

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

2001/0252(COD) - 07/10/2003 - Commission communication on Council's position

The Commission supports the texts of the common position, adopted by qualified majority, for a regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. The Commission takes note that the Council has accepted, partly, the European Parliament amendment, which aimed at establishing the data protection period automatically linked with the one applicable in the context of the medicinal products authorised through the national procedures. However, the Commission takes also note that the Council has limited the application of this amendment to the products to be authorised, on an optional basis, through the centralised procedure. For these products, the same data protection scheme as the one foreseen for the nationally authorised products is applicable. For the medicinal products to be authorised, on a mandatory basis, through the centralised procedure, the Council has agreed with the Commission proposal to keep the 10 years period as it is currently applied on the basis of the existing Regulation with the possibility to extend this period with one extra year when a new indication bringing a significant clinical benefit in comparison with existing therapies is approved.