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3 Veterinary Medicines Division

4 **Procedural advice for vaccine platform technology master**
5 **file (vPTMF) certification**
6 Draft

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8 Comments should be provided using this [template](#). The completed comments form should be sent to vet-guidelines@ema.europa.eu

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35 **1. Introduction**

36 This document is intended to provide advice to marketing authorisation (MA) applicants and marketing
37 authorisation holders (MAHs) on issues associated with the submission, evaluation, certification and
38 use of a veterinary vaccine platform technology master file (vPTMF) by the European Medicines Agency
39 (EMA). The detailed scientific requirements for an application for veterinary vPTMF certification are
40 described in Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to
41 Regulation (EU) 2019/6 of the European Parliament and of the Council and in the Guideline on data
42 requirements for vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/286631/2021).

43 **2. Legal framework**

44 The principles, evaluation and certification of vPTMF are described in Section V.4 of the Commission
45 Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of
46 the European Parliament and of the Council.

47 **3. Principles of the vPTMF certification**

48 A vPTMF is defined as a stand-alone part of the marketing authorisation application dossier for a
49 vaccine, which contains all relevant data relative to the platform for which there is reasonable scientific
50 certainty that will remain unchanged regardless of the antigen(s)/gene(s) of interest added to the
51 platform. The nature of the data to be included in the vPTMF will depend on the type of platform.

52 The stand-alone part may be common to one or more monovalent and/or combined vaccines presented
53 by the same applicant or marketing authorisation holder for the same target species.

54 The use of the vPTMF certification system is optional. For combined vaccines, containing active
55 substances produced using different vaccine platform technologies, as defined in V.4.1.1 of Annex II of
56 Regulation (EU) 2019/6, the platform technology(ies) to be included in vPTMF(s) shall be specified and
57 a separate vPTMF shall be required for each of those selected by the applicant.

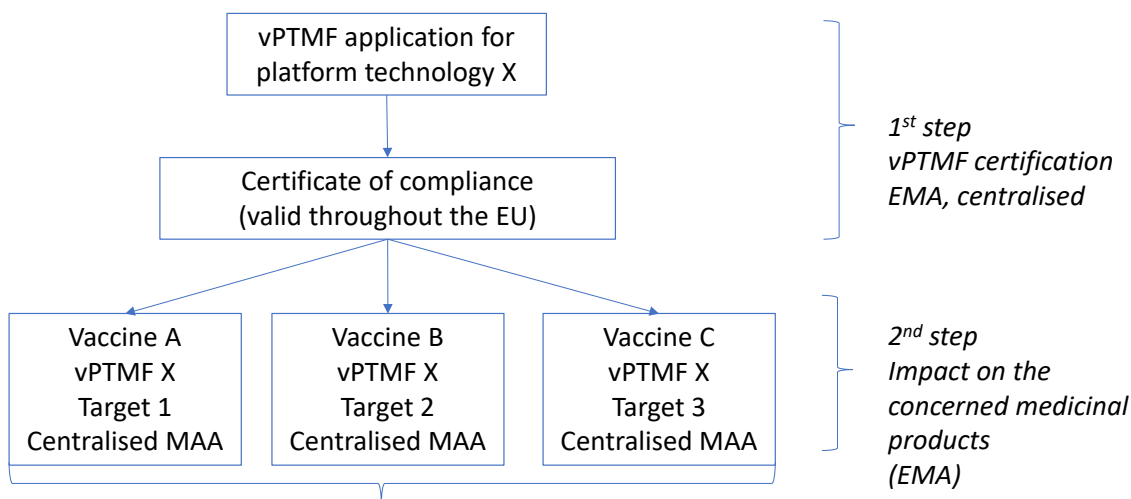
58 It is expected that all platform technologies fulfilling the definition in Annex II of Regulation (EU)
59 2019/6 will be generated using biotechnological processes (recombinant technology, controlled
60 expression of genes, etc.). Therefore, the vaccines they are included in would fall under the scope of
61 the centralised procedure as described in Article 42(2) of Regulation (EU) 2019/6.

62 The vPTMF certification (1st step) consists of a centralised assessment of the vPTMF application dossier
63 submitted by the applicant/MAH, which results in a certificate of compliance to Union legislation, issued
64 by the EMA. This certificate is valid throughout the European Union.

65 As a second step, the EMA shall take into account the certification, re-certification or variation of the
66 vPTMF for the concerned medicinal product(s) (Figure 1).

