Medicinal products for human and veterinary use: marketing authorisations

2008/0045(COD) - 09/09/2008

The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Francoise **GROSSETETE** (PES, FR) and amended the proposal for a directive 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.

The main amendments are as follows:

- the possibility of filing a single application for one or more identical changes to the terms of a number of marketing authorisations must be extended to all the types of change in order to simplify and optimise the procedures;

- under the current system, Regulations (EC) No 1084/2003 and No 1085/2003 provide for the possibility, in the case of an extension of a marketing authorisation, of filing a complete, separate request for authorisation for a medicinal product that has already been authorised, but under another name and with a different product characteristic summary. It is essential that this possibility should be retained. Some names of medicines have strong associations to a certain pathology, and it could have a damaging effect on patients if the same name were kept when the pathology treated by the medicine had changed completely;

- the appropriate arrangements adopted by the Commission must take the following considerations into account: for practical reasons of efficiency, the possibility should be extended to all the categories of change of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations. As regards extensions of marketing authorisations, the possibility should be provided, on the basis of arguments in justification, of submitting a complete, separate application for authorisation for a medicinal product that has already been authorised under another name and with a different product characteristic summary;

- a new clause states that Member States may continue to apply national provisions on variations applicable at the time of entry into force of this 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;

- the committee deleted the provisions in the proposal which were intended solely to bring Directive 2001/82/EC into line with the relevant new comitology procedure (the regulatory procedure with scrutiny). It stated that those provisions were not directly related to the subject of the proposal, that is to say, changes to marketing authorisations. They already appear, moreover, in the Commission's 'all-inclusive' proposal (see COD/2008/0032) and are consequently redundant in this proposal;

- transposition should be 18 months (rather than 12 months) after entry into force of the Directive.