PROCEDURAL NOTE CONCERNING THE APPLICATION OF ARTICLES 28(3), 36 AND 37 OF REGULATION 1901/2006

Pursuant to Article 36(1) of *Regulation (EC) No 1901/2008 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*[1], the holder of a patent or supplementary protection certificate is entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92[2] under certain conditions. Article 36(2) provides that "the inclusion in a marketing authorisation of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article".

Pursuant to Article 37 of Regulation (EC) No 1901/2006, the holder of a marketing authorisation for an orphan medicinal product is entitled to an extension of the ten year period referred to in Article 8(1) of Regulation (EC) No 141/2000 to twelve years under certain conditions, including that "the statement referred to in Article 28(3) of this Regulation is subsequently included in the marketing authorisation".

In the context of the review of Commission Regulation (EC) 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products ("Variations Regulation"), the European Commission and the Member States have agreed that the statement provided for under Article 28(3) of Regulation (EC) No 1901/2006 shall be included together with other technical information that forms part of the marketing authorisation ("technical dossier").

For reasons of legal certainty, the competent authorities in the Member States or, in the case of centralised marketing authorisations, the European Medicines Agency ("Agency") shall provide the marketing authorisation holder with a confirmation that the compliance statement is included in the technical dossier of the marketing authorisation.

The confirmation shall be provided to the holder within the following deadlines:

(i) For centralised marketing authorisations, within 30 days after the Agency has terminated the relevant assessment.

(ii) For marketing authorisations granted in accordance with Directive 87/22/EC or Chapter 4 of Directive 2001/83/EC, within 30 days after the competent authority has been informed by the competent authority of the reference Member State of the outcome of the relevant assessment.

(iii) For purely national marketing authorisations, within 30 days after the competent authority has terminated the relevant assessment.

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[1] OJ L 378, 27.12.2006, p. 1.

[2] From 6 July 2009, this Regulation has been repealed by Regulation (EC) No 469/2009.