24 June 2020
EMA/313114/2020
Stakeholders and Communication Division

Meeting summary - PCWP/HCPWP joint meeting

24 June 2020, 14:00hrs to 17:30hrs – Virtual meeting

Co-Chairs: K. Immonen (PCWP), U. Jäger (HCPWP) via Adobe

Welcome and introduction

Melanie Carr (EMA) opened the meeting by conveying apologies on behalf of Juan Garcia Burgos (EMA PCWP and HCPWP co-chair) and introducing the agenda topics.

1. Risk minimisation measures

Ulrich Jaeger (HCPWP Co-Chair) introduced the topic remarking the importance of risk minimisation both for patients and healthcare professionals but also for regulators as this is a major area of regulatory activity and healthcare. Even though Good Pharmacovigilance Practices (GVP) are aimed at providing guidance to medicines developers and regulators, it is acknowledged that the specific areas of designing risk minimisation measures and implementing them in healthcare are very challenging. Therefore, an early engagement with patients and healthcare professionals will provide additional insight on the feasibility of what is being proposed as part of the revision of GVP module XVI on additional risk minimisation measures and ultimately support the development of a strengthened and improved guidance. This is in fact the first time such early engagement of patients and healthcare professionals has been foreseen as part of a GVP module revision. The open public consultation of GVP module XVI is planned to be launched at the end of the year or beginning of 2021.

Prior to the targeted discussion on specific questions, Priya Bahri (EMA) introduced the overall concept of GVP and the set of existing modules addressing different areas of pharmacovigilance and Nuria Semis (EMA) explained the purpose of the revision of GVP module XVI, which specifically covers additional risk minimisation measures (see presentation). In addition, perspectives from both patients and healthcare professionals were presented by François Houyez (PCWP) (see presentation) and Jan de Belie (HCPWP) (see presentation).

In addition to the input already collected in writing in advance of the meeting, further feedback was gathered on aspects related to use of printed materials, web-based and interactive tools, specific terminology, use of checklists and other forms, and the utility of patient diaries:

- Importance to consider a new reality where virtual consultations become more the norm than the exception and how risk minimisations measures need to be designed and implemented in such context (e.g. are there any potential issues if documents need signing and the consultation is held virtually)

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
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- Need to user-test risk minimisation measures such as pictograms to ensure they are properly understood, no one is confused by their meaning, and they are effective
- Importance of education during the entire specialist training and taking into account different levels of experience amongst healthcare professionals (i.e. some conditions are routinely treated by some and very seldom by others; how to ensure implementation of the same measure by different healthcare professionals)
- Continue to explore reporting systems where accumulated experience can support further learning and training; interactive adverse reactions reporting tools could help getting all the information needed in a report, as often important information is missing
- Interactive information and tools can be very helpful, though need to be easily available; too many different access points will be problematic; however not all patients can handle interactive information and printed information is still needed even though keeping it up to date is challenging
- The term "educational" as part of education materials is not considered paternalistic, as chronic patients know they need to learn about their disease/condition and treatments continuously, as part of their patient journey; furthermore, the term incorporates a notion of an active role from patients whereas 'information' can be received without involving reactions; healthcare professionals also do not consider the term to be paternalistic.
- The terms "risk minimisation materials" or "risk information materials" sound too technical and few patients will understand them as important and easy to read information
- Important to keep in mind the accurate translations of terms in all EU languages and terms such as "educational materials" should be used in the same way nationally to avoid confusion
- Do not underestimate the need to continue reviewing the package information leaflet as the first document patients will consult. Often these are not sufficiently clear leading to medication errors
- There is an overload of forms and there is a risk these are transformed into a 'tick box' exercise. It depends very largely on how the forms are implemented; need to think carefully when to use forms, the design and not see it as a waiver of responsibility or a red flag that might affect the adherence
- Some Member States adopted a new type of consultation, "Educational consultation", with no prescription, but time to exchange information on the treatment and the disease, where for example the patient can respond to quizzes to check he/she remembers key information. Or the consultation is prolonged with some time dedicated to education so that the healthcare professional is compensated for the time spent.
- There are different types of diaries depending on the condition or the treatment; if well completed is a vital source of information; need to also consider the use of electronic diaries with a function in the diary that could give feedback when there is a mistake.
- Patient cards continue to be seen as essential; consider the use of electronic patient cards that could be accessible on the patient's mobile phone.
- Healthcare professionals considered that it was useful to have a reminder about ongoing registries/studies in the educational materials (guides)
- A conservative approach should be taken when deciding to remove educational materials (e.g. once the measures have been established within clinical practice). Although the burden of information should be considered, it is better to be "safe than sorry".

Actions:

- Review comments received during the meeting and continue to progress and further develop the guidance.
- Send any additional comments to the draft guidance, both on the identified questions or the whole draft **by 9 July 2020**.
- Organise follow up meeting in 2021 once public consultation is closed to address more complex issues where divergent views emerged, and further debate is needed.

2. Registry-based studies

Xavier Kurz (EMA) gave a presentation on EMA's activities in relation to registries (see presentation). EMA launched its Patient Registry initiative back in September 2015 to promote dialogue between regulators, companies and registry holders to understand barriers and opportunities of using disease registries and to provide guidance on methodological concepts and regulatory requirements. The work is coordinated by an EMA cross-committee task force on registries and several multi-stakeholder workshops have been held to understand challenges and barriers; PCWP/HCPWP was involved since the start.