67 This document focusses on the first step. For the second step, changes to existing marketing
68 authorisations resulting from vPTMF certification procedures (i.e. inclusion of a new, updated or
69 amended vPTMF) will be introduced via variation following the relevant guidance (see References).

70



Veterinary medicinal products (linked MAs) using vPTMF X

71

72 Figure 1: General principles of a vPTMF

73

74 A marketing authorisation (MA) or a marketing authorisation application (MAA) may contain one or
75 more vPTMF certificates and respective vPTMF data.

76 Two different scenarios referred to as 'triggers' are possible for the initial certification of a vPTMF (see
77 Annex 1):

78 - **Trigger 1:** For new vaccine platform technologies which have not been already authorised in the
79 Union, the evaluation of vPTMF(s) will be carried out as part of the evaluation of the full marketing
80 authorisation dossier of the vaccine in which they are included. To this end, a full marketing
81 authorisation application dossier should be submitted to the Agency, including all the vPTMFs
82 corresponding to each single vaccine platform technology for which the use of a vPTMF is intended. It
83 is also possible to evaluate a vPTMF application as part of an initial marketing authorisation for a
84 vaccine containing a platform technology already used in an authorised vaccine(s) in cases where the
85 introduction of vPTMF(s) in the existing vaccine(s) is not envisaged.

86 - **Trigger 2:** For platform technologies used in currently centrally authorised vaccines, the evaluation
87 and certification of a vPTMF will be performed through a separate procedure. In this case, an
88 application for a vPTMF will be submitted to the Agency containing the data corresponding to the
89 platform technology for which a vPTMF is intended.

90 The decision as to whether a particular vPTMF is to be used for an existing MA rests with the MAH, who
91 may decide that even though the same platform technology is used in several MAs, the MAH only
92 wishes to link the certificate to some, not all such MAs.

93 Once the applicant/MAH chooses to use the vPTMF certification system, all variations to the
94 corresponding MAs concerning the platform technology included in an approved vPTMF will have to be
95 submitted through the same certification system. Either the same change is made to all linked MAs or
96 the particular MA in question is removed from the vPTMF system.

97 **4. Initial certification of a vPTMF**

98 **4.1. Trigger 1 – New MAA for a vaccine via the centralised procedure**

99 In the framework of a new MAA assessment via the centralised procedure for a vaccine based on a new
100 platform technology or an existing platform technology used in centrally authorised vaccines. In this
101 case, the certification of the vPTMF is an intrinsic part of the assessment of the MAA dossier submitted
102 to the Agency.

103 **4.1.1. Pre-submission activities**

104 The MA applicant should inform the Agency that they intend to use the EU vPTMF certification system
105 (see Annex 2). Applicants may ask for a pre-submission meeting to obtain further procedural and
106 regulatory advice from the Agency.

107 **4.1.1.1. Letter of intent to the Agency**

108 For applications for vPTMFs linked to the submission of an initial MAA, the intention to use vPTMF shall
109 be confirmed no later than 2-3 months prior to the submission of the MAA, either via notification to the
110 Agency or via inclusion in the pre-submission request form. Information that should be provided:

- 111 • Intent to use the EU vPTMF certification system. For combined vaccines, identification of the
112 platform technology(ies) for which the use of vPTMF is intended.

113 **4.1.1.2. Appointment of rapporteurs**

114 The rapporteur and co-rapporteur appointed by the CVMP for the evaluation of the MAA will also be
115 responsible for the evaluation of the corresponding vPTMF(s). The appointment of rapporteurs will be
116 notified to the MA applicant.

117 **4.1.2. Submission activities**

118 The submission dates for vPTMF(s) will follow the standard submission deadlines for MAAs published by
119 the Agency and available on the EMA website. The final submission date will be agreed by the applicant
120 and the Agency.

121 The MA applicant shall submit the application and accompanying documentation to the Agency. All
122 submission requirements for the Agency are published on the [EMA website](#). The vPTMF data package
123 should arrive simultaneously with the marketing authorisation application.

124 The validation of the submission will be performed by the Agency and the outcome communicated to
125 the MA applicant with the evaluation timetable. Applicants should ensure that a technically valid
126 submission is received by the Agency before the submission deadline. Any technically invalid
127 applications will result in non-acceptance, which may cause a delay in the start of MAA the procedure.

