EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Highlights from the EMA Pharmacovigilance Industry Platform meeting held on 12 January 2015 on the Operation of EU pharmcovigilance legislation

The following records announcements and action points from the 2nd Pharmacovigilance Industry Platform meeting held on 12 January 2015 on topics presented/discussed, namely Risk Management Plans (RMP), Post-Authorisation Safety Studies (PASS), Post-authorisation Efficacy Studies (PAES) Periodic Safety Update Reports (PSURs) and potential new topics to be considered for future platform meetings.

Risk Management Planning (RMP)

- **Action**: EMA will liaise with the industry associations to pilot use of the simplified template in Q1 2015 prior to formal consultation.
- **Action**: Consultation on a revision of the RMP GVP module (GVPV) is foreseen for Q2 2015.
- **Action**: EMA to consider a procedural Q&A to give greater procedural clarity on RMPs (this may be combined with procedural Q&As on PASS – see below).
- **Action**: Training targeting the industry will be delivered Q2 2015 through an InfoDay.
- ***Note***: Under the auspices of the CMDh, the PSUR work-sharing group mandate is being reviewed with a view to develop and maintain a list of RMPs with links to summary information that can be used as a resource for MA applications.
- **Action**: CMDh RMP group to set up a forum with industry association representatives to look at possible practical solutions to having common RMPs for the same substance (where appropriate), and to efficiency gains and risk proportionality.
- **Action**: EMA to consider, in the context of the GVP update, the various industry proposals including: that sections I to V of the RMP could be common / cumulative, and section VI could be procedure specific; a revised approach to consideration of important risks, as well as missing information; a revised operational definition of risk focussed on outcome rather than occurrence.

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Post-authorisation safety studies (PASS)

- ***Note***: the GVP guidance on PASS is being updated – this includes considerations stemming from the new clinical trial regulation. Public consultation currently targeted for Q2 2015.
- ***Note***: Joint studies - in addition to the existing guidance in PASS GVP, EMA will start to systematically write to companies impacted by the need for a joint study and in exceptional cases a joint company meeting may be organised. Industry supported the initiative and called for deadlines for submission of draft protocols to reflect the complexities of establishing consortia. It was noted that CMDh is open to receive justified requests regarding deadlines, in such circumstances.
- ***Note***: ENCePP provides expertise and capacity for PASS and may be particularly useful for joint studies and for smaller companies – companies can post requests to the network, via the secretariat which is managed by EMA (ENCePP_Secretariat@ema.europa.eu).
- **Action**: ENCePP – industry indicated it would welcome more information and knowledge on how to leverage ENCePP and the capacity of ENCePP beyond drug safety, to other needs of observational research (supporting the product lifecycle development). EMA to consider how to provide enhanced information to industry on ENCePP.
- ***Note***: Industry was reminded of the need to register PAS (Post Authorisation Studies) in the EU PAS register to fulfil EU requirements to post PASS protocols and results (http://www.encepp.eu/encepp/studiesDatabase.jsp).
- **Action**: EMA is exploring how to enhance scientific advice on PASS. This will likely include enrichment of SAWP with PRAC experts and industry being welcomed to submit PASS protocol questions for scientific advice – an enhanced service to industry with enhanced opportunity for face to face dialogue. EMA to make public reference information to support the trade associations to disseminate information on scientific advice for PASS.
- **Action**: EMA is looking to improve data collection using registries through a cross-committee initiative on patient registries. This will likely deliver core data elements, core protocols and governance models to support a pilot of registries to support product development – delivery through scientific advice will act as service to industry. Industry supported holding a dedicated meeting on registries and asked for a public reference document on the initiative to be developed.
- **Action**: EMA to consider in the drafting of GVP V and possibly in a procedural Q&A, the industry suggestions regarding non-EU safety studies, the definition of safety studies (focus on “safety hazard”), and the procedures to update Mas and RMPs when studies change.

Post-authorisation efficacy studies (PAES)

- ***Note***: There has been good progress in developing the scientific guidance on PAES, which will remain a relatively high level document. Public consultation is foreseen for Q3 2015.

Periodic Safety Update Reports (PSURs)

- ***Note***: 2015 will see a big increase in the number of single assessments including signal assessment procedures only involving NAPs.
- **Action**: the PSUR repository will be released end of January 2015 and companies submitting PSURs in February 2015 will be asked to pilot use of the repository.
- **Action**: Industry to register for training webinars on use of the repository.

Other issues

- ***Note***: Translations into all EU official languages of wording for product information based on the assessment of safety signals to start in months ahead as a service to industry (simplification).
- ***Note***: There has been good progress in developing a Q&A to respond to questions from the industry on collecting and reporting information on off-label use of medicines – currently planned for publication by end of Q2 2015.
- ***Note***: IT systems development – recent progress includes: extension of web data on suspected ADRs to cover substances in NAP; publication of the ICSR implementation guide - implementation support for industry. Further details are available in the Update document at: http://www.ema.europa.eu/docs/en_GB/document_library/Newsletter/2014/12/WC500178901.pdf
- ***Note***: EMA is issuing the QPPV emails for queries on pharmacovigilance fees and article 57. As EMA has no alternative contacts for all MAHs, industry is asked to accommodate requests through this channel.

Future meetings

EMA – Industry Stakeholders Pharmacovigilance platform meetings will initially be held every three months, with the next meeting held on 13 March 2015.

Based on industry and regulator suggestions, subsequent meetings may include:

- Referrals and their implementation;
- Coordination of the EU Pharmacovigilance system (simplification of regulatory steps);
- Implementation following signal evaluation at PRAC;
- Impact of pharmacovigilance and collaboration on its measurement;
- Joint PASS;
- Registries;
- GVP on biologicals;
- PSUR single assessment.