Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)

TITLE II

MARKETING AUTHORISATION REQUIREMENTS

CHAPTER 1

General authorisation requirements

Article 7

1 An application for marketing authorisation under Article 6 of Directive 2001/83/EC in respect of a medicinal product for human use which is not authorised in the Community at the time of entry into force of this Regulation shall be regarded as valid only if it includes, in addition to the particulars and documents referred to in Article 8(3) of Directive 2001/83/EC, one of the following:

a the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;

b a decision of the Agency granting a product-specific waiver;

c a decision of the Agency granting a class waiver pursuant to Article 11;

d a decision of the Agency granting a deferral.

For the purposes of point (a), the decision of the Agency agreeing the paediatric investigation plan concerned shall also be included in the application.

2 The documents submitted pursuant to paragraph 1 shall, cumulatively, cover all subsets of the paediatric population.

Article 8

In the case of authorised medicinal products which are protected either by a supplementary protection certificate under Regulation (EEC) No 1768/92, or by a patent which qualifies for the granting of the supplementary protection certificate, Article 7 of this Regulation shall apply to applications for authorisation of new indications, including paediatric indications, new pharmaceutical forms and new routes of administration.

For the purposes of the first subparagraph, the documents referred to in Article 7(1) shall cover both the existing and the new indications, pharmaceutical forms and routes of administration.

Article 9

Articles 7 and 8 shall not apply to products authorised under Articles 10, 10a, 13 to 16 or 16a to 16i of Directive 2001/83/EC.

Article 10

In consultation with the Member States, the Agency and other interested parties, the Commission shall draw up the detailed arrangements concerning the format and content which applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals must follow in order to be considered valid and concerning the operation of the compliance check referred to in Articles 23 and 28(3).

CHAPTER 2

Waivers

Article 11

1 Production of the information referred to in point (a) of Article 7(1) shall be waived for specific medicinal products or for classes of medicinal products, if there is evidence showing any of the following:

a that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population;

b that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations;

c that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

2 The waiver provided for in paragraph 1 may be issued with reference either to one or more specified subsets of the paediatric population, or to one or more specified therapeutic indications, or to a combination of both.

Article 12

The Paediatric Committee may of its own motion adopt an opinion, on the grounds set out in Article 11(1), to the effect that a class or a product-specific waiver, as referred to in Article 11(1), should be granted.

As soon as the Paediatric Committee adopts an opinion, the procedure laid down in Article 25 shall apply. In the case of a class waiver, only paragraphs 6 and 7 of Article 25 shall apply.

Article 13

1 The applicant may, on the grounds set out in Article 11(1), apply to the Agency for a product-specific waiver.

2 Following receipt of the application, the Paediatric Committee shall appoint a rapporteur and shall within 60 days adopt an opinion as to whether or not a product-specific waiver should be granted.

Either the applicant or the Paediatric Committee may request a meeting during that 60-day period.

Whenever appropriate, the Paediatric Committee may request the applicant to supplement the particulars and documents submitted. Where the Paediatric Committee avails itself of this option, the 60-day time-limit shall be suspended until such time as the supplementary information requested has been provided.

3 As soon as the Paediatric Committee adopts an opinion, the procedure laid down in Article 25 shall apply.

Article 14

1 The Agency shall maintain a list of all waivers. The list shall be regularly updated (at least every year) and made available to the public.

2 The Paediatric Committee may, at any time, adopt an opinion advocating the review of a granted waiver.

In the case of a change affecting a product-specific waiver, the procedure laid down in Article 25 shall apply.

In the case of a change affecting a class waiver, paragraphs 6 and 7 of Article 25 shall apply.

3 If a particular product-specific or class waiver is revoked, the requirement set out in Articles 7 and 8 shall not apply for 36 months from the date of the removal from the list of waivers.

CHAPTER 3

Paediatric investigation plan

Section 1

Requests for agreement

Article 15

1 Where the intention is to apply for a marketing authorisation in accordance with Article 7(1)(a) or (d), Article 8 or Article 30, a paediatric investigation plan shall be drawn up and submitted to the Agency with a request for agreement.

