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

2001/0252(COD) - 02/12/2002

The Council held an exchange of views, on the basis of a progress report from the Presidency, on some of the key issues raised by the proposal for a Regulation of the European Parliament and of the Council aimed at amending the rules regarding the European Agency for the Evaluation of Medicinal Products. The Council requested the Permanent Representatives Committee to pursue work actively on the proposal, taking into account the positions expressed by delegations and the opinion of the European Parliament in first reading. In the light of this discussion, the President concluded that: - views continue to differ on the scope of the centralised authorisation procedure, with a slight majority opposed to its extension as regards medicinal products for Human use and a clear majority opposed as regards veterinary medicinal product; - a majority of delegations are favourable to each Member State being represented on the management board of the European Agency for the Evaluation of Medicinal Products; - a majority of delegations are in favour of maintaining a first renewal of market authorisations after five years, with unlimited validity thereafter.