

Medicinal products for human and veterinary use: marketing authorisations

2008/0045(COD) - 18/06/2009 - Final act

PURPOSE: to amend Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products.

LEGISLATIVE ACT: Directive 2009/53/EC of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products.

CONTENT: following a first reading agreement with the European Parliament, the Council adopted a directive amending two directives on the Community code relating to medicinal products. The German delegation abstained. The Directive aims to ensure that all medicinal products are subject to the same criteria for the evaluation, approval and administrative treatment of variations in the production process, in the packaging or in the address of the manufacturer.

Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, lay down harmonised rules for the authorisation, supervision and pharmacovigilance of medicinal products within the Community.

Under those rules, marketing authorisations may be granted in accordance with harmonised Community procedures. The terms of those marketing authorisations may subsequently be varied where, for instance, the production process or the address of the manufacturer has changed.

The Directives empower the Commission to adopt an implementing regulation as regards variations subsequently made to marketing authorisations. The Commission therefore adopted Regulation (EC) No 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

However, the majority of medicinal products for human or veterinary use currently on the market have been authorised under purely national procedures and, as such, fall outside the scope of Regulation (EC) No 1084/2003. Variations to marketing authorisations granted under purely national procedures are thus subject to national rules.

Consequently, while the granting of all marketing authorisations for medicinal products is subject to harmonised rules within the Community, this is not the case for variations to the terms of marketing authorisations.

For reasons of public health and legal consistency, and with a view to reducing the administrative burden and strengthening predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.

The rules on variations adopted by the Commission should pay particular attention to simplifying administrative procedures. To this effect, the Commission should provide, when adopting these rules, for the possibility of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations.

As part of the compromise between the European Parliament and the Council, the Directive stipulates that 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.

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

Directive 2001/82/EC and Directive 2001/83/EC is therefore amended accordingly.

ENTRY INTO FORCE: 20 July 2009.

TRANSPOSITION: 20 January 2011 at the latest.