2 The paediatric investigation plan shall specify the timing and the measures proposed to assess the quality, safety and efficacy of the medicinal product in all subsets of the paediatric population that may be concerned. In addition, it shall describe any measures to adapt the formulation of the medicinal product so as to make its use more acceptable, easier, safer or more effective for different subsets of the paediatric population.

Article 16

1 In the case of the applications for marketing authorisation referred to in Articles 7 and 8 or the applications for waiver referred to in Articles 11 and 12, the paediatric investigation plan or the application for waiver shall be submitted with a request for agreement, except in duly justified cases, not later than upon completion of the human pharmaco-kinetic studies in adults specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, so as to ensure that an opinion on use in the paediatric population of the medicinal product concerned can be given at the time of the assessment of the marketing authorisation or other application concerned.

2 Within 30 days following receipt of the request referred to in paragraph 1 and in Article 15(1), the Agency shall verify the validity of the request and prepare a summary report for the Paediatric Committee.

3 Whenever appropriate, the Agency may ask the applicant to submit additional particulars and documents, in which case the time-limit of 30 days shall be suspended until such time as the supplementary information requested has been provided.

Article 17

1 Following receipt of a proposed paediatric investigation plan which is valid in accordance with the provisions of Article 15(2), the Paediatric Committee shall appoint a rapporteur and shall within 60 days adopt an opinion as to whether or not the proposed studies will ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or subsets thereof, and as to whether or not the expected therapeutic benefits justify the studies proposed. When adopting its opinion, the Committee shall consider whether or not the measures proposed to adapt the formulation of the medicinal product for use in different subsets of the paediatric population are appropriate.

Within the same period, either the applicant or the Paediatric Committee may request a meeting.

2 Within the 60-day period referred to in paragraph 1, the Paediatric Committee may request the applicant to propose modifications to the plan, in which case the time-limit referred to in paragraph 1 for the adoption of the final opinion shall be extended for a maximum of 60 days. In such cases, the applicant or the Paediatric Committee may request an additional meeting during this period. The time-limit shall be suspended until such time as the supplementary information requested has been provided.

Article 18

As soon as the Paediatric Committee adopts an opinion, whether positive or negative, the procedure laid down in Article 25 shall apply.

Article 19

If, having considered a paediatric investigation plan, the Paediatric Committee concludes that Article 11(1)(a), (b) or (c) applies to the medicinal product concerned, it shall adopt a negative opinion under Article 17(1).

In such cases, the Paediatric Committee shall adopt an opinion in favour of a waiver under Article 12, whereupon the procedure laid down in Article 25 shall apply.

Section 2

Deferrals

Article 20

1 At the same time as the paediatric investigation plan is submitted under Article 16(1), a request may be made for deferral of the initiation or completion of some or all of the measures set out in that plan. Such deferral shall be justified on scientific and technical grounds or on grounds related to public health.

In any event, a deferral shall be granted when it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population or when studies in the paediatric population will take longer to conduct than studies in adults.

[[F1]2 On the basis of the experience acquired as a result of the operation of this Article, the Commission may adopt provisions, in accordance with the regulatory procedure with scrutiny referred to in Article 51(2), amending or supplementing non-essential elements of this Regulation to define further the grounds for granting a deferral.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use (Text with EEA relevance).

Article 21

1 At the same time as the Paediatric Committee adopts a positive opinion under Article 17(1), it shall, of its own motion or following a request submitted by the applicant under Article 20, adopt an opinion, if the conditions specified in Article 20 are met, in favour of deferring the initiation or completion of some or all of the measures in the paediatric investigation plan.

An opinion in favour of a deferral shall specify the time-limits for initiating or completing the measures concerned.

2 As soon as the Paediatric Committee adopts an opinion in favour of deferral, as referred to in paragraph 1, the procedure laid down in Article 25 shall apply.

