# Medicinal products for human and veterinary use: marketing authorisations

2008/0045(COD) - 22/10/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 675 votes to 21 with 8 abstentions, a legislative resolution amending 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 report had been tabled for consideration in plenary by Francoise **GROSSETETE** (PES, FR) on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments were the result of a compromise between the Council and the Parliament.

The main amendments - adopted under 1st reading of the codecision procedure - were as follows:

- Parliament considered that the rules on variations adopted by the Commission should pay particular attention to simplifying administrative procedures. To this effect, the Commission should foresee, when adopting these rules, certain possibilities of filing a single application for one or more identical changes to the terms of a number of marketing authorisations. Accordingly, the Commission shall make efforts to extend the possibility of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations;

- 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 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. If a notification has not been made by 18 months after entry into force of the directive, the implementing regulation shall apply.