15 October 2014

Submission of comments on 'Draft rules of procedures on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC)’ – EMA/624809/2013

Comments from:

| Name of organisation or individual |
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*Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.*

*When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).*

1. General comments

| Stakeholder number*(To be completed by the Agency)* | General comment (if any) | Outcome (if applicable)*(To be completed by the Agency)* |
| --- | --- | --- |
|  | We welcome the opportunity to comment on this document. In general, we believe the content of the draft rules of procedure reflect our understanding of the legislation.EFPIA have, however, further suggestions for improvements on the **criteria** for a safety issue to classify for public hearing at the PRAC, the **procedure** and the **rules** which are specified below. |  |
|  | **The criteria:** In the draft document it is not specified what would be the specific criteria for an issue to classify for a public hearing. The draft rules of procedures do mention the criteria as stated in the legislation: “*The decision to hold a public hearing is taken by the Committee on a case-by-case basis, depending on the urgency of the matter in question and on other justified grounds, particularly with regard to the extent and seriousness of the safety issue.*” However, there is no description of how the extent and seriousness will be calculated. Without this, it seems difficult to predict the frequency of the public hearings and to ensure consistency among the public hearings. |  |
|  | **Communication:**The rules of procedures clarify that EMA will make arrangements for ‘wide media coverage’ and yet, PRAC will not take any decision during a public hearing.As participation of both specialised and non-specialised press can be expected, we are concerned that (non-specialised) press articles could present unbalanced or scientifically incorrect reporting on often complex matters, which then could be potentially misleading and/or confusing to the general public, and therefore not in the best interest of Public Health.Suggestions to mitigate risks:* A PRAC report should be made available on the EMA website shortly after the meeting to provide formal meeting conclusions.
* PRAC should use the EMA media center to maintain contacts with correspondents of mainstream media for public hearings.
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|  | **MAH involvement:**The proposal is very much targeted to obtaining input from the public. However, it should be clearer that the concerned MAH will have the opportunity to participate and (if they wish) present at the hearing, as a key stakeholder that could be directly affected by the views presented at the public hearings. The key principles seem to indicate that this is the case, but this is not completely clear and appears to be contradicted in section 4.4.Also, the concerned MAHs should be notified by the EMA/PRAC prior to the public hearing announcement. (See also specific comment, line 88) |  |
|  | **Safety in the context of benefits**:The oral hearings are to be held in the context of safety referrals under Art. 20 of Regulation 726/2004, Art. 31 or Art. 107i of Directive 2001/83/EC. While these are referrals triggered by a safety issue, it is important that the safety issue is looked at in the context of a risk-benefit assessment rather than risk assessment only, as acknowledged in the legislation (‘*In the public hearing, due regard shall be given to the therapeutic effect of the medicinal product*’). The draft rules of procedures do not ensure this happens; in particular there are no participants or panel that can represent the benefit aspects of the product(s). Thus, we propose that extra experts attend public hearings such as CHMP members (or/and Scientific Advisory Group members).  |  |
|  | **Revision of the rules based on gained experience:**The possibility to hold public hearings in the context of European-level medicinal product regulatory procedures is new. The benefits of these public hearings – particularly in the specific format described in these draft rules of procedures – have, therefore, yet to be demonstrated. Clearly, all stakeholders need to gain some experience with PRAC public hearings to properly assess their usefulness. We propose that the EMA commit to conduct such an assessment, in consultation with stakeholders, after a reasonable period or number of hearings have passed (e.g. within the first 2 years of implementation or after 8 to 10 public hearings). The need for any revisions or refinements to the procedure could then be considered.The assessment could consider aspects such as: the quality and value of contributions made at the hearings (based on their impact on the PRAC opinion) by different stakeholder groups; whether the proposed approach (speakers make their interventions one-by-one, providing only responses to the questions posed by the PRAC) allows for a fruitful scientific discussion. |  |

