



1 23 July 2015  
2 EMA/CHMP/697051/2014-Rev. 1  
3 Committee for Medicinal Products for Human Use

4 **Guideline on the scientific application and the practical**  
5 **arrangements necessary to implement the procedure for**  
6 **accelerated assessment pursuant to article 14(9) of**  
7 **regulation (EC) No 726/2004**  
8 **Draft**

Adoption by CHMP for release for consultation	December 2005
End of consultation (deadline for comments)	February 2006
Revised draft adopted by CHMP	July 2006
Draft presented to CHMP, PRAC and CAT	May/June 2015
Adopted by the CHMP for release for consultation	23 July 2015
Start of public consultation	27 July 2015
End of consultation (deadline for comments)	30 September 2015
Date for coming into effect	To be confirmed

9 This guideline replaces 'Guideline on the procedure for Accelerated Assessment pursuant to Article  
10 14(9) of Regulation (EC) No 726/2004' (EMA/419127/05).

Comments should be provided using this [template](#). The completed comments form should be sent to [AA\\_guideline@ema.europa.eu](mailto:AA_guideline@ema.europa.eu)

**Keywords** *Accelerated Assessment*

**Note for the public consultation on this draft revision:** The European Medicines Agency is developing a scheme to facilitate development and accelerated assessment of innovative medicines of major public health interest and in particular from the viewpoint of therapeutic innovation to address unmet needs. The criteria for accelerated assessment laid down in this guideline are being considered for the access to this scheme.



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20 accelerated assessment pursuant to article 14(9) of  
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## 39 **Executive summary**

40 Based on the experience gathered by reviewing the approach taken to the assessment of past  
41 applications since the last version of the guideline in July 2006, it became apparent that some areas of  
42 the guideline would benefit from further clarifications, in particular with regards to the justifications  
43 provided by the applicant that the medicinal product falls within the scope of the accelerated  
44 assessment.

### 45 **1. Introduction**

46 Recital 33 of Regulation (EC) No 726/2004<sup>1</sup> states that “in order to meet, in particular the legitimate  
47 expectations of patients and to take account of the increasingly rapid progress of science and therapies,  
48 accelerated assessment procedures should be set up, reserved for medicinal products of major  
49 therapeutic interest, and procedures for obtaining temporary authorisations subject to certain annually  
50 reviewable conditions”.

51 Article 14 (9) of Regulation (EC) No 726/2004, states that “when an application is submitted for a  
52 marketing authorisation in respect of medicinal products for human use which are of major interest  
53 from the point of view of public health and in particular from the viewpoint of therapeutic innovation,  
54 the applicant may request an accelerated assessment procedure. The request shall be duly  
55 substantiated.

56 If the Committee for Medicinal Products for Human Use (CHMP) accepts the request, the time limit (of  
57 210 days to give an opinion) laid down in Article 6(3), first subparagraph, shall be reduced to 150  
58 days”

59 The accelerated assessment procedure is applicable to marketing authorisation applications for  
60 medicinal products for human use falling within the scope of articles 3(1) and 3(2) of Regulation (EC)  
61 No 726/2004. This includes medicinal products for treatment, prevention or diagnosis.

62 Recital 7 of Regulation (EC) No 507/2006<sup>2</sup> states that “applications containing requests for conditional  
63 marketing authorisations may be the subject of an accelerated assessment procedure in accordance  
64 with Article 14(9) of Regulation (EC) No 726/2004”.

### 65 **2. Scope**

66 The scope of this guideline is to provide applicants with guidance on the accelerated assessment  
67 request and the practical arrangements necessary to implement the legal provisions on the accelerated  
68 assessment procedure. It forms the basis for requesting an accelerated assessment, and should be  
69 followed unless otherwise justified. This guideline has to be read in conjunction with Notice to  
70 Applicants (Eudralex Volume 2), as well as other pertinent EU guidelines.

### 71 **3. Legal basis**

72 This guideline has been developed in accordance with Article 14 (9) of Regulation (EC) No 726/2004  
73 which refers to marketing authorisation applications for medicinal products of a major interest from the  
74 point of view of public health and in particular from the viewpoint of therapeutic innovation.

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<sup>1</sup> OJ L 136, 30/4/2004 p. 1 - 33.

<sup>2</sup> OJ L 92, 30/3/2006 p. 6 – 9.

## 75 **4. Justification that the medicinal product falls within the** 76 **scope of the accelerated assessment**

77 Based on the legislation, a medicinal product of major public health interest may be reviewed under an  
78 accelerated assessment procedure. However, there is no single definition of what constitutes major  
79 public health interest. This should be justified by the applicant and assessed by the CHMP on a case by  
80 case basis. Typically, the justification could present the arguments to support the claim that the  
81 medicinal product addresses to a significant extent the unmet medical needs for maintaining and  
82 improving the health of the Community, for example, by introducing new methods of therapy or  
83 improves existing ones. It is noted that a new mechanism of action or a *technical* innovation *per se*  
84 may not necessarily represent a valid argument for justifying major interest from the point of view of  
85 public health.

