Medicinal products for human use: Community code

2001/0253(COD) - 07/10/2003

The Commission supports the text of the common position, adopted by qualified majority, for a Directive amending Directive 2001/83/EC on the Community code relating to the human medicinal products. The Council could not support the amendment inviting patients to report suspected adverse reactions to a health-care professional and to the competent authority for pharmacovigilance. Similarly, the Council could not support the amendment as reworded by the Commission in its amended proposal, requiring Member States to oblige health-care professionals to notify of suspected adverse reactions. The Commission would have preferred to keep these requirements. The Council has rejected the amendments regarding information to patients. The Commission has shown its flexibility on this point so as to facilitate rapid progress in reaching a common position on this important file. In this sense, it has declared that in view of information technology developments, the deletion of the provision regarding information to patients, might leave patients exposed anyway to unchecked and unverified information. The Commission regrets the deletion by the Council of the provision designed to provide patients with information which has been checked and verified. The Commission considers that, in view of information technology developments, the omission of that provision might leave patients exposed to information not affording such assurances.