1. Specific comments on text

| Line number(s) of the relevant text*(e.g. Lines 20-23)* | Stakeholder number*(To be completed by the Agency)* | Comment and rationale; proposed changes*(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome*(To be completed by the Agency)* |
| --- | --- | --- | --- |
| Lines 24-26 |  | Comment: The definition of public hearing mentions that therapeutic effects will be considered. If this is the case then the panel should consist of additional experts (e.g. CHMP/SAG members) that can bring in the efficacy perspectives of the medicine.  |  |
| Line 27 |  | Proposed change (if any): “*Public hearings give the PRAC a channel to hear the public’s views and concerns* **on pre-defined questions** *and take them into…”* |  |
| Lines 36-40 |  | Comment: The draft text mentions that the public hearing can be used to “*hear the public views on the acceptability of the risks*” and “*seek suggestions and recommendations on the feasibility and acceptability of risk management and minimisation activities*”. Therefore, it will be helpful if the risks are characterised and that the risk minimisation measures are preliminary discussed with the MAH prior to initiation of the public hearing. This will ensure a reasonable outcome from the public hearing. Therefore, we propose a fine-tuning of the wording in the last sentence of this paragraph.Proposed change: “*The value of a public hearing is considered to be greater in that phase of the process, when the PRAC has assessed the scientific evidence coming from different sources,* **including from MAHs, has taken a preliminary position on the risks and risk minimisation measures that may be needed** *and when different regulatory options to manage and/or minimise risks are to be considered in a wider public-health context.”* |  |
| Line 47 |  | Comment: It is envisioned that the PRAC may proactively invite “*representatives of patients, consumers, healthcare professionals or researchers…”*.It should be clarified whether the PRAC will also prioritise those stakeholders as speakers compared to other non-invited stakeholders. Consequently the rules should introduce an element of equal opportunity to participate to public hearing for invited and non-invited representatives in order to ensure representation of diversity of opinion.Finally, we think that the list of stakeholders should also refer to the families and the care-takers who often take a predominant role with some patients in specific disease areas, e.g. dementias. Also, referring to consumers in this context seems indistinct.Proposed change: “*The PRAC may proactively invite representatives of patients, ~~consumers~~,* **families/care-takers***, healthcare professionals or researchers with specific expertise in relation to the medicine(s) concerned by the public hearing.*” |  |
| Lines 49-50 |  | Comment: The participation of concerned MAHs (particularly the innovator MAH, when generic products are available) at public hearings is important: the MAH is a key stakeholder that could be directly affected by the views presented at the hearings. It is not clear, however, whether the MAHs will always be permitted to participate at public hearings, or whether an MAH’s request to participate can be refused.The document states “*The marketing authorisation holder(s) has the opportunity to present its/their view(s) to the participants of the public hearing*” it seems to indicate that the concerned MAHs will always be permitted to speak if they wish. This statement, however, seems to be contradicted elsewhere in the draft rules of procedure: lines 200-201 state that the MAH “may” be given the opportunity to present his(their) view(s) to the participants of the public hearing, which seems to indicate that MAH participation could be refused.There is also no clear statement that the MAHs will always be allowed to participate (as an observer), even when they do not wish to present their views.It should be made clearer that the concerned MAHs will have the opportunity to participate and (if they wish) present at the hearing.Proposed change:“*The marketing authorisation holder(s)* **will, in all cases, be permitted** *~~has the opportunity~~ to* **participate as an observer or** *present its/their view(s) to the participants of the public hearing.* **Where several marketing authorisation holders request participation, priority will be given to the innovator(s).**” |  |
| Lines 53-55  |  | Comment: We understand that public hearings should be conducted in English. However, this may lead to discrimination with EU inhabitants who do not have sufficient fluency in English. In the [EU-Charter of Fundamental Rights](http://en.wikipedia.org/wiki/Charter_of_Fundamental_Rights), legally binding since its inclusion in the [Lisbon Treaty](http://en.wikipedia.org/wiki/Lisbon_Treaty), the EU declares that it respects linguistic diversity (Article 22) and prohibits discrimination on grounds of language (Article 21).Local organisations/individuals with relevant expertise to provide the diversity in terms of context and perspective in the discussion may only have the opportunity to provide written comments if they are not confident enough in English. This may result in inadequacy of the representativeness in public hearings.As the speakers are selected in advance, we recommend EMA/PRAC to consider having translators’ services during the meeting if beneficial/crucial verbal contributions could be made only in another EU language. |  |
| Lines 72-84 |  | Comment:Although we recognise the need for a case-by-case approach to holding public hearings, to ensure a level of consistency, greater clarity should be provided around the criteria –particularly in terms of extent and seriousness-for triggering hearings.Proposed change:Include a non-exhaustive list of examples that may trigger public hearings. (either as an annex or as a separate document) |  |
| Line 81 and 83 |  | Comment: It would be useful to understand how the EMA/PRAC will “*measure*” the expected impact. |  |
| Line 85  |  | Comment: For transparency reason, the merits of a public hearing should be established and communicated (particularly considering the current given option of PRAC meeting with patients, patients associations, representatives or carers). Proposed change: Proposed additional phrasing “**Based on these considerations, a conclusion on the added value of conducting a public hearing should be established and communicated in the public announcement**”.  |  |