86 The items to be described in the justification, and the appropriate level of detail, should be evaluated  
87 on a case-by-case basis. The request should be presented as a short but comprehensive document  
88 (ideal length of 5-10 pages). The following aspects could be considered, as appropriate, in the  
89 justification:

- 90 – The unmet medical need and the available methods of prevention, diagnosis or treatment. In  
91 general, the justification may be more convincing if based as much as possible on epidemiological  
92 data about the disease (e.g., life expectancy, symptoms and duration, health-related quality of  
93 life). The claims could be substantiated e.g., from published literature or registries. If relevant, the  
94 unmet medical need could be described separately for different indications or subpopulations. In  
95 addition, a description of the available treatment options/standard of care (SOC), including all  
96 relevant treatment modalities, e.g., medicinal products used in clinical practice (whether approved  
97 or not), devices, surgery, radiotherapy could be included. The effect of available treatments could  
98 also be described together with a description of how the unmet medical need is not fulfilled by the  
99 available treatments.
- 100 – The extent to which the medicinal product is expected to fulfil the unmet medical need. This could  
101 include a description of the medicinal product's effects, their importance, the added value of the  
102 medicinal product and its impact on medical practice. This could include benefits and risks based  
103 on traditional efficacy and safety endpoints or other health outcomes (e.g., patient-reported  
104 outcomes, number of hospitalisations).
- 105 – The strength of evidence to support justifying major interest from the point of view of public health,  
106 for example the available evidence to establish that the product fulfils an unmet medical need,  
107 taking into account the regulatory requirements applicable for the intended application. It is  
108 acknowledged that in a number of situations (e.g., within the context of a conditional marketing  
109 authorisation) that comprehensive clinical data may not be available. The description of the  
110 strength of evidence could include a brief outline of the main available evidence (e.g., number and  
111 types of clinical trials, sample size, design and key results) on which the applicant bases its claim  
112 of addressing a major public health interest.

## 113 **5. General considerations regarding the granting of an** 114 **accelerated assessment procedure**

### 115 **5.1. Pre-submission dialogue**

116 The applicant is strongly advised to proactively enter into dialogue in order to prepare for an  
117 evaluation under accelerated assessment. When preparing the submission of a marketing authorisation

118 application, applicants have the opportunity to contact the PM to discuss relevant procedural or  
119 regulatory issues on the proposed submission. In view of a potential request for accelerated  
120 assessment, applicants should seek guidance from the PM to ensure timely submission of their request.

121 The intent to submit a request for an accelerated assessment should be notified as part of the  
122 notification of intent to submit a marketing authorisation application.

123 It is strongly recommended that the applicant requests pre-submission meetings with the Rapporteurs  
124 and EMA as early as possible, to discuss details of the upcoming accelerated assessment procedure  
125 including the available data package. The pre-submission meeting might be a joint meeting with  
126 Rapporteurs and the EMA product team attending. It is crucial for the accelerated assessment to  
127 achieve a mutual understanding of the data package that is planned to be included in the application.  
128 In case the applicant might foresee that relevant supplemental data will become available during the  
129 evaluation, details should be provided about timelines and how these supplemental data are  
130 considered of relevance for their marketing authorisation application. The rapporteurs might then  
131 advise on the submission strategy for the marketing authorisation application. It should be noted that  
132 applications should be mature in terms of the data submitted at the start of the evaluation, and that  
133 the planned submission timing is to be respected.

## 134 ***5.2. Timing of the request for an accelerated assessment and general*** 135 ***considerations***

136 The formal request for an accelerated assessment is submitted in a second step, as early as possible  
137 before the actual submission of the marketing authorisation application. This is to allow the relevant  
138 evidence to be included into the justification (see 4). In practice, the request should be submitted 2-3  
139 months before the actual submission of the marketing authorisation application in order to allow  
140 sufficient time for its assessment.

141 The applicant should ensure that the indicated date for submission of the Marketing Authorisation  
142 Application is accurate for planning purposes as changes to the date might impact availability of  
143 assessment teams.

144 Furthermore, an early identification of a need for pre-authorisation Good Manufacturing Practices  
145 (GMP) or Good Clinical Practices (GCP) inspections is advisable. The applicants should provide  
146 information relevant information with the request for accelerated assessment to allow identifying such  
147 need.

148 The request (consisting of the form and the justification) should be sent electronically. For procedural  
149 details please refer to the pre-authorisation guidance. It is recommended to copy the PM in the  
150 correspondence.

151 Depending on the applicant's submission date, the PM will set a timetable for the assessment of the  
152 request.

153 The Rapporteurs will produce a briefing note including the Rapporteurs' recommendations as to the  
154 appropriateness of an accelerated assessment.

155 Based on the request, the argumentations provided, and the recommendations of the Rapporteurs, the  
156 CHMP will take a decision on the request for accelerated assessment. If necessary, the CHMP may  
157 request clarifications from the applicant about the request.

158 The CHMP conclusion will be communicated to the applicant. The reasons for accepting or rejecting the  
159 request will also be summarised in the final CHMP assessment report of the marketing authorisation.

