Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (Text with EEA relevance)

Article 2

Amendments to Directive 2001/83/EC

Directive 2001/83/EC is hereby amended as follows:

1. the following Article shall be inserted:

Article 23b

1 The Commission shall adopt appropriate arrangements for the examination of variations to the terms of marketing authorisations granted in accordance with this Directive.

2 The Commission shall adopt the arrangements referred to in paragraph 1 in the form of an implementing regulation. That measure, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).

3 When adopting the arrangements referred to in paragraph 1, the Commission shall make efforts to make it possible to submit a single application for one or more identical changes made to the terms of a number of marketing authorisations.

4 A Member State may continue to apply national provisions on variations applicable at the time of entry into force of the implementing regulation to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions in accordance with this Article is subsequently granted a marketing authorisation in another Member State, the implementing regulation shall apply to that medicinal product from that date.

5 Where a Member State decides to continue to apply national provisions pursuant to paragraph 4, it shall notify the Commission thereof. If a notification has not been made by 20 January 2011, the implementing regulation shall apply.

2. the second and third subparagraphs of Article 35(1) shall be deleted.