128 **4.1.3. Evaluation**

129 For vPTMF certification applications submitted within a new centralised MAA, the assessment will by
130 definition be embedded in the centralised evaluation procedure. The timetable will follow that of the
131 respective MAA. An evaluation report of the vPTMF will be prepared in addition to the MA evaluation
132 report. The vPTMF certification will occur at the stage of the CVMP opinion on the MAA.

133 **4.1.4. Certification**

134 Within 15 working days of the adoption by the CVMP of a positive evaluation report, the Agency will
135 issue a vPTMF certificate. The vPTMF evaluation report will accompany the certificate. At the end of the
136 certification procedure, the certified vPTMF will effectively form part of the MA dossier of the vaccine. A
137 variation not requiring assessment (VNRA) to add the vPTMF to the MA dossier is not needed in this
138 case (Trigger 1).

139 Within 15 working days of the adoption by the CVMP of a negative evaluation report, the Agency will
140 issue a letter refusing the grant of a certificate for a vPTMF to the applicant. The vPTMF evaluation
141 report will be attached to the refusal letter.

142 **4.2. Trigger 2 – New vPTMF for a vaccine platform technology used in** 143 **authorised vaccine(s) via the centralised procedure**

144 In the case of vaccine platform technologies contained in vaccines authorised via the centralised
145 procedure, the MAH may initiate the vPTMF certification at any time.

146 It is encouraged that the data submitted for certification are identical to the corresponding data
147 approved in one linked MA, and no changes are proposed during the certification. In the case of a
148 vPTMF application for a vaccine platform technology used in different authorised vaccines where
149 differences in the data packages exist, the MAH may consider harmonising the respective dossiers
150 before applying for a vPTMF. Alternatively, the MAH could choose one of the MA dossiers to apply for
151 the initial vPTMF and then consider harmonising the rest of the dossiers based on the approved vPTMF.

152 It is not possible to certify a vPTMF that might change during the procedure. Therefore, it is strongly
153 advised not to initiate a vPTMF certification when there are ongoing variations related to the content of
154 the vPTMF in the individual MA(s). Additionally, MAHs should not submit variations related to the
155 content of the vPTMF until the vPTMF is certified.

156 **4.2.1. Pre-submission activities**

157 Prior to the submission of the vPTMF application, the MAH should inform the Agency that they intend to
158 use the EU vPTMF certification system (see Annex 2). MAHs may ask for a pre-submission meeting to
159 obtain further procedural and regulatory advice from the Agency.

160 **4.2.1.1. Letter of intent to the Agency**

161 MAHs should ideally inform the Agency of their intention to submit vPTMF applications approximately
162 2-3 months before submission, specifying the intended submission date. Information that should be
163 provided:

- 164 • For combined vaccines, identification of the vaccine platform technology(ies) for which the use
165 of vPTMF is intended.
- 166 • A list of MAs to which the respective vPTMF will apply.

167 **4.2.1.2. Appointment of rapporteur(s)**

168 For the evaluation of the vPTMF, one rapporteur and one co-rapporteur will be appointed by the CVMP.
169 The appointment of rapporteur(s) will be notified to the MAH. The rapporteur and co-rapporteur
170 responsible for the authorised product(s) will be appointed as rapporteurs for the evaluation of the
171 vPTMF application.

172 The rapporteur(s) will be responsible for the evaluation of the vPTMF certification application on behalf
173 of the EMA.

174 **4.2.2. Submission and validation**

175 The monthly deadlines for submission of applications for vPTMF certification will be published on the
176 EMA website.

177 The MAH shall submit the application and accompanying documentation to the Agency. All submission
178 requirements for the Agency are published on the [EMA website](#).

179 The validation of the submission will be performed by the Agency and the outcome communicated to
180 the MAH.

181 **4.2.3. Evaluation**

182 An evaluation report will be prepared by the appointed rapporteur(s) and circulated for review by the
183 CVMP. The CVMP will then make appropriate recommendations on the outcome of the evaluation.

