Safeguarding public health

Third Stakeholders forum on the implementation of the new Pharmacovigilance legislation

Pharmacovigilance system master file – an approach towards system simplification

Joanna Harper
Inspections, Enforcement & Standards Division (MHRA)

New legislation – provisions for PSMF

Amendment of Article 1 – insertion of definitions

'Pharmacovigilance system: a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance'

'Pharmacovigilance system master file: A detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products'

Current status

The new Directive and Regulation do not contain details on the content and maintenance of the PSMF. Elements of its content and maintenance will be required by implementing measures under consultation and the Good Vigilance Practices guidance under development.

Current Status

Feedback requested / consultation covers:

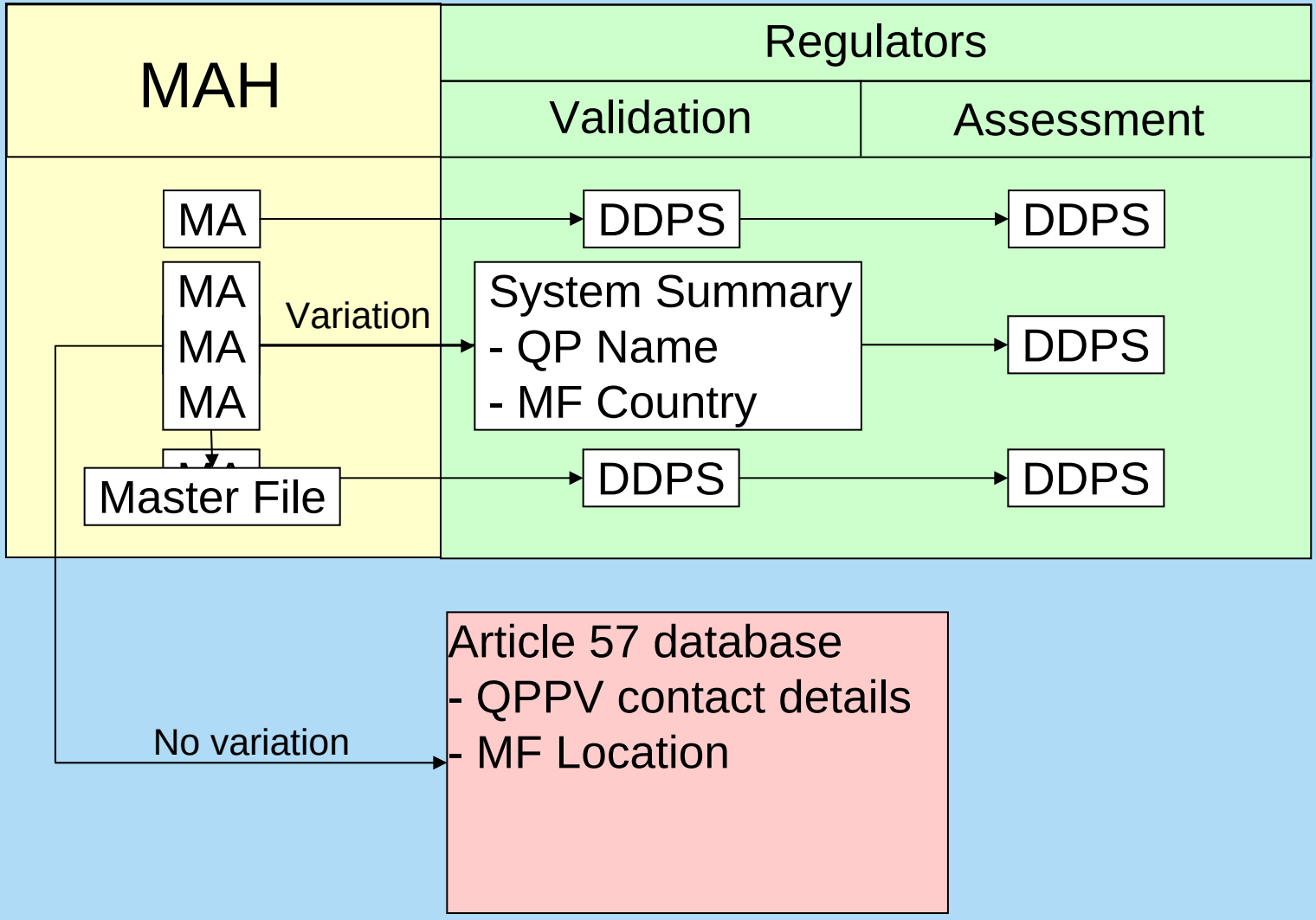
- Which pharmacovigilance tasks and processes to be covered by IMs (as opposed to in GVP) ?
- Notifications of changes to the pharmacovigilance system and how should this be achieved?
- Change control
- Delegated activity
- Audit documentation