160 A decision on accelerated assessment will be taken without prejudice to the CHMP opinion (positive or  
161 negative) on the granting of a marketing authorisation.

### 162 **5.3. Possible change to standard timetable**

163 Following the granting of a request, the CHMP shall adhere to the accelerated timetable in accordance  
164 with Article 14(9) of Regulation (EC) No 726/2004 for the assessment. However, at any time during  
165 the marketing authorisation application assessment, if the CHMP considers that it is no longer  
166 appropriate to conduct an accelerated assessment, the CHMP may decide to continue the assessment  
167 under the standard centralised procedure assessment timelines, following an appropriate timetable to  
168 be adopted by the CHMP, according to Article 6 (3) of Regulation (EC) No 726/2004.

169 Examples of such situations are when major objections have been identified that cannot be handled in  
170 an accelerated timetable, when a longer clock-stop longer is requested by the applicant (e.g. to  
171 prepare for the oral explanation), or when the need for GMP or GCP inspection becomes apparent.  
172 Similarly, in case of a negative trend following the oral explanation, the CHMP may decide to continue  
173 the assessment under standard assessment timelines.

174 The new timetable will be communicated to the applicant. Where appropriate, the CHMP will explain  
175 the reasons for the change to the assessment timetable.

176 The applicant may also submit a justified request for a change to a “normal” assessment procedure,  
177 for example if additional time is needed for the applicant to provide any information requested by the  
178 CHMP. The CHMP shall consider such requests on a case-by-case basis and if appropriate adopt a  
179 revised timetable following Article 6 (3) of Regulation (EC) No 726/2004. The new timetable will be  
180 communicated to the applicant.

## 181 **6. Timetable for the accelerated assessment procedure**

### 182 **6.1. Pre-submission phase**

183 – 6 – 7 months before the actual submission of the marketing authorisation application: Notify the  
184 intention to submit a request for accelerated assessment as part of the letter of intent.

185 – Pre-submission meetings with the Rapporteurs and the EMA

186 – 2 – 3 months before the actual submission of the marketing authorisation application: Submission  
187 of request for accelerated assessment:

- 188 • Circulation of Rapporteurs’ briefing note to the CHMP with  
189 recommendations on the request for accelerated assessment.
- 190 • CHMP discussion and conclusion on the request for accelerated assessment.  
191 The conclusions are communicated to the applicant at the end of the CHMP  
192 meeting during which the request was discussed.

### 193 **6.2. Accelerated assessment procedure**

194 – Day 1 Start of the procedure.

- 195 • CHMP Rapporteurs’ assessment reports
  - 196 • PRAC Rapporteur updated assessment report
  - 197 • Peer-review phase
-

- 198 – Day 90 CHMP week with adoption of either:
- 199 • CHMP positive opinion or;
- 200 • CHMP list of questions to the applicant to be addressed in writing and at an
- 201 oral explanation if necessary with maintenance of the accelerated
- 202 timetable. The CHMP may also adopt questions for a Scientific Advisory
- 203 Group, as applicable; or
- 204 • CHMP list of questions to the applicant to address in writing and at an oral
- 205 explanation if necessary with switch to a standard timetable (see 5.2).
- 206 – Stop of the clock: One month stop of the clock by default.
- 207 – Day 91 Restart of the clock by submission of the applicant's written responses.
- 208 • CHMP and PRAC assessment report of the responses
- 209 – Day 120 CHMP week with either:
- 210 • CHMP positive opinion or;
- 211 • CHMP list of questions to the applicant to address in writing if necessary
- 212 with maintenance of the accelerated timetable.
- 213 • CHMP list of questions to the applicant to address in writing and at an oral
- 214 explanation if necessary with switch to a standard timetable (see 5.2).
- 215 – No Stop of the clock: The CHMP would request the submission of the written responses without
- 216 clock-stop
- 217 – D121 Submission of written responses
- 218 • CHMP and PRAC assessment report of the responses
- 219 – Day 150 CHMP opinion
- 220 Applicants are reminded of the importance in complying with their intended submission date of the
- 221 application as any unexpected delay may considerably impact the CHMP and PRAC Rapporteurs' team
- 222 organisation in handling the procedure under the accelerated timetable. Any changes to the submission
- 223 time should be communicated promptly to the Agency.
- 224 In case of Advanced Therapy Medicinal Products, the timetable would be arranged to include the
- 225 review by the Committee for Advanced Therapies. Also a request for accelerated assessment would be
- 226 reviewed by this committee before endorsement of the outcome by CHMP.
- 227 In order to allow for adequate evaluation periods the Agency will not initiate any accelerated
- 228 assessment evaluation with a starting date in December.
- 229

230 **Definitions**

231 CHMP: Committee for Medicinal Products for Human Use

232 EC: European Commission

233 EMA: European Medicines Agency

234 EU: European Union

235 GCP: Good Clinical Practice

236 GMP: Good Manufacturing Practice

237 MAA: Marketing Authorisation Application

238 SAG: Scientific Advisory Group

239 SOC: Standard of Care

240 PM: Procedure Manager