

# Traditional herbal medicinal products

2002/0008(COD) - 04/11/2003 - Council position

The Council's common position, adopted by unanimity, is in accordance with the objectives of the Commission's proposal and accepts in totality or in principle, 17 amendments adopted by the European Parliament in first reading. The amendments taken on board by the Council concern the following issues: - in relation to the Committee for Herbal Medicinal Products' tasks and composition : the Council agrees with the aim of Parliament's amendments which are to set out a broad competence for the Committee in respect of herbal medicinal products, with due regard to the necessary coordination with the Committee for Human Medicinal Products, and to ensure the necessary expertise for evaluating herbal medicinal products. The Council has considered it useful to set out more precisely which tasks the Committee for Herbal Medicinal Products is to be entrusted with in relation to authorisations and registrations. The council also believes that the aim shall be achieved by applying the same provisions on the composition of the Committee for Herbal Medicinal Products as for the Committee for Human Medicinal Products in that they will provide for the possibility of appointing five additional members and for the members to be accompanied by experts; - concerning allowing for other references than monographs : the Council prefers as the Commission to restrict this possibility for cases where no monograph has yet been established. Where a monograph has been established, it should be taken into account when applying for registration as it constitutes a harmonised reference. In addition, the information referred to by the European Parliament can be used when establishing a monograph; - on having mutual recognition for registered traditional herbal medicines : the Council . However, given that products and traditions vary between Member States, the Council believes that it is advisable to make the mutual recognition dependant on the existence of a common reference that will facilitate mutual recognition. Therefore the Council has agreed to provide for mutual recognition when a Community herbal monograph has been established as well as when the product contains substances etc. figuring on the list established in accordance with Article 16f. For other products, there will be an obligation to take due account of registrations granted by other Member States in accordance with the new procedure; - registration of herbal medicines : this amendment allows for registration of herbal medicinal products that contain non herbal ingredients, however only as concerns vitamins and minerals and only if their action is ancillary regarding the specified claimed indication(s). The Council has chosen not to include other "non herbal ingredients" as this term is too vague, and there is the risk that, in opening up the registration procedure to other unspecified combination products, the concept of a herbal medicinal product may be diluted. For similar reasons and for the sake of clarity, the Council believes that rather than opening up for such combination products via the definitions, it is more appropriate to do this via the criteria for registrations, cf. Article 16a (2). - concerning specified daily doses : the Council has incorporated this amendment but believes that a reference to the strength should be maintained and that it would be appropriate to use the general term "posology" which means dosage schedule, be it a daily schedule or other (Articles 16a (b) and 16f (1)); - the Council accepts the idea contained in the amendment concerning the duration of the minimum use of products. It states that it could be justified to open up for registration of products that have been in use for less than 15 years in the Community but believes that for public health reasons the basic criteria should be kept but with the possibility to derogate from this criterion in cases where the Member State and the Committee for Herbal Medicinal Products consider that the product otherwise fulfils all criteria, in particular in relation to safety, efficacy and quality. - on labelling and packaging : this amendment concerning labelling and package leaflets have been incorporated as these provide for more neutral and concise labelling. The common position incorporates a number of changes, including editorial and linguistic changes. The Council has also introduced changes as to certain provisions, which do not respond directly to an amendment of the European Parliament or a provision of the Commission's proposal. The Council has modified point 31 of Article 1 with a view to clarifying the definition of herbal medicinal products. The Commission supports this amendment, which does not represent a change in substance. The common position provides Member States with the possibility to request the Committee for Herbal Medicinal Products for an opinion on the adequacy of the evidence of longstanding use (under Article 16c(1)(c)). The Commission accepts this

amendment, which will permit the application of European expertise in the particular area of longstanding use of herbal medicinal products. The common position clarifies that medicinal use related to other corresponding products than corresponding medicinal products shall be taken into account for the purposes of fulfilling the criteria of longstanding use in Article 16 c (1) c if the corresponding product falls under the definition of Article 16 c (2). The Commission agrees to the wording proposed by the Council, which does not amend the substance of the provision. The Council has amended the scope of the competent authorities' obligation to inform the applicant and the Commission of decisions on refusals of applications for traditional use registration (Article 16e (2)). In particular, it has deleted the reference to "safety grounds", so that the obligation to inform will apply in every case of refusal, whatever the grounds.