Areas to be further clarified:

- Optimising the use of the article 57 database
- Legal considerations for variations to MA for Article 8
- Transition (transfer from DDPS in absence of renewal)
- Changes to the classification guideline

GVP is drafted and on track for public consultation in early 2012

Simplification – the proposed concept



Simplification – submissions

The MAA no longer contains the detailed description of the PV system (DDPS), referring to its location only (article 8)

A summary of the applicant's pharmacovigilance system which shall include the following elements:

- proof that the applicant has at his disposal a qualified person responsible for pharmacovigilance,

- the Member States in which the qualified person resides and carries out is/her tasks,

- the contact details of the qualified person,

- a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Title IX,

- a reference to the location where the pharmacovigilance system master file for the medicinal product is kept'

No content of the PSMF is submitted as part of the MAA: review of the PSMF is on request (at MS discretion)

Simplification – variations

- Currently DDPS Variations are according to the current classification guideline, type I or II

Changes to PSMF content will not require variations as it is not part of MA dossier:

Variations are only required to change the items in article 8 (QPPV and PSMF location)

The current proposal for the implementing measures is to specify that changes to the PSMF location will be notified via the product list described in Article 57 of the Regulation (therefore a single repository), and that this address is the same as that of the QPPV.

Since MAHs will simply be notifying NCAs/ EMA of an administrative change, only type IA IN variations are currently proposed.

Replacement of the DDPS

- MAHs should be able to fully adopt Master File at the earliest opportunity:
  - To cover all products for which the system is used (i.e. removal of requirement to maintain a DDPS).
  - To allow submission of PhV system summary details at times other than renewal or application for new MA.
- Legal and practical proposals are being addressed:
  - To enable changes to an existing PhV system summary
  - To facilitate early transition and realise the efficiencies of not maintaining two systems.

Simplification – operational

•A uniform information set describing the pharmacovigilance system is available to the QPPV and for the purposes of audit. Tool for QPPV to oversee and manage system.

• There is a reduced burden in terms of documentation submitted as part of the MAA, for MAHs and NCAs: version control, storage.

•Less routine assessment of the system description: more oversight by QPPV, by audit and inspection and practical reference for inspection and audit

•There will be a harmonised and consistent PSMF for NCAs to use to plan inspections, MAHs will not necessarily need to manage ad hoc versions of pre-inspection documentation.

• NCAs do not have to assess and file multiple DDPSs ,per MA, and can choose which PSMFs to request (according to risk and supervisory duties)

•Opportunity to use existing systems to maintain oversight and to generate content for submission when requested

Benefits / Objectives of the PSMF

Pharmacovigilance oversight should be strengthened since reviewers of the PSMF (NCA or MAH/QPPV) should be able to:

- gain assurance that a PV system has been implemented in accordance with the requirements

- confirm aspects of compliance in relation to the system

- obtain information about deficiencies in the system

- obtain information about risks or actual failure in the conduct of specific aspects of PV

Thank you for your attention

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