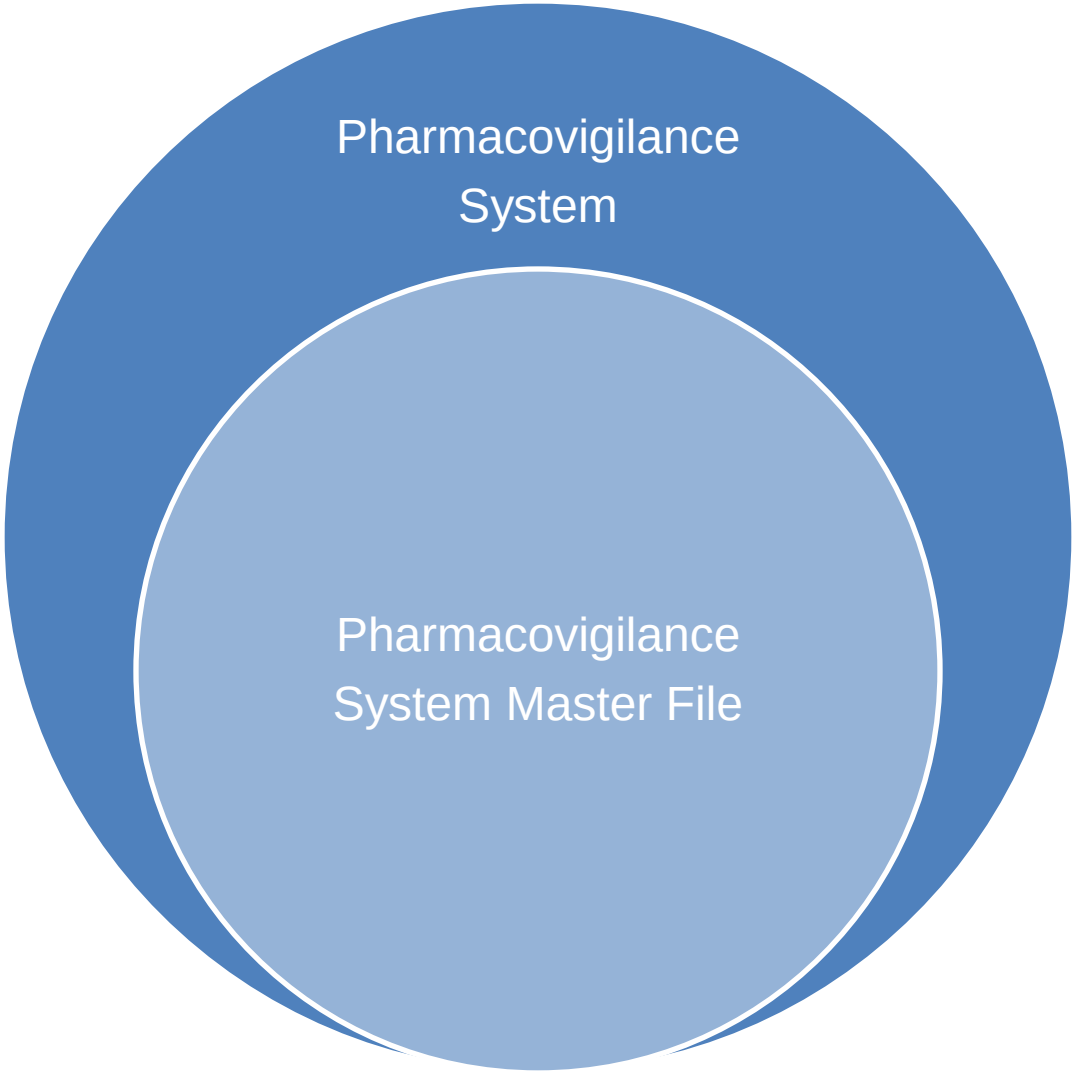
PHARMACOVIGILANCE SYSTEM MASTER FILE

PHARMACOVIGILANCE SYSTEM MASTER FILE

Describe the Pharmacovigilance System

Support/Document Compliance

PHARMACOVIGILANCE SYSTEM MASTER FILE



PHARMACOVIGILANCE SYSTEM MASTER FILE

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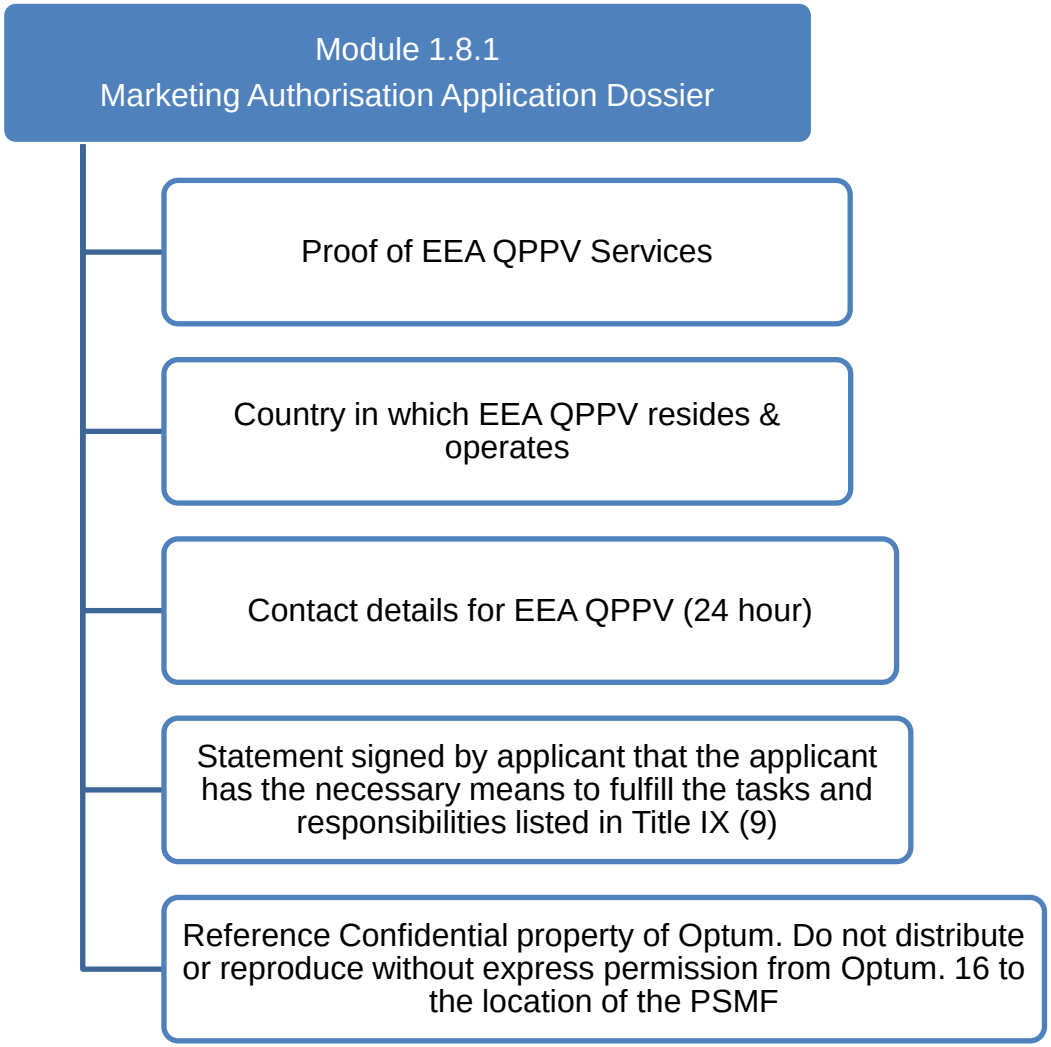
PHARMACOVIGILANCE SYSTEM OVERVIEW



PSMF LOCATION

Within the EEA

– Site where main Pharmacovigilance activities are performed
OR

– Where the EEA QPPV operates

- Physical office address where the data can be directly accessed
- Location must be entered into the eXtended EudraVigilance Medicinal
- Product Dictionary (xEVMPD)
- Change in location must be immediately notified to EMA
- Location will indicate supervisory agency (centrally authorised products only)

PSMF STRUCTURE

EEA QUALIFIED PERSON FOR PV SECTION

- Description of responsibilities guaranteeing
- EEA QPPV has sufficient authority
- Summary CV
- Contact Details
- Details of Back-Up Arrangements
- National QPPV information

PSMF – ORGANISATIONAL STRUCTURE SECTION

Organisational structure of MAH

Sites where Pharmacovigilance activities take place

Description of delegated Pharmacovigilance activities

PSMF – SOURCES OF SAFETY DATA

- Who, What, How & When
- Spontaneous
- List of solicited programmes
- Patient Support Programmes, Reimbursement Programmes, Marketing Surveys, etc.
- Studies
- Literature
- Agencies
- Contract Partners

Flow Diagram / Description of Process

PSMF – DATABASES

- Location, functionality, operational responsibility for computerized systems and databases used to receive, collate, record and report safety information
- Assessment of their fitness for purpose
- Validation status
- Change control, nature of testing, back-up procedures, and electronic data repositories, nature of documentation available

PSMF – PHARMACOVIGILANCE PROCESSES SECTION

Description of Procedural Documentation

- SOPs/Manuals, etc
- Nature of data held
- Indication of how records held

Description of Process, Data Handling and Records

