Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

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The Council held a policy debate on the basis of a Presidency questionnaire on three proposals - a Regulation (the current text) and two Directives (COD/2001/0253) and (COD/2001/0254) - the main aims of which are to achieve completion of the single market in the medicinal products sector, to improve the competitiveness of the pharmaceutical industry (particularly small and medium-sized enterprises) and to simplify Community legislation. The Opinion of the European Parliament at first reading should be available in October 2002. Two topics were discussed at this stage following the proceedings of the Working Party: - the scope of the proposal for a Regulation: the text provides for extension of the compulsory centralised Community procedure to medicinal products for human or veterinary use containing new active substances; a majority of delegations wanted to be able to continue to choose between a centralised system and a system of national authorisations with the principle of mutual recognition. Some delegations, however, made distinctions depending on whether the medicinal product was for human or veterinary use. Some delegations said they could support an extension of the scope for medicinal products for human use only. Delegations which recommended an optional system put forward the following main arguments: several delegations wanted the Commission to provide a better definition of medicinal products containing new active substances; several delegations expressed concern regarding the situation of small and medium-sized enterprises and argued that some flexibility was the best solution for them; some delegations expressed fears that extension of a centralised procedure would not take sufficient account of the views of national authorities. As regards medicinal products for veterinary use, some delegations pointed out that, since in some cases their use and authorisation involved only a few regional animal species (e.g. northern Finland), a national authorisation system would be preferable. Some delegations stressed in particular the need to improve the technical resources of the European Agency for the Evaluation of Medicinal Products (EMEA) - computerised files, national databases - and to extend its evaluation methods, along the lines of the methods available to the United States Food and Drug Administration. - the new composition of the Management Board of the European Agency for the Evaluation of Medicinal Products (EMEA): under the proposal this Board would consist of four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission and four representatives of patients and the industry; a very large majority of delegations wanted to maintain representation by Member States only. Two delegations stressed in particular the need for the Management Board to have a composition different from that of the European Food Safety Authority (EFSA) - a consultative body - taking account of the executive role of the EMEA in issuing authorisations for placing medicinal products on the market. The Council agreed to take account of these positions expressed by the Member States when continuing its discussions in the second half of 2002.