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 III

MARKETING AUTHORISATION PROCEDURES

Article 27

Save where otherwise provided in this Title, marketing authorisation procedures for the marketing authorisations covered by this Title shall be governed by the provisions laid down in Regulation (EC) No 726/2004 or in Directive 2001/83/EC.

CHAPTER 1

Marketing authorisation procedures for applications falling within the scope of Articles 7 and 8

Article 28

1 Applications may be submitted in accordance with the procedure laid down in Articles 5 to 15 of Regulation (EC) No 726/2004 for a marketing authorisation as referred to in Article 7(1) of this Regulation which includes one or more paediatric indications on the basis of studies conducted in compliance with an agreed paediatric investigation plan.

Where authorisation is granted, the results of all those studies shall be included in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product, provided that the competent authority deems the information to be of use to patients, whether or not all the paediatric indications concerned were approved by the competent authority.

2 Where a marketing authorisation is granted or varied, any waiver or deferral which has been granted pursuant to this Regulation shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

3 If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan. For the purpose of the application of Article 45(3), this statement shall also indicate whether significant studies contained in the agreed Paediatric Investigation Plan have been completed after the entry into force of this Regulation.

Article 29

In the case of medicinal products authorised under Directive 2001/83/EC, an application as referred to in Article 8 of this Regulation may be submitted, in accordance with the procedure laid down in Articles 32, 33 and 34 of Directive 2001/83/EC, for authorisation

of a new indication, including the extension of an authorisation for use in the paediatric population, a new pharmaceutical form or a new route of administration.

That application shall comply with the requirement laid down in point (a) of Article 7(1).

The procedure shall be limited to the assessment of the specific sections of the summary of product characteristics to be varied.

CHAPTER 2

Paediatric use marketing authorisation

Article 30

1 Submission of an application for a paediatric use marketing authorisation shall in no way preclude the right to apply for a marketing authorisation for other indications.

2 An application for a paediatric use marketing authorisation shall be accompanied by the particulars and documents necessary to establish quality, safety and efficacy in the paediatric population, including any specific data needed to support an appropriate strength, pharmaceutical form or route of administration for the product, in accordance with an agreed paediatric investigation plan.

The application shall also include the decision of the Agency agreeing the paediatric investigation plan concerned.

3 Where a medicinal product is or has been authorised in a Member State or in the Community, data contained in the dossier on that product may, where appropriate, be referred to, in accordance with Article 14(11) of Regulation (EC) No 726/2004 or Article 10 of Directive 2001/83/EC, in an application for a paediatric use marketing authorisation.

4 The medicinal product in respect of which a paediatric use marketing authorisation is granted may retain the name of any medicinal product which contains the same active substance and in respect of which the same holder has been granted authorisation for use in adults.

Article 31

Without prejudice to Article 3(2) of Regulation (EC) No 726/2004, an application for a paediatric use marketing authorisation may be made in accordance with the procedure laid down in Articles 5 to 15 of Regulation (EC) No 726/2004.

CHAPTER 3

Identification

Article 32

1 Where a medicinal product is granted a marketing authorisation for a paediatric indication, the label shall display the symbol agreed in accordance with paragraph 2. The package leaflet shall contain an explanation of the meaning of the symbol.

2 By 26 January 2008, the Commission shall select a symbol following a recommendation of the Paediatric Committee. The Commission shall make the symbol public.

3 The provisions of this Article shall also apply to medicinal products authorised before the entry into force of this Regulation, and to medicinal products authorised after the entry into force of this Regulation but before the symbol has been made public, if they are authorised for paediatric indications.

In this case, the symbol and the explanation referred to in paragraph 1 shall be included in the labelling and package leaflet respectively of the medicinal products concerned not later than two years after the symbol has been made public.

Status:
Point in time view as at 31/12/2020.

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.