In 2018, a discussion paper on the "Use of patient disease registries for regulatory purposes – methodological and operational considerations" was developed and put for public consultation. Following feedback received the task force started work on transforming it into a more formal "Guideline on registry-based studies". The key objective of the guideline is to provide recommendations on key methodological aspects of registry-based studies and the relevant legal basis and regulatory requirements – it is relevant to anyone involved in the funding, creation and management of registries, those participating in the collection and analysis of registry data, and those planning to use the registry to perform registry-based studies with a possible regulatory purpose. It does not address product registries.

It is expected that the draft guideline will be open for public consultation in September 2020.

Some questions from the floor following the presentation: is there still a window for the Working Parties to comment before the public consultation? = Xavier explained that the WPs will receive the draft guideline when it is sent to all committees early July, for comments by mid-August.

We need an integrated registry universe = Xavier agreed, and the Guideline proposes adoption of core common data, terminologies and quality criteria to allow harmonisation of the data collected by registries in a same format. This is an important aspect to be achieved for multinational registry platforms.

Another question related to whether registry based randomised studies are included in this guideline? = EMA explained that they are included, in the section covering study protocol and data analysis, where it includes issues to be considered if registries are used in CTs or to supplement data from CTs, incl. how study protocols should be presented etc, but it does not cover in which cases they should be used, as this needs to be decided on a case-by-case basis by the Committees.

A participant asked if there would be any future workshops? = Xavier explained that we do not currently plan any further disease-related workshops, however a workshop on the methodological recommendations included in the Guidance is considered. He also highlighted that scientific advice procedures can be used to provide advice on specific registries use.

Actions:

- Draft guideline to be sent to PCWP/HCPWP members for input at the same time as to EMA committees

3. Vaccine confidence

2.1 International Coalition of Medicines Regulatory Authorities (ICMRA) statements

Marie-Agnes Heine (EMA) gave a presentation on shared work on vaccine confidence (see presentation). EMA is collaborating with ICMRA, which is a coalition of medicines regulatory authorities' leaders, created 8 years ago to provide strategic direction for enhanced cooperation on common scientific, regulatory or safety challenges and improve communication and information sharing to achieve effective global crisis response mechanisms. Promoting vaccine confidence is a priority for ICMRA as many people are still hesitant to immunise themselves or their children and vaccine hesitancy is one of the main global threats to public health.

Two joint ICMRA statements have been developed, one for healthcare professionals and one for the general public to highlight the importance, safety and effectiveness of vaccines, to reiterate that it's everyone's responsibility to get vaccinated and explain the processes for evaluation and safety monitoring of vaccines. The working parties were asked to disseminate the ICMRA statements with their networks and also to share feedback on the dissemination (feedback form) so we can see if our approach is working but how we can improve.

Christopher Gadd (EMA) then gave an overview of the European Vaccine Information Portal. Some of the WP members contributed during the development of the website which has been live since middle of April; unfortunately coinciding with Covid-19. The aim of the portal is to provide easily understandable information for a non-specialist audience who may have a range of questions about vaccines. The information is available in all official EU languages and includes text, infographics and interactive elements, and will soon also have videos. It was built by ECDC with the support of EMA and the European Commission, and it brings together the scope of both agencies in one website.

Members were encouraged to look at and use the portal, and to share it with colleagues, families etc. The aim is for it to become the hub for information on vaccines across Europe. It is an ongoing project and will be enhanced in the future with more content (currently on hold due to Covid-19).

Following the presentation, a member asked if ECDC's reports are on the portal = Chris explained that they have avoided duplicating content from the two websites; but that there are links to, and from, each. However, this is something to consider as we move forward with further website development.

Another member asked if the timelines for the evaluation and safety monitoring of vaccines will be shortened for Covid-19 = Chris highlighted that the portal does not yet include any information on Covid-19 related aspects, and that information on the regulatory processes for Covid-19 treatments and vaccines is available on EMA's website.

Actions:

- Link to the portal shared with the Working Parties.

4. EMA annual report

2.1 Annual Report 2019: interactive online version

Monika Benstetter (EMA) gave a live demonstration of EMA's annual report which was published in June. The report has previously been prepared for printed publication, however for the first time this one is specifically for digital consumption. Monika took the participants though the report, which is embedded on EMA's website, highlighting the various parts starting from the landing page which includes the table of contents to choose the various elements within the report. The report includes an interactive timeline where you can click on various icons to get to more information. The full report is still available in its full 'printable' format too. As this is a new initiative it is very important that we hear from you what you think of it and how we can potentially improve. Members are invited to use the "Help us with your feedback" button at the bottom of the report.

One post presentation comment: The graphs in the Regulatory Science Strategy section are difficult to distinguish between colours = Monica thanked the particiant and will pass on to colleagues.

Actions:

- Link to the online annual report was shared with the Working Parties.

5. AOB

5.1 Feedback on EMA Virtual meetings

Nora Lazaro (EMA) gave a presentation regarding the results of the survey which was sent to Working Party members to gather their feedback on experience holding PCPW/HCPWP meetings virtually so we can see where we need to try and improve in the future (see presentation).

The survey was sent to all participants of the June PCWP-HCPWP virtual meetings on 2 and 3 June and responses were received from 59 participants (45% response rate). The overall feedback indicated that in general 93% felt that the virtual meetings were 'very good/good'. Some key suggestions for improvement were to consider shortening future meetings (max. 3h), to explore the use of an audience interaction tool e.g. mentimeter, break-out virtual rooms, and to tackle recurrent technical problems by sharing best *virtual meetings* practices (virtual etiquette).

Following the presentation one participant noted that less than 50% of participants had taken up the offer of the adobe training offered by EMA and so recommended that this could potentially help improve participation, although this would not help with issues such as poor sound quality.

End of meeting