17 November 2021
EMA/582239/2021 Corr[1]
Human Division

Highlights from the 16th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 17 November 2021

The following records announcements and action points from the 16th Pharmacovigilance Industry Platform meeting.

Welcome and matters arising

- S. Straus and E. Korakianiti welcomed the participants to the 16th EMA Industry Platform, one year after the last meeting (30 October 2020)

Monitoring of COVID-19 products: toolkit

- The regulators provided an overview of all the EU network activities related to the monitoring of COVID-19 products, including the EudraVigilance reporting and outputs screening, observational studies performed or ongoing, procedures employed to deal with the large volume of data reported (i.e. signals, PSURs and the MSSRs used specifically for the pandemic situation), the measures implemented and additional assessments performed. Some workload challenges from industry related to pharmacovigilance procedures were noted, including MSSRs, EMA is in the process of updating the guidance.
- The excellent cooperation of all stakeholders was highlighted as key to success to the early availability of vaccines on the market and to protect public health.

  https://www.ema.europa.eu/documents/presentation/presentation-monitoring-covid-19-products-toolkit_en.pdf

Periodic safety update report (PSUR): Adherence to PRAC recommendations for national authorized products (NAPs)

- The regulators provided high-level objectives of a project intended to measure the implementation of the PRAC recommendations for of the PSUSA outcomes for NAPs. Specifically, the MAHs were invited to share their experience, including any possible obstacles to the timely implementation of

[1] A minor editorial amendment was implemented in the section : *Access of the off-patent sector to aRMMs/follow up questionnaires (FUQ) of the reference products* (page 3).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

PRAC PSUSAs recommendations for NAPs on the level of the MSs. Areas of improvements will be explored to ensure timely delivery of updated product information to patients across the EEA/EU.

https://www.ema.europa.eu/documents/presentation/presentation-periodic-safety-update-report-psur-adherence-prac-recommendations-national-authorized_en.pdf

- The industry welcomed the initiative and acknowledged that there could be challenges at the national level. From industry perspective, this concerned in particular "well-established use" medicinal products. The future update of GVP VII was highlighted as a potential vehicle to communicate any improvements needed.

  Action: Industry committed to work closely with the regulators to understand any possible obstacles to implementation of the PRAC outcomes and bring specific industry feedback/proposals at the next platform.

GVPs update

- Industry stakeholders represented by EFPIA and Medicines for Europe provided an overview of industry comments submitted during the public consultation on GVP M.XVI, specifically they discussed aRMM programmes (i.e. consistency across products, uniform logo), adaption to the local health culture with the NCAs as key players in the communication and further implementation, flexibility and avoiding burden due to aRMM and effectiveness evaluation by focussing on important risks. A request to provide more information on digital risk management in the context of reducing the use of paper-based and physical materials was made. The regulators highlighted that it might indeed be helpful to further explore the use of digital risk minimisation tools alongside the paper versions of these materials.
- In addition, the regulators updated the participants on the review status of comments received during the public consultation of the GVP XVI (revision 3); a vast majority of have been implemented. Expected publication in 2022. The regulators also provided follow up on GVP Module XVI Addendum III on pregnancy specific RMM. The public consultation planned for 8 or 10 weeks (at least until 28 February 2022) and the publication of the final addendum, depending on COVID-19 prioritised work, is planned for Q4 2022.

  https://www.ema.europa.eu/documents/presentation/presentation-good-pharmacovigilance-practices-eu-gvp_en.pdf

  Actions:

  1. A working group on digital solutions and approaches to delivering digital risk management, expertise in both pharmacovigilance and technology is expected to be set up by EMA. Industry stakeholders will be asked for nominations in due course.
  2. A new chapter of the GVP specific to the elderly is under consideration and industry proposals will be welcome.

Guideline on registry-based studies

- In view of the increasing use of registries in the frame of marketing authorisation applications (MAA) and post-approval commitments to monitor long term safety and effectiveness of medicinal products[1, 2], the regulators updated on the Patient Registry Initiative (link) created in 2015. To

promote the use of patients registries and streamline the quality of clinical trials or non-interventional studies using the infrastructure of (a) registry(ies), the EMA cross committee Task Force established by the initiative and the EU Regulatory Network developed a Guideline on registry-based studies.

