Medicinal products for human use: Community code

2001/0253(COD) - 03/04/2003 - Modified legislative proposal

The Commission accepted 30 amendments proposed by the European Parliament. These include: - any authorisation, which is not followed within three years by the actual placing on the market of the authorised product, will cease to be valid; - the possibility of unannounced inspections by the competent authorities; - Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected spread of a pathogen which could cause harm; - clarification that the data protection period of 11 years constitutes the maximum time; - the documents to be submitted by the applicant on the constituents of the medicinal product include the reference to its international non-proprietary name recognised by the WHO; - an applicant has to submit documents to prove that he will be able to meet certain pharmacovigilance obligations; - homeopathic products authorised before December 1993 do not need to be updated according to the new legislation; - the rules of procedure of the coordination group are to be made public; - the committee must specify the time limit for explanations by the applicant; - the Commission must prepare a draft decision in 15 and not 30 days; - the Rules of Procedure of the Standing Committee must be made public. The Commission accepted 48 amendments in part or in principle. These include: - the change in the period of validity foe the marketing authorisation. The latter for new medicinal products must initially be limited to five years' validity. After the first renewal, the marketing authorisation shall be considered to be valid indefinitely; - further clarification on the definition of a medicinal product. A reformulation is required to refer, in addition to pharmacological action, to immunological and metabolic action; - the deletion of certain parts of the definition of a homeopathic medicinal product. There is a rewording to reintroduce the reference to homeopathic stocks, which are an important step in the production of a homeopathic medicinal product; - the introduction of a definition of the risk/benefit balance; - the situation that a given product could fulfil the definition of different regulatory regimes. This excludes food, food supplements, medical devices and cosmetics from the scope of the Directive; reinforcement of the arbitration procedures. The option to refer to the Agency will be made into an obligation in the cases of referral where a Community interest is involved. A requirement for the marketing authorisation holder, and, within the limits of their responsibilities, the distributors, to provide suitable supplies; it is compulsory for Member States to take measures to require doctors and other healthcare professionals to report adverse reactions The Commission rejected 79 amendments proposed by the Parliament. These include: - the requirement for generic medicinal products authorised bythe Member States to be identified with the same denomination; - amendments which introduce the possibility of conducting the tests and trials needed for authorisation, submitting the application for authorisation, and authorising generic medicinal products during the ten year period of data protection; - amendments which require the competent authorities to set up a website containing information on the medicinal product and to include its address on the packaging; - including patients as a source of information adverse reactions that is forwarded directly to the holder of marketing authorisations; the proposal that a new category of medicinal product "herbal health product" be introduced.