

Community code relating to medicinal products for human use: implementing powers of the Commission

2006/0295(COD) - 26/06/2007

The Committee on the Environment, Public Health and Food Safety adopted by a large majority the report drafted by Françoise **GROSSETETE** (EPP-ED, FR) and made three amendments to the Commission's proposal:

- a new clause was inserted stating that a list of herbal substances, and preparations and combinations of such substances for use in traditional herbal medicinal products, designed to amend non-essential elements of the Directive by supplementing it, must be established in accordance with the regulatory procedure with scrutiny. This list must contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product;
- the final measures designed to amend non-essential elements of the Directive by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny;
- whilst the Commission had proposed the deletion of Article 121(4), the Committee felt that this paragraph should remain, since the comitology committee should be obliged to publish its internal rules.