184 The timetable for vPTMF certification applications for Trigger 2 will be as follows (see Annex 3):

Day -15	Submission of vPTMF application
Day 0	Validation of the vPTMF application
Day 1	Start of the procedure
Day 45	Rapporteur's evaluation report
Day 52	Co-rapporteur's comments
Day 66	CVMP comments
Day 70	Revised rapporteur's evaluation report
Day 90	Adoption of vPTMF certificate and evaluation report <i>or adoption of list of questions and clock stop</i>
Day 91	Re-start after submission of responses
Day 108	Rapporteur's assessment of responses and evaluation report
Day 115	Co-rapporteur's comments
Day 119	CVMP comments
Day 129	Revised rapporteur's evaluation report
Day 150	Adoption of vPTMF certificate and evaluation report

185

186 **4.2.4. Certification**

187 Within 15 working days of the adoption of a positive evaluation report by the CVMP, the Agency will
188 issue a vPTMF certificate. The evaluation report will accompany the certificate.

189 Within 15 working days of the adoption of a negative evaluation report by the CVMP, the Agency will
190 issue a letter refusing the grant of a certificate for a vPTMF to the MAH. The evaluation report will be
191 attached to the refusal letter.

192 The vPTMF certificate holder will need to introduce the vPTMF certificate in the corresponding MA(s) via
193 the relevant variation. A variation not requiring assessment shall be submitted where the vPTMF data
194 package is identical to the corresponding sections of the authorised marketing authorisation dossier(s)
195 or, if changes have been made, these do not have an impact on the finished product. A variation
196 requiring assessment shall be submitted in case of changes in the vPTMF data package that may have
197 an impact on the finished product.

198 **5. Data requirements for initial application for certification**

199 The content of a vPTMF to be submitted for initial certification is briefly described in Annex II (section
200 V.4.1.2) to Regulation (EU) 2019/6. Further guidance on technical data requirements for vPTMF is
201 provided in the 'Guideline on data requirements for vaccine platform technology master files (vPTMF)'
202 (EMA/CVMP/IWP/286631/2021).

203 **6. Changes to the content of a vPTMF (Variations)**

204 **6.1. Legal framework**

205 A variation to the terms of a vPTMF certificate must be submitted in accordance with Commission
206 Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring
207 assessment in accordance with Regulation (EU) 2019/6 and with the EMA/CMDv Guidance on the
208 details of the classification of variations requiring assessment according to Article 62 of Regulation (EU)
209 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those
210 variations (EMA/CMDv/7381/2021; see Chapter H).

211 **6.2. Procedure for variations to the terms of a vPTMF certificate**

212 Changes to the content of a vPTMF for a vaccine authorised in the Union shall be subject to a scientific
213 and technical evaluation carried out by the Agency. The variation submission, data requirements and
214 evaluation will follow the current established procedure for variations to centralised MAs.

215 The Certificate Holder shall submit the vPTMF variation application and accompanying documentation
216 to the EMA. For variations requiring assessment, an expert statement including the Certificate Holder's
217 view of the possible impact of the vPTMF to each linked MA should be provided.

218 In the case of a positive evaluation, the Agency shall re-issue the certificate of compliance with Union
219 legislation for the vPTMF with the variation evaluation report attached, if applicable.

220 The vPTMF certificate holder will need to introduce the updated vPTMF certificate in the corresponding
221 MA(s) via the relevant variation. The type of variation required i.e. variation not requiring assessment
222 or variation requiring assessment, will depend on the impact of the change introduced in the vPTMF on
223 the finished product.

224 **7. Use of vPTMF certificates when submitting new MAAs**

225 When submitting an application for a new MA, the applicant should notify the EMA, if appropriate, of
226 the use of vPTMF certificates in the application.

227 The applicant will be required to provide to the EMA all valid vPTMF certificates of compliance to Union
228 legislation and accompanying evaluation reports.

229 The list of relevant medicinal products to which the vPTMF applies should be updated by the MAH after
230 the new MA has been granted. The MAH should have a record of the MAs to which the vPTMF applies
231 and should provide it to competent authorities upon request.

232 8. References

233 Regulation (EU) [2019/6](#) of the European Parliament and the Council of 11 December 2018 on
234 veterinary medicinal products and repealing Directive 2001/82/EC

235 Commission Delegated Regulation (EU) [2021/805](#) of 8 March 2021 amending Annex II to Regulation
236 (EU) 2019/6 of the European Parliament and of the Council.