- Continuous monitoring of risk-benefit profile
- Risk management systems, including effectiveness of risk minimisation
- Safety data processing
- PSUR scheduling, production & submission
- Communication of safety concerns to agencies, healthcare professionals and patients
- Implementation of safety variations to product information

PSMF – PHARMACOVIGILANCE SYSTEM PERFORMANCE

- How timeliness of expedited submissions is monitored
- Description of metrics for monitoring quality of submissions, including information provided by agencies
- How timeliness of periodic submissions is monitored
- How timeliness of safety variation submissions is monitored
- How adherence to agency commitments is monitored

PSMF – QUALITY SYSTEM

- Document & record control / Archiving
- Management of procedural documents

  - Note of open SOP deviations
- Training procedures
- Auditing

  - Note of open CAPA for critical & major audit findings

PSMF – ANNEXES

- List of medicines products, authorisation & marketing status, safety monitoring requirements
- List of Ongoing Studies
- List of written policies & procedures
- List of contractual agreements
- List of tasks delegated by EEA QPPV
- List of all audits completed in last 5 years
- Audit schedule
- List of performance indicators

CHANGE CONTROL

- Main PSMF Sections
  – Formal change control process & version control
- PSMF Annexes
  – History of changes
  – Maintain inside or outside of PSMF structure
  – If maintained outside of PSMF, keep history of when generated for PSMF purposes

THE SECRETS TO SUCCESS

- Planning, planning, planning
- Identification of resources
  - People
    - Cross-functional expertise
- Technology
  - Network folder?
  - SharePoint?
  - In-house Documentation Management System?
  - Off-the-shelf IT solution?
  - Custom-built solution?
- Implementation Project Management
- Access rights
  - Who?
  - Prevention of inappropriate distribution
- Maintenance
  - Who? PSMF Administrator?
  - How frequently? Main Documents Versus Annexes?

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THANK YOU!