EMA thanked industry stakeholders for their contribution during the public consultation of the guideline. A clear differentiation between registry-based studies and patient registries was made. Feasibility analysis recommended to marketing authorisation applicant/holders and to research organisations when setting up studies to assess the suitability of a particular registry to address the study objectives was highlighted.

https://www.ema.europa.eu/documents/presentation/presentation-guideline-registry-based-studies_en.pdf

Action: It is important for this guidance to be shared amongst Industry Stakeholders and use/implemented as appropriate.

[1] https://doi.org/10.1002/pds.4196
[2] https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2461?af=R

Industry perspective on PASS impact and Pharmacovigilance obligations

- The industry, on behalf of AESGP, Medicines for Europe and EFPIA, provided feedback on the maturity of the PASS protocol at submission, the feasibility of the studies, proposals to accelerate PASS studies start (e.g. delay due to multiple RSI in the PASS protocol), category 3 studies, PASSs in COVID19 and the PASS protocols with PRAC involvement including any areas for improvement. The proposal to differentiate feedback on PASS for which a PRAC agreed protocol is required (Cat 1-2) from Cat 3 PASSes (without this requirement) was highlighted. Additional suggestions included the differentiation between 'Joint' vs 'Non-joined' PASSes (Cat 1-3), data on duration of the studies, for Cat 1-3, (overall and main steps), active feedback on up to the last 3 (or 5) PASS initiated by any company (Cat 1-3).
- The regulators welcomed the feedback which will be considered in longer time frame (at least one year), they have noted the challenges in patients' involvement.

Action: Industry Stakeholders to coordinate detailed feedback on specific points for discussion at the next 2022 Pharmacovigilance platform meeting.

Access of the off-patent sector to aRMMs/follow up questionnaires (FUQ) of the reference products

- The industry, on behalf of off-patent product manufacturers, updated on the aRMMs and on the follow up questionnaires, highlighting the need for simplification of the documents with the reference products. Difficulties in obtaining the RMP content involving lengthy access to documents requests to relevant competent authorities were highlighted. Some interim solutions suggested, included an automated dissemination of the RMP via Art. 57 or creating a common repository.
- The industry presented their follow up questionnaires position paper (in line with GVP V). The topic poses some challengers to the generic medicines MAHs and the need for further harmonisation in the process has been suggested. Based on legislation, part of RMP, the VI summary should be

published, similarly, it has been suggested that FU questionnaires shall be accessible to off-patent MAHs and HCPs. In addition, well-defined structure of FUQ may facilitate higher response rates.

- The regulators welcomed those initiatives, concrete solutions to reduce complexity and an alignment of information flow are appreciated

EMA Medical Literature Monitoring (MLM) service update

- The regulators provided an update on the 6 years of the operation of the EMA MLM service with an overall high-quality service as documented in user acceptance surveys and the recent independent audit results. For the areas of improvement identified (e.g. most notably ICSR data quality), EMA is committed to work alongside all stakeholders to provide further enhancements.

  https://www.ema.europa.eu/documents/presentation/presentation-ema-medical-literature-monitoring-service-update_en.pdf

  Actions: Industry kindly asked to provide their input via the most recent survey by 30 November 2021.

- **Post-meeting note:** The deadline to respond has been extended by a few days.

Conclusions and next steps

E. Korakianiti concluded that notwithstanding the immense work in the area of COVID-19, progress in other pharmacovigilance activities has been achieved, e.g. work related to MSSRs guidance, the initiative to measure the adherence to PRAC recommendation for NAPs, the reflection on the PASSEs conduct, enhancement of the EMA MLM service, or the digital technology advancement in GVPs drafting. In addition, the commitment of all stakeholder to work on new GVPs chapters (e.g. for the elderly) has been noted.

Regulators and industry recognised the benefit of the continuation of these platform meetings to foster dialogue and discussions on issues related to pharmacovigilance. The commitment to continue those in 2022 was confirmed, and the need to reinstate the frequency of two meetings annually will be explored and communicated depending on the evolution of COVID-19 pandemic and resources capacity.

Future topics as proposed by industry associations:

- Periodic safety update report (PSUR): Adherence to PRAC recommendations for national authorized products (NAPs) (beg. 2022)
- Industry perspective on PASS impact and Pharmacovigilance obligations (Q4 2022)
- Update on the pilot of MAH EudraVigilance Signal detection
- Risk Minimization Measures / additional Risk minimisation Measures e.g. DHPC, PPP