27 January 2023
EMA/CVMP/695453/2022

Overview of comments received on 'Procedural advice for vaccine platform technology master file (vPTMF) certification ' (EMA/CVMP/184591/2022)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	European Federation of Pharmaceutical Industries and Associations (EFPIA) and Vaccine Europe

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1. General comments – overview

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
1	For this guidance to be applicable also for Human Medicinal products, not only Vaccines and not only for Veterinary Vaccines	Human medicinal products are not within the scope of Regulation (EU) 2019/6, where the provisions for the vaccine platform technology master file certification scheme are laid down.
1	The guideline only describes situations in which the applicant of the vPTMF and MA is the same entity. However, as the vPTMF is a standalone submission reviewed in parallel to the MAA that cross-refers it, it should be possible to have a different applicant for the vPTMF than for the MA. This possibility would considerably increase the benefits of using vPTMFs in submissions.	In section V.4.1.2 of the Commission Delegated Regulation (EU) 2021/805 amending Annex II to Regulation (EU) 2019/6, it is stated *'a full dossier is required for the first product from a manufacturer based on a particular platform technology for a particular target species. At the time of submission of the first (full) dossier based on the platform technology, the applicant may submit in parallel a "Platform Technology Master File" comprising all data relative to the platform for which there is reasonable scientific certainty that will remain unchanged regardless of the antigen (s)/gene(s) of interest added to the platform.'* The vPTMF certification process is a totally new scheme that has not been used before. For the sake of simplicity, it has been initially conceived for cases where the applicant for the vPTMF and for the initial marketing authorisation (MA) application is the same.

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		However, the text in Annex II is not prescriptive. Once experience with the vPTMF scheme is gained, it might be further developed to cover scenarios where the applicants for the vPTMF and for the initial MA application are different. This would require careful consideration of aspects such as handling of confidential/proprietary information and of the type of data that could be included in a vPTMF in such a scenario.
1	There is an opportunity to allow the submission of sections of the VPTMF that could be used across multiple products and avoid repetition of the preparation and review e.g. facilities sections, method validation, linkers, conjugates, adjuvants etc	Advice on the data to be included in a vaccine platform technology master file is given in the 'Guideline on data requirements for vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/286631/2021).
1	Could it be possible to be a stand-alone submission separate of an MAA (similar to the US DMF approach), i.e. a standalone submission?	A separate, stand-alone submission for a PTMF is not foreseen in the Commission Delegated Regulation (EU) 2021/805 amending Annex II to Regulation (EU) 2019/6. Section V.4.1.2 which states that *'A full dossier is required for the first product from a manufacturer based on a particular platform technology for a particular target species. At the time of submission of the first (full) dossier based on the platform technology, the applicant may submit in parallel a "Platform Technology Master File" (…)'. Given the nature of immunological veterinary medicinal products for which quality, safety and efficacy are inherently interrelated, it is not considered feasible from a scientific stance to carry out an appropriate assessment of a vPTMF if not within the context of the evaluation of the*

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		first marketing authorisation application based on that platform technology. *However, for platform technologies already used in vaccines authorised via the centralised procedure, the submission of a vPTMF application can be done at any time, as a stand-alone vPTMF submission.*
1	There is an opportunity to allow to file information and data relating to prior knowledge that could be taken into consideration for other filing, the prior knowledge information would therefore only need to reviewed once, and an assessor could then concentrate on the applicability to the new product	The comment is not considered to be relevant to the procedural guidance but to the actual content of a vaccine platform technology master file. Advice on the data to be included in a vPTMF is given in the 'Guideline on data requirements for vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/286631/2021).

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Line 146	1	Duplication between PTMF and MAA should be avoided Lines 146 ff: "It is encouraged that the data submitted for certification are identical to the corresponding data approved in one linked MA, and no changes are proposed during the certification." This requirement would reduce the benefit of having a separate MF and it would duplicate the information submitted. It is unclear whether the information transferred to the vPTMF should be deleted from the MA or not. To avoid duplication of information, it should be stated that the MA should be amended at the same time to remove the corresponding data. Proposed change (if any): Add 'The information transferred from the MA to the vPTMF should be removed from the MA'.	Not accepted. The comment refers to Section 4.2, new vPTMF used in an authorised vaccine(s) via the centralised procedure. The first step (1st step) consists of a centralised assessment of the vPTMF application dossier submitted by the applicant/MAH, which results in a certificate of compliance to Union legislation, issued by the EMA. The vPTMF certification is standalone and, as such, not related in any way to one or more MAs. To this purpose, all the data to be included in the vPTMF will need to be provided, and therefore marketing authorisations cannot be amended at the same time as suggested in the comment. This will follow in the second step (as described in section 3 - lines 62-69 + Figure 1- and section 4.2.4 - lines 192) where the changes to existing marketing authorisation(s) will be made via variation following the relevant guidance. This second step, introducing the certified vPTMF into the corresponding marketing authorisation, will in practice remove the information contained in the vPTMF from the original marketing authorisation dossier.