| Line 88 |  | Comment: To enable the MAHs to address public and media questions, The EMA/PRAC should always inform the concerned MAHS before the public announcement. Concrete timelines should be mentioned in the rules of procedure.Proposed change: Suggest adding: “**Relevant/concerned MAHs will be informed of the decision to conduct a public hearing via Eudralink notification at least one calendar month before the hearing and at least 2 days before the public announcement.**” |  |
| Line 89 |  | Comment: There should be indication that the announcement would also be available on national competent authorities’ websites and in the different alert/email systems of competent authorities reaching out to the public. Proposed change: Add elements to indicate that the information will also be relayed via the national competent authorities’ media (website and email system). |  |
| Lines 89-99 |  | Comment: To avoid unbalanced media headlines with publishing only the summary of the safety concerns without the context of benefit and the therapeutic alternatives, a truly transparent public hearing needs full information, and not to be pre-judged by media coverage of a one sided argument.Along with the announcement the “justified grounds” to hold a public hearing, what stakeholders are invited proactively, a summary of benefit/risk assessment of the product and a list of products affected should also be published.Proposed change: ”*together with:* * **Objectives to be achieved with the public hearing;**
* **Specific elements justifying the merits to hold a public hearing;**
* **Conclusion on the added-value of conducting a public hearing;**
* *a summary of the safety concern;*
* **a summary of the risk/benefit assessment;**
* *a list of specific questions on which information from the public is sought during the public hearing;*
* **a list of stakeholders proactively invited by the EMA/PRAC;**
* **a list of products affected, etc.**
 |  |
| Line 96 |  | Comment: The draft rules of procedure indicate that information on how to submit written contributions will be included with the announcement of the public hearing. We recognise that certain specific aspects of the hearing cannot be addressed until a decision has been taken to hold a public hearing. It would, however, be helpful to provide some general guidance on the EMA website to aid with the timely preparation of written contributions (e.g. format, general points to consider), especially given the likely short period between the announcement and the deadline for submissions. |  |
| Line 99  |  | Comment: Live broadcast/web stream should not be optional unless integral meeting video/audio/minutes are shortly available after the public hearing in order to provide equal opportunity of information to the public. |  |
| Line 105 |  | Comment: Members of the public will need to understand whether their contribution in person or via telephone will be reimbursed or at their own expense. This should be clarified in this section. |  |
| Lines 106 |  | Comment: members of the public may not understand the term “teleconference” or understand/have access to Adobe Connect and therefore may need support with this.Proposed change: “*Speakers can make an intervention in person or via* **telephone (e.g. teleconferencing using facilities such as Adobe Connect)** *where possible and feasible.*” |  |
| Line 114 |  | Proposed change: “*Requesters will receive a confirmation of their request ~~in advance~~* **at least 2 calendar weeks ahead** *of the hearing*” |  |
| Lines 115-116 |  | Comment: See comment line 99. |  |
| Lines 123-132 |  | Comment: When appropriate, speakers should reference or detail the data source as well as the methodology used for the analysis, being in compliance with relevant quality standards for data management that will allow the attendees to have a critical point of view of the information presented.Proposed change: suggest adding a bullet “**When appropriate, speakers should reference or detail the data source as well as the methodology used for the analysis, to allow the attendees to have a critical point of view of the information presented.**” |  |
| Lines 124-125 |  | Comment: There may be occasions when a MAH might want to bring along some external support, for example a patient, or representative of a patient group, or an expert in the therapeutic area. It is not clear from the draft rules whether this would be permitted and, if so, how the affiliation of the accompanying expert should be declared. We would welcome clarification on these points - lines 124 and 125 would seem the appropriate place to do this.Proposed change: add “**brief organisation/group description (mission, background information on activities** …)” |  |
| Line 126  |  | Proposed change: add declaration of interests. |  |
| Line 137 |  | Comment: It is unclear as to when the speakers will have access to the information described in this section.Proposed change: add “**ahead of the meeting and at least two calendar weeks before the meeting**”.  |  |
| Line 144 |  | Comment: It should be clarified whether the first come first served rule applied for observers’ participation. |  |
| Line 154  |  | Comment: The EMA/PRAC should ensure both the relevant representativeness and the legitimacy of each participation/intervention to a public hearing. Therefore additional conditions should be requested before validating a request (such as presentation pre-reading, background information on the organisation/group represented …). Propose change: “*a matter that is not 153 related to the subject matter of the public hearing* **or that does not bring any added value to the discussion**. **Before the meeting date, and upon receipt of the presentation, the Agency may review the acceptance of any request**.” |  |
| Lines 155-159 |  | Comment: It should be mentioned that the MAHs can possibly speak.Propose change: include MAHs to line 157. |  |
