Medicinal products for human use: Community code. Codification

1999/0134(COD) - 29/09/2008 - Follow-up document

The Commission presented its report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to **traditional herbal medicinal products**.

Under Articles 16a to 16i of Directive 2001/83/EC, introduced by Directive 2004/24/EC, a specific registration procedure is to be used by the Member States for herbal medicinal products that meet the criteria for a traditional herbal medicinal product. Herbal medicinal products are defined as any medicinal product exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations. Article 16i requires the Commission to submit a report to the European Parliament and to the Council concerning the application of the simplified registration procedure and including an assessment of the possible extension of traditional-use registration to other categories of medicinal products. This document was prepared in consultation with the European Medicines Agency and the Committee on Herbal Medicinal Products (HMPC) and was submitted for consultation to the Member States and interested parties. As a major source of information, the Commission welcomed the HMPC report of 31 October 2006 (Doc.Ref.EMEA/HMPC/187219/2006) presenting the views of the EMEA and the HMPC.

The report recalls that Directive 2004/24/EC was intended to address the specific situation of medicinal products that, despite their long tradition of use, do not fulfil the requirements for a marketing authorisation as set out in the Community pharmaceutical legislation. By introducing a simplified registration procedure with specific requirements, the Directive aimed to allow these products to be marketed under harmonised conditions and to ensure the protection of public health by making such products subject to the necessary guarantees of quality, safety and efficacy. During the public consultation on the draft of this report, numerous supportive views were expressed on the setting of harmonised safety standards for traditional products.

During the public consultation, some stakeholders referred to the experience with the application of the requirements of the simplified registration procedure. In particular, **the issue of genotoxicity data** needs careful consideration from a scientific and legal point of view. The requirement for genotoxicity data should be considered on a case by case basis in the framework of the simplified registration, because wrong interpretation of the legal requirements could possibly lead to the marketing of some products under another qualification that would not necessarily offer the same guarantees of quality, safety and efficacy. Such a result would be contrary to the public health and harmonisation objectives of Directive 2001/83/EC and Directive 2004/24/EC. In order to overcome this difficulty, **a case-by-case decision**, where specific concerns about safety exist, appears to be a proportionate and balanced approach and in line with the objectives of the Directive.

As regards the **possible extension of the scope of the Directive**, any such extension should be in line with the objectives of Directive 2004/24/EC, i.e. to have harmonised rules for the placing on the market of certain medicinal products with a long tradition of use but which do not generally satisfy the requirements for marketing authorisation, while ensuring the protection of public health by introducing specific requirements for proof of quality, safety and efficacy. In this regard, the European Commission is prepared to **consider extending the simplified registration procedure to products other than herbal substances with a long tradition of safe use**. This proposal received general support during the public consultation on the draft of this report. On the other hand, the key requirements of the simplified

registration procedure, based on public health considerations, such as the limitation to products with 15 years use in the Community, to certain routes of administration and to products that do not need the supervision of a medical practitioner, should be maintained. For certain requirements, more experience is needed before any change to the system can be proposed.

The proposed extension would enable certain medicinal products from specific European or non-European medicine systems (such as — in alphabetical order — anthroposophic, Ayurvedic, Chinese, Kampo Korean, Mongolian, Thai, Tibetan Unani, or Vietnamese medicine), as well as **traditional products with a long-standing tradition** in the European Union (such as honey, royal jelly, propolis, fish oils, minerals, micro-organisms and other substances) to be eligible for the simplified registration procedure with a view to placing them on the market as traditional medicinal products.

Many of these products are present in the Community market, and their inclusion under the simplified registration procedure will introduce harmonisation in a sector where differences currently exist between Member States as regards classification and placing on the market and will increase the protection of public health since the quality, safety and efficacy of the products concerned will be assessed during the simplified registration procedure.

During the public consultation, proponents of **three traditional medical systems** using products with a long-standing tradition expressed support for the global regulation of their traditions within the EU: anthroposophic, Ayurvedic and traditional Chinese medicine. It was suggested that proof of the plausibility of efficacy should not be by medicinal product, but by therapeutic approach.

Medical traditions such as those mentioned above are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, **the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such**. Nevertheless, independently of this report, the suitability of a **separate legal framework** for products of certain traditions should be assessed.