237 Commission Implementing Regulation (EU) [2021/17](#) of 8 January 2021 establishing a list of variations
238 not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and
239 of the Council

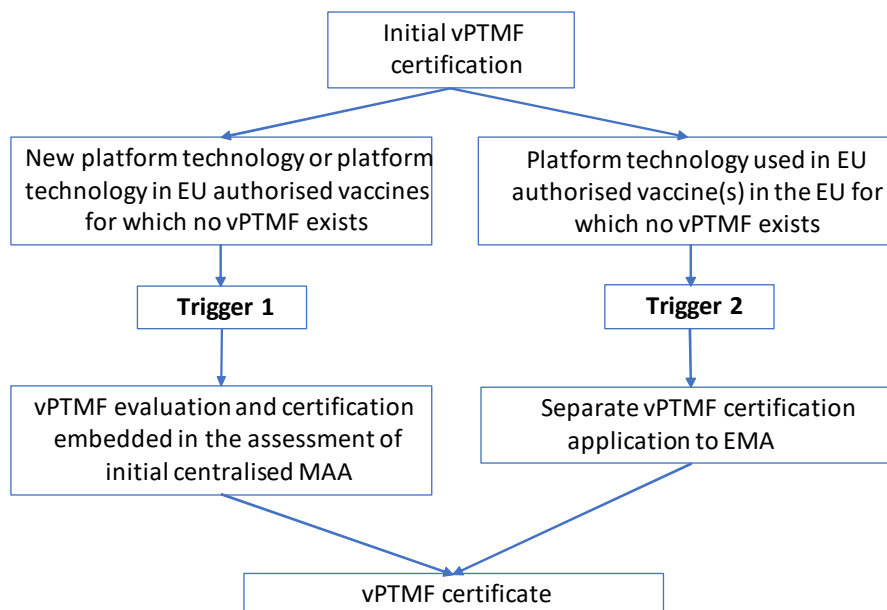
240 EMA/CMDv Guidance on the details of the classification of variations requiring assessment according to
241 Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be
242 submitted pursuant to those variations ([EMA/CMDv/7381/2021](#))

243 Guideline on data requirements for vaccine platform technology master files (vPTMF)
244 ([EMA/CVMP/IWP/286631/2021](#))

245 9. Annexes

246 Annex 1 - Triggers for vPTMF certification

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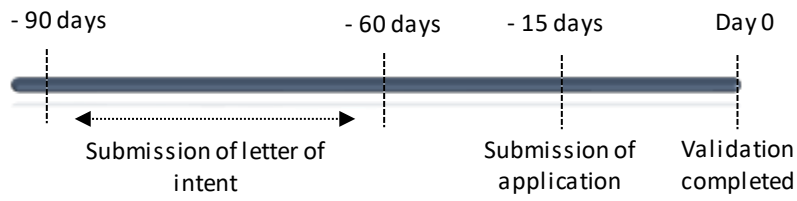


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250 Annex 2 - Pre-submission activities for initial certification of a vPTMF

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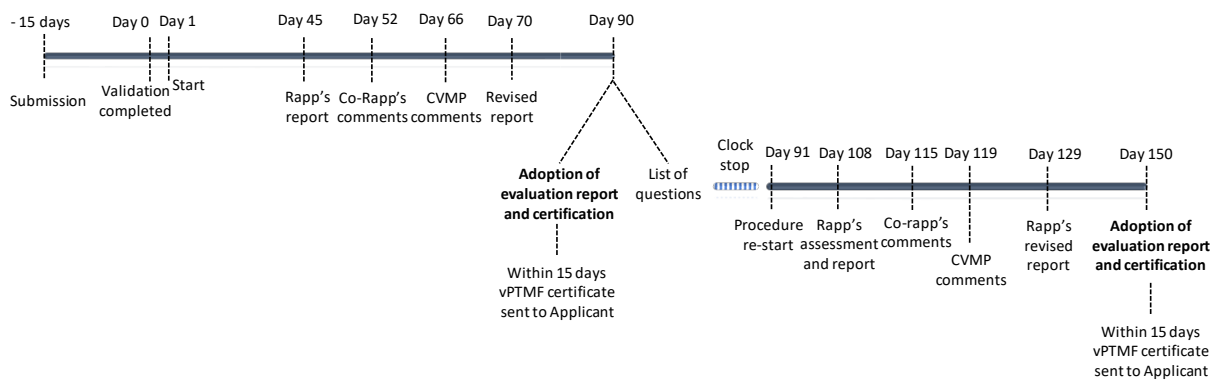


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254 Annex 3 – Timetable for certification of a vPTMF – Trigger 2

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