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 VI

COMMUNICATION AND COORDINATION

Article 41

1 The European database created by Article 11 of Directive 2001/20/EC shall include clinical trials carried out in third countries which are contained in an agreed paediatric investigation plan, in addition to the clinical trials referred to in Articles 1 and 2 of that Directive. In the case of such clinical trials carried out in third countries, the details listed in Article 11 of that Directive shall be entered into the database by the addressee of the Agency's decision on a paediatric investigation plan.

By way of derogation from the provisions of Article 11 of Directive 2001/20/EC, the Agency shall make public part of the information on paediatric clinical trials entered in the European database.

2 Details of the results of all the trials referred to in paragraph 1 and of any other trials submitted to competent authorities in compliance with Articles 45 and 46 shall be made public by the Agency, whether or not the trial was terminated prematurely. These results shall be submitted without delay to the Agency by the clinical trial sponsor, the addressee of the Agency's decision on a paediatric investigation plan, or by the marketing authorisation holder as appropriate.

3 In consultation with the Agency, Member States and interested parties, the Commission shall draw up guidance on the nature of the information referred to in paragraph 1 to be entered in the European database created by Article 11 of Directive 2001/20/EC, on which information shall be made accessible to the public in application of paragraph 1, on how clinical trial results shall be submitted and be made public in application of paragraph 2, and on the Agency's responsibilities and tasks in this regard.

Article 42

Member States shall collect available data on all existing uses of medicinal products in the paediatric population and shall communicate these data to the Agency by 26 January 2009.

The Paediatric Committee shall provide guidance on the content and the format of the data to be collected by 26 October 2007.

Article 43

1 On the basis of the information referred to in Article 42 and after consulting the Commission, the Member States and the interested parties, the Paediatric Committee shall establish an inventory of therapeutic needs, in particular with a view to identifying research priorities.

The Agency shall make the inventory public at the earliest by 26 January 2009 and at the latest by 26 January 2010 and shall update it regularly.

2 In establishing the inventory of therapeutic needs, account shall be taken of the prevalence of the conditions in the paediatric population, the seriousness of the conditions to be treated, the availability and suitability of alternative treatments for the conditions in the paediatric population, including the efficacy and the adverse reaction profile of those treatments, including any unique paediatric safety issues, and any data resulting from studies in third countries.

Article 44

1 The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.

2 The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

3 By 26 January 2008, the Management Board of the Agency shall, on a proposal from the Executive Director and following consultation with the Commission, the Member States and interested parties, adopt an implementing strategy for the launching and operation of the European network. This network must, where appropriate, be compatible with the work of strengthening the foundations of the European Research Area in the context of the Community Framework Programmes for Research, Technological Development and Demonstration Activities.

Article 45

1 By 26 January 2008, any paediatric studies already completed, by the date of entry into force, in respect of products authorised in the Community shall be submitted by the marketing authorisation holder for assessment to the competent authority.

The competent authority may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly. Competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

The Agency shall coordinate the exchange of information.

2 All existing paediatric studies, as referred to in paragraph 1, and all paediatric studies initiated prior to the entry into force of this Regulation shall be eligible to be included in a paediatric investigation plan, and shall be taken into consideration by the Paediatric Committee when assessing applications for paediatric investigation plans, waivers and deferrals and by competent authorities when assessing applications submitted pursuant to Article 7, 8 or 30.

3 Without prejudice to the previous paragraph, the rewards and incentives of Articles 36, 37 and 38 shall only be granted provided that significant studies contained in an agreed Paediatric Investigation Plan are completed after the entry into force of this Regulation.

4 In consultation with the Agency, the Commission shall draw up guidelines to establish assessment criteria for the significance of studies for the purposes of applying paragraph 3.

Article 46

1 Any other marketing authorisation holder-sponsored studies which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation, whether

or not they are conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the competent authority within six months of completion of the studies concerned.

2 Paragraph 1 shall apply independent of whether or not the marketing authorisation holder intends to apply for a marketing authorisation of a paediatric indication.

3 The competent authority may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly.

4 Competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

5 The Agency shall coordinate the exchange of information.

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.