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European Medicines Agency

Highlights from the first Expert Panels and Notified Bodies workshop

22 April 2024 - Chaired by Alberto Gañan Jimenez; Moderated by Silvy da Rocha Dias

1. Welcome and introduction

The chair and the moderator extended a warm welcome to the delegates from the Notified Bodies (NBs), the European Commission (EC), and the Co-Chair of the Notified Body Oversight Subgroup of the MDCG to the workshop. The introduction underscored the significance of this first workshop, marking the beginning of more regular interactions. Similarly, the representatives of the EC greeted the participants and emphasized the crucial need for ongoing collaboration between the NBs and the Expert Panels. The NBs representatives expressed appreciation for organising the workshop and highlighted the importance of establishing links with the Expert Panel secretariat with more regular exchanges.

2. The CECP and PECP – The Expert Panel's perspective

The Expert Panels secretariat presented an in-depth review of the Clinical Evaluation Consultation Procedure (CECP) and the Performance Evaluation Consultation Procedure (PECP). The CECP is applicable to a subset of medical devices: class III implantable devices and class IIb active devices intended to administer and remove a medicinal substance. The devices for which the CECP is applied are further reduced by the possibility to exempt devices from the procedure due to three exemption criteria laid down in Article 54 (2) of Regulation (EU) 2017/745, the medical device Regulation (MDR). The secretariat provided an overview of its role in the process, including the completeness check of the submission and support to the experts on the application of the criteria to judge if a scientific opinion is needed, as laid out in 5.1 (c) of Annex IX of the MDR.

Regarding the PECP, the secretariat provided an overview of the differences compared to the CECP and highlighted the limited applicability of the procedure as only Class D in vitro diagnostic devices are in scope of this procedure. In addition, only the first device of its type is in scope of the PECP or devices for which common specifications are not available.

A short discussion followed in which NBs highlighted the need for direct interaction with the Expert Panels during the procedure.

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The next topic was the publication process, which has been adapted to fit the needs of all stakeholders. More specifically, opinions in scope of the CECP are now published after conclusion of the certification process. NBs welcomed this change in the publication process as it simplifies the process for identification of commercially confidential information. No changes have been made to the publication process of the views issued in the PECP. The information on the Expert Panels will be moved shortly from the EC webpage to the EMA webpage.

Lastly, the methodology for forecasting submissions for the CECP was discussed. It was highlighted that it is important to accurately forecast the number of submissions to the CECP and PECP process, as this information is required for the EMA to manage internal resources, to manage allocation and availability of experts and to ensure that the right expertise is present in the panels to be able to provide timely CECP opinions. NBs have highlighted the difficulties of forecasting submissions at early stages of the review of the file and have suggested that, in addition to the survey conducted by the EC, regular bilateral meetings between NBs and the secretariat would be helpful.

3. The CECP and PECP procedure – Notified Body experience and feedback

Four NBs voluntarily shared their experiences with the CECP and PECP. The excellent collaboration between NBs and the Expert Panel secretariat was highlighted by the NBs, and the clear and accurate communication during the procedure was specifically noted as beneficial for the NBs. The NBs emphasized that a more systematic use of the provision for NBs to present their conclusions, as foreseen in 5.1 (b) of Annex IX of the MDR, would be beneficial for them to address the Expert Panels' concerns and recommendations. The Expert Panels secretariat elaborated that this possibility is being considered, and a risk-based approach may be applied with every dossier that requires a CECP opinion.

The NBs further highlighted the need for a revision of the CEAR template (MDCG 2020-13). This request has been forwarded to the European Commission for further consideration. Lastly, the NBs also noted that a revision of the opinion template would be beneficial to increase readability. The Agency has committed to taking this feedback into consideration for the next revision of the template.

4. Scientific Advice – Outline of the pilot and the Advice to manufacturers' process

The Expert Panels secretariat presented an overview of the currently running pilot for advice to medical device manufacturers. It was clarified that for now only Class III devices and Class IIb active devices destined to administer or remove a medicinal product are within the scope of the pilot, as set out in Article 61 (2) of the MDR. A general overview of the devices currently accepted in the pilot was provided, with a summary of the most requested type of questions that the Expert Panels are asked to answer during this procedure. It was noted that the scope of the procedure is limited to the clinical development strategy and/or proposals for clinical investigation. The NBs highlighted that some of the feedback they have received from the industry relates to a need to have a platform to discuss and receive regulatory advice in addition to the scientific advice from the panels, which is currently outside the scope of the advice procedure.

5. Expert Panel involvement in orphan medical devices

For the final agenda point, the EC briefly presented the potential involvement of the Expert Panels in the clinical development/evaluation of orphan medical devices. The EC provided the background to the initiative and the progress made by the multi-stakeholder orphan device task force of the MDCG,

involving the EC, Member States, industry, NBs, patient representatives, and healthcare professionals. It was discussed that it is anticipated that the Expert Panels can provide support in three different areas. The first area relates to the advice to manufacturers that is currently being piloted (see point 4), followed by a new process for the confirmation of the orphan status of a device as requested by a manufacturer. Lastly, the Expert Panels would be available to advise the NB (and the manufacturer as long as there is no interference with the NBs' assessment) on the criteria for an appropriate data set for the assessment of the conformity of a device, particularly with regard to the clinical data required for clinical evaluation. The consultation of Expert Panels for orphan devices is voluntary as an additional measure to support the implementation of the MDR with the aim of assisting both NBs and manufacturers with devices only intended for use in a small number of individuals each year that may be particularly challenging to meet the regulatory requirements. NBs are encouraged to participate in this activity, in collaboration with the respective manufacturer.

6. A.O.B

The participants have highlighted the need to have regular interactions between NBs and the Expert Panels secretariat.