CMDh

Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

CMDh feedback on

- Informal WS procedure for follow up requests after a PSUSA for NAPs (PSUFU)
- CMDh project on ideas for WS of assessment of RMPs

12th industry stakeholder platform - operation of EU pharmaocvigilance - 24 November 2017

Kora Doorduyn-van der Stoep (NL-CMDh member)

PSUFU

CMDh created a new informal WS procedure for the submission and assessment of follow-up after a PSUSA for NAPs

PSUSA Follow-Up

(PSUFU)

PSUFU

Rationale

- No official EU procedure exists for NAPs (equivalent to LEG-CAPs)
- Analysis of existing regulatory tools to handle the follow-up requests not always possible (have limitations)/may not be proportionate
  - Official worksharing variation
  - signal procedure at PRAC level (*only if a new potentially causal association or a new aspect of a known association but not a safety issue that has been (partly) assessed in a PSUSA*)
  - bringing the next PSUR submission forward
  - initiating an appropriate referral procedure

PSUFU

PSUFU – why/when

- To avoid parallel national assessments & duplication of work
- Enhance the consistency of the assessment
- Exceptional Use: will not be used for issues that could/should have been dealt with and resolved within the PSUSA procedure

PSUFU

Key elements defined for operational success

- Appointment of a Lead MS
- Assignment of a specific procedure number (to be published by CMDh in press release)
- Submission route and requirements
- AR template
- Timetable
- Publication & implementation of the outcome

PSUFU

Outcome published

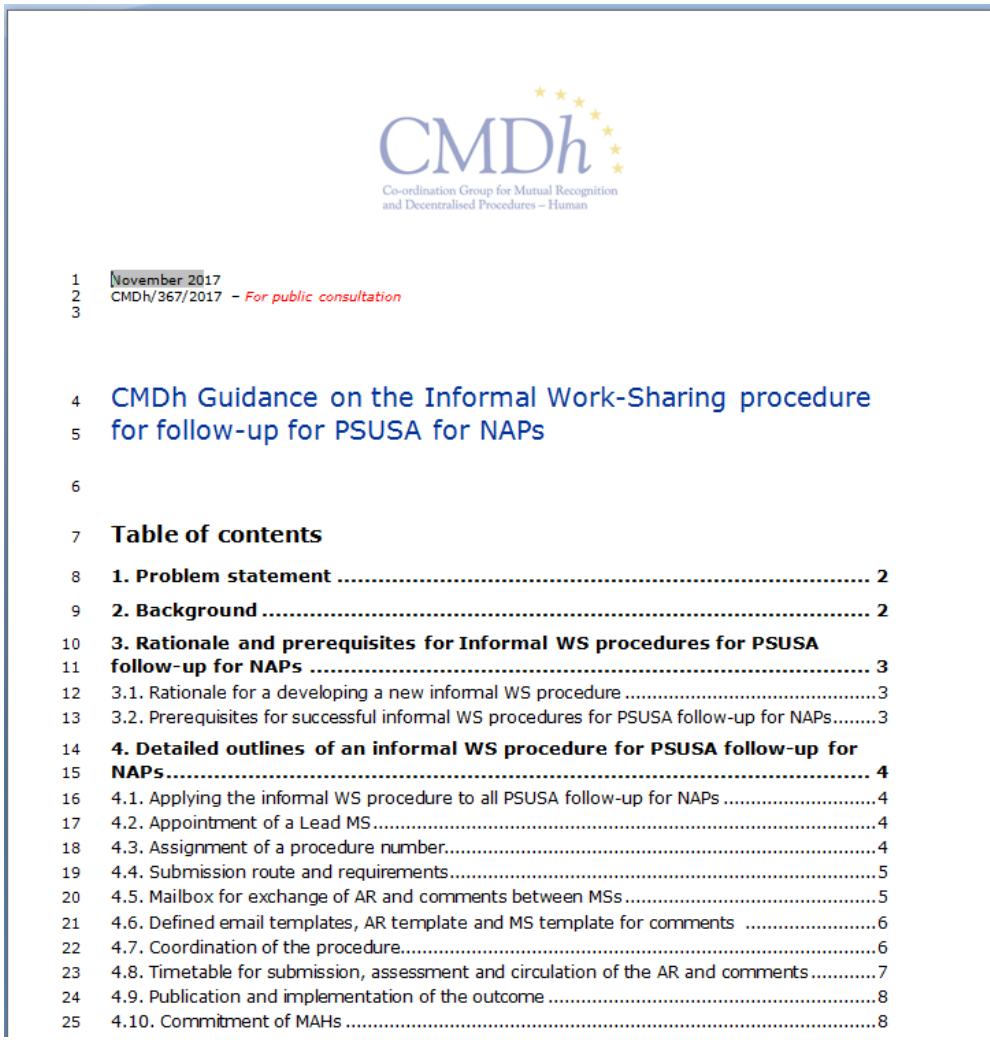
The outcome of the procedure will be published on the CMDh website (Summary, not full report)