Section 3

Modification of a paediatric investigation plan

Article 22

If, following the decision agreeing the paediatric investigation plan, the applicant encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate, the applicant may propose changes or request a deferral or a waiver, based on detailed grounds, to the Paediatric Committee. Within 60 days, the Paediatric Committee shall review these changes or the request for a deferral or a waiver and adopt an opinion proposing their refusal or acceptance. As soon as the Paediatric Committee adopts an opinion, whether positive or negative, the procedure laid down in Article 25 shall apply.

Section 4

Compliance with the paediatric investigation plan

Article 23

1 The competent authority responsible for granting marketing authorisation shall verify whether an application for marketing authorisation or variation complies with the requirements laid down in Articles 7 and 8 and whether an application submitted pursuant to Article 30 complies with the agreed paediatric investigation plan.

Where the application is submitted in accordance with the procedure set out in Articles 27 to 39 of Directive 2001/83/EC, the verification of compliance, including,

as appropriate, requesting an opinion of the Paediatric Committee in accordance with paragraph 2(b) and (c) of this Article, shall be conducted by the reference Member State.

2 The Paediatric Committee may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan:

a by the applicant, prior to submitting an application for marketing authorisation or variation as referred to in Articles 7, 8 and 30, respectively;

b by the Agency, or the national competent authority, when validating an application, as referred to in point (a), which does not include an opinion concerning compliance adopted following a request under point (a);

c by the Committee for Medicinal Products for Human Use, or the national competent authority, when assessing an application, as referred to in point (a), where there is doubt concerning compliance and an opinion has not been already given following a request under points (a) or (b).

In the case of point (a), the applicant shall not submit its application until the Paediatric Committee has adopted its opinion, and a copy thereof shall be annexed to the application.

3 If the Paediatric Committee is requested to give an opinion under paragraph 2, it shall do so within 60 days of receiving the request.

Member States shall take account of such an opinion.

Article 24

If, when conducting the scientific assessment of a valid application for Marketing Authorisation, the competent authority concludes that the studies are not in conformity with the agreed paediatric investigation plan, the product shall not be eligible for the rewards and incentives provided for in Articles 36, 37 and 38.

CHAPTER 4

Procedure

Article 25

1 Within ten days of its receipt, the Agency shall transmit the opinion of the Paediatric Committee to the applicant.

2 Within 30 days following receipt of the opinion of the Paediatric Committee, the applicant may submit to the Agency a written request, citing detailed grounds, for a re-examination of the opinion.

3 Within 30 days following receipt of a request for re-examination pursuant to paragraph 2, the Paediatric Committee, having appointed a new rapporteur, shall issue a new opinion confirming or revising its previous opinion. The rapporteur shall be able to question the applicant directly. The applicant may also offer to be questioned. The rapporteur shall inform the Paediatric Committee without delay in writing about details of contacts with the applicant. The opinion shall be duly reasoned and a statement of reasons for the conclusion reached shall be annexed to the new opinion, which shall become definitive.

4 If, within the 30-day period referred to in paragraph 2, the applicant does not request re-examination, the opinion of the Paediatric Committee shall become definitive.

5 The Agency shall adopt a decision within a period not exceeding 10 days following receipt of the Paediatric Committee's definitive opinion. This decision shall be communicated to the applicant in writing and shall annex the definitive opinion of the Paediatric Committee.

6 In the case of a class waiver as referred to in Article 12, the Agency shall adopt a decision within ten days following receipt of the opinion of the Paediatric Committee as referred to in Article 13(3). This decision shall annex the opinion of the Paediatric Committee.

7 Decisions of the Agency shall be made public after deletion of any information of a commercially confidential nature.

CHAPTER 5

Miscellaneous provisions

Article 26

Any legal or natural person developing a medicinal product intended for paediatric use may, prior to the submission of a paediatric investigation plan and during its implementation, request advice from the Agency on the design and conduct of the various tests and studies necessary to demonstrate the quality, safety and efficacy of the medicinal product in the paediatric population in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004.

In addition, this legal or natural person may request advice on the design and conduct of pharmacovigilance and risk management systems as referred to in Article 34.

The Agency shall provide advice under this Article free of charge.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1901/2006 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.