| Line 162 |  | Comment: In case of high number of people willing to speak at the public hearing the Agency may decide to determine the speakers by lottery. We believe that in such cases the decision should be taken based on scientific ground and relevance to the questions posed rather than a lottery. Especially in case where clear conflicting scientific/medical evidence exists on the issues raised and the balance between proponents and opponents would be key.  |  |
| Line 164  |  | Comment: Further details should be given regarding written statement option (How they will be addressed during the public hearing? Will they be published? Etc. …).  |  |
| Line 167 |  | Proposed change: “*all individuals admitted as speakers will receive a confirmation ~~in advance~~* **at least two calendar weeks ahead** *of the hearing*”.  |  |
| Line 171 |  | Comment: The current text of the guideline does not specify whether the speakers’ declaration of interest will be published along with the draft agenda. In order to ensure transparency it will be beneficial that they are also made available prior to the meeting. Proposed change: “*The Agency will prepare a list of speakers* **with their affiliation** **and** **with their declaration of interest**” |  |
| Line 171 |  | Comment: A clear timetable should be provided for clarity purpose.Proposed change: We propose that the rules of procedure should include an outline timeframe for the organisation of a public hearing including an indicative timeframe for:* when the confirmation and relevant information will be sent to speakers and observers (including for non-public hearing)(e.g. 2 calendar weeks prior to the planned meeting);
* when the draft agenda and meeting materials will be distributed (e.g. 2 days prior to the planned meeting);
* when meeting records will be made available;
* Expectations when the PRAC opinion following the public hearing would be expected to be issued.
 |  |
| Line 180 |  | Comment: We propose that extra experts attend public hearings such as CHMP members (or/and Scientific Advisory Group members) that can represent the benefit aspects of the product(s).  |  |
| Lines 200-201 |  | Comment: These lines seem to contradict lines 49-50 (see also comment above). As the holder has a broad experience with the product, it should be able to participate in the hearingIt should be made clearer that the concerned MAH will have the opportunity to participate and (if they wish) present at the hearing.In addition, where a public hearing involves several holders, the EMA should use their best endeavour to ensure that all the holders could present their views during the hearing.Proposed change:“*The marketing authorisation holder(s)* **will, in all cases, be permitted** *~~may be given the opportunity~~ to* **participate as an observer or** *present his(their) view(s) to the participants of the public hearing.* **Where several marketing authorisation holders request participation, priority will be given to the innovator.**” |  |
| Lines 205-207 and 197-199 |  | Comment: One section is redundant (repetitive) unless it refers to personal interests for line 197-199 and to the interest of the organisation the individual is representing for line 205-206, in which case it should be clearly stated.Proposed change**:** Remove the sentence line 205-207 or mention that it relates to the interest of the organisation the individual is representing. |  |
| Line 222 |  | Comment: The draft rules of procedure should provide details on the modalities of the non-public hearings. They should where possible take place in the margins of the public hearings to maximise the hearing exercise and outcomes for PRAC.  |  |
| Lines 223-224 |  | Comment:It should be recognised that material presented in a non-public hearing may not be released as part of the meeting records. Generally, a non-public hearing is to be held because confidential information is to be presented and discussed; this information should therefore not be released under the EMA’s policies on access to information.Proposed change:Add the following text “**The official record of the meeting shall not contain any confidential information and the EMA shall not release any information from a non-public hearing that is not permitted under the Agency’s policy on access to documents**.” |  |
| Lines 226-228 |  | Comment: The PRAC chair should endeavour to allocate enough time to open the floor to participants at the end of the public hearing.Also, if related to a specific product (or a group of products), the MAHs should ideally be given the opportunity to provide a ‘summing-up’ comment.Proposed change: “~~Where time permits~~ The chair ~~can~~ **should endeavour** open the floor to all participants in the room, for additional statements on the points made during the hearing. **The MAHs would ideally have the opportunity to comment on key issues raised during the public hearing**.” |  |
| Line 232 |  | Comment: Details on the meeting record should indicate that they are integral records and specify if they are written, audio or/and video. Integral record will allow complete and transparent information to the public.Proposed change: “*~~A record~~* **An integral record of** *the meeting, the list of speakers and other participants,* **including the vector/media,** *their declarations of interests, any supporting documentation presented by speakers and a summary of the conclusions of the meeting will be made available following the public hearing on the Agency’s website.”* |  |
| After Line 234 |  | Comment: In order for the EMA to have accurate documents published on its website, we suggest that a process should be in place to make sure that it is possible to report any error or inaccuracy identified in the published meeting records. Once identified, these errors should be corrected/highlighted in the published documents or published in a list. Proposed change: We suggest adding “**Following the initial publication, any errors or inaccuracy identified in the meeting records or supporting documentation should be published**.” |  |
| Lines 236-239 |  | Comment: The last paragraph of the document is very vague. It is important to have more information on how the contributions will be considered and assessed. Also to understand the timing of the hearing in relation to the overall procedural timeframes and the relationship on timing of the hearing to the PRAC decision etc, procedures should not be unduly extended or delayed. |  |