Medicinal products for human use: Community code

2001/0253(COD) - 17/12/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Francoise GROSSETETE EPP-ED, France) making some amendments to the Council's common position. The amendments adopted by Parliament were agreed in advance with the Council for both human and veterinary products: - in order to take account both of the emergence of new therapies and of the growing number of so-called "borderline" products between the medicinal product sector and other sectors, the definition of "medicinal product" should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products; - biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. When a biological medicinal product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both; - environmental impact must be assessed and, on a case-by-case basis, specific arrangements to limit it must be envisaged. In any event this impact should not constitute a criterion for refusal of a marketing authorisation; - if, during the first eight years of ten years given for marketing protection, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies, the protection can be extended to a maximum of eleven years; - Member States should also take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days of the submission of a valid application; - within three years the Commission will, following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision - particularly on the Internet - and its risks and benefits for patients. Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good- quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability; - appropriate collection systems must be in place for medicinal products that are unused or have expired; - Member States must ensure that members of staff of the competent authority responsible for issuing authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affecttheir impartiality; - the name of the medicinal product must also be expressed in Braille format on the packaging. The marketing authorisation holder should ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted. Member States should ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.