- Changes to the RMP will be detailed (if app)
- Recommendation to update the product information, the SmPC wording and PL wording to be implemented will also be published, together with the timelines for implementations (Type IB var, C.I.3.z category) (if applicable)

PSUFU

Current Status

- Procedure guidance recently publicated on the CMDh website (CMDh/367/2017)
- 2 months of public consultation (Jan 19th, 2018)
- A pilot phase will run until sufficient experience is gained



November 2017
CMDh/367/2017 – *For public consultation*

CMDh Guidance on the Informal Work-Sharing procedure for follow-up for PSUSA for NAPs

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Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

CMDh "Generic" RMP project (temporary name of the project)

CMDh "Generic" RMP project

Problem statement

- Huge workload for the MSs to assess RMPs in similar generic applications
- Inconsistency in the List of Safety Concerns within generic products as well as with the reference product
- Incomplete overview in the Excel table published on the CMDh website

CMDh "Generic" RMP project

Project proposal

Two domains:

1. (*Prospective approach*) Developing up-to-date generic RMPs from the innovator document for active substances for which the data exclusivity of the reference product will expire soon

2. Clean-up of the current existing Excel list as published on the CMDh website

CMDh "Generic" RMP project

Summary - **Domain 1** - RMPs for which data exclusivity of reference product will expire

- Clean-up of reference product RMP *before* the first generic submission commences (up-to-date version)
  - Focus on the relevance of the safety concerns, studies and additional risk minimisation measures (GVP Module V Rev 2)
- Up-to-date version of RMP of reference product will serve as RMP to be used by other MAHs after expiration of data exclusivity

CMDh "Generic" RMP project

Summary - **Domain 2** - Clean-up of the current existing Excel list

- Active substance for which there is no innovator product or the innovator has no RMP
- The list as published by the CMDh will have to be reviewed and information captured there should be aligned (safety concerns, overview of studies [if applicable], and additional risk minimisation measures)
- This will subsequently be published on the website of the CMDh for the MAHs to use

CMDh "Generic" RMP project

Challenges

- It is important for this project to be a success that all the stakeholders commit to align new generic RMPs with the agreed upon and published RMPs
- EMA/PRAC needs to be involved

- Time-lines and procedures (including assessment/approval/adoption/implementation) need to be developed

- Who does what? Need for Lead NCA and Lead MAH

CMDh "Generic" RMP project

Brainstorming meeting with ad hoc CMDh small WP and Industry on 9 November 2017

- Problem statement as expressed by Industry very similar to concerns presented by CMDh
- Industry's first preliminary feedback on CMDh proposal positive
- Industry will provide "candidates" for both domains

CMDh "Generic" RMP project

Next steps

- Comments received from members CMDh PhVig WSP WP will be included in draft proposal as prepared by NL
- New version/comments discussed by WP in December en presented in CMDh
- Further feedback from Industry based on new version document and parallel to pilot (see below)
- Proposal to start with an active substance with different lists of safety concerns in the published CMDh list: NL prepared to take on first procedure/substance
- Start with pilot for Domain 2 in Q1 2018?

CMDh

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THANK YOU

ANY QUESTIONS?