

**IVAA response to:
the Commission's report to the Council and the European Parliament
[COM(2007)XXX], entitled:**

“Report on the experience acquired as a result of the application of the provisions of Chapter 2a of the Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to herbal medicinal products”

1. IVAA

The IVAA (International Federation of Anthroposophic Medical Associations) represents and coordinates the political and legal concerns of National Anthroposophic Doctors' Associations at both a European and international level.

- Anthroposophic medicine, from its inception in 1920 to the present day, has developed well in Europe and found increasing recognition both from the general public and the academic world.¹
- Anthroposophic medicinal products are prescribed by approximately 30,000 doctors in 18 of the 27 EU member states (Austria, Belgium, Czech Republic, Denmark, Eire, Estonia, Finland, France, Germany, Italy, Latvia, Netherlands, Poland, Portugal, Romania, Spain, Sweden, United Kingdom), in Norway, Switzerland, and globally in 65 countries throughout the world.
- Anthroposophic medicine has so far been recognised by the medical councils / registration boards of Austria, Italy and Switzerland.
- Anthroposophic medicine is practised in hospitals, clinics and other in-patient facilities in Austria, Germany, Italy, Netherlands, Sweden, Switzerland and the UK, including a teaching hospital and a district general hospital.
- Anthroposophic medicine is taught at universities in Germany, Italy, Spain, Switzerland and the UK.

2. General considerations

The IVAA welcomes the direction and recent developments of the European framework of directives for registration and market authorisation of medicinal products. The IVAA supports the general aim of European regulations to safeguard availability of traditional herbal medicinal products in all member states, as an indispensable part of medication to improve the health of European citizens. This applies not only to self-medication but also to prescribed/supervised medical treatment, and accords with the free choice of a significant number of EU citizens to choose milder and more holistic treatment with fewer side effects. The IVAA appreciates the intention of existing regulations to ensure availability of these traditional herbal medicinal products in compliance with the rules of the Internal Market, to take account of continuing jurisdiction of Member States over national registration processes, and to guarantee quality standards and safety for patients.

¹ Kienle G et al. 2006

The IVAA welcomes the Commission's report. It adequately and correctly describes the difficulties of applying Directive 2004/24/EC in the different member states, and the existing and still restricted possibilities for simplified registration of traditional herbal medicinal products in the EU and Member States. In addition to these difficulties it also describes shortcomings in relation to specific traditional therapeutic systems such as anthroposophic medicine (a European tradition) and traditional Chinese medicines and Ayurveda, both Asian traditions.

The IVAA views this report as the Commission's intention not only to explain the present state of affairs but to address these shortcomings in existing regulations for traditional herbal medical products, and to invite stakeholders to come forward with suggestion of how to optimise these procedures.

For the IVAA, these problems include the uneven implementation of Directive 2004/24/EC by responsible agencies in the Member States, the way that HMPC (Herbal Medicinal Product Committee) is organised and the pace at which it proceeds, the limited initial scope of the new simplified registration procedure for traditional herbal medicinal products, the procedural requirements for registration, and the influence which current regulation has on the existence and availability of certain medicinal products – such as anthroposophic medicinal products.

The current European regulative framework still creates inappropriate and unnecessary obstacles to registration, licensing and marketing authorisations for anthroposophic medical products in the Member States. To safeguard the anthroposophic medical system and its medicinal products, a new approach needs to be considered to secure their availability for patients and doctors as well as their free, Internal Market circulation in Europe.

3. HMPC (§3 of the report)

The IVAA welcomes the establishment of the HMPC within the EMEA, as well as the work which the HMPC has initiated. However, the IVAA very much regrets the failure so far to complete appointments of all positions on the experts group of the HMPC. A qualified anthroposophic medicine expert is still lacking. Despite the fact that IVAA experts have already proposed a co-opted additional member, none has so far been accepted.

As described above, anthroposophic medicine has a long tradition and widespread support in Europe, and should therefore be given the opportunity to bring its knowledge and expertise to bear on the Committee's discussions. The IVAA points to Germany, where the German committee of experts specifically engaged with anthroposophic medicinal products, the so-called 'Kommission-C', has successfully engaged in such work for 30 years.

The IVAA is greatly concerned about the extent of the HMPC's workload. According to the report, 10 monographs have been adopted so far, and 10 monographs are at the public consultation stage. To cover the whole sector as specified by the Directive, 200–300 monographs will need to be published. IVAA raises the question of whether the present pace of the HMPC's work is sufficient to handle this large number of monographs, which at the current rate of progress would require dozens of years. IVAA suggests creating an intermediate agreement to guarantee that the substances whose consideration falls within the scope of Directive 2004/24/EC can be kept on the market until a decision is made by the HMPC. Since it is obvious that the deadline of April 2011 is not realistic after the delays in

implementation and the enormous work still to be done by the HMPC, acceptable plans should be drawn up not only for individual herbal remedies but also for the special preparations and the compounds made from them.

The IVAA supports the need for a periodical update of Community monographs to prevent them from becoming outdated. However, a fixed period of time for such updating (e.g. 3, 5 or 10 years) should be considered realistically in relation to available resources. This task must be undertaken by the HMPC, which must be enabled to handle it. The IVAA calls on the European Commission to safeguard these requirements so as to avoid shortfalls in availability of traditional herbal medicinal products.

5. Genotoxicity data issue (§4.2 of the report)

The IVAA agrees with the report's position that in assessing traditional herbal medicinal products a systematic request for genotoxicity data should be replaced by a case-by-case approach, and only where there is a specific justified concern in relation to safety requirements.

A generalised request for genotoxicity data for all applications creates the risk that, on the one hand, important medicinal products disappear from the market; and, on the other, that they end up being marketed under another classification without the necessary quality, safety and efficacy controls applicable under pharmaceutical legislation.

6. Current situation and consideration of extending the scope of the simplified registration procedure (§5.1. and §5.2 of the report)

The IVAA notes the intention to discuss the present version of Directive 2004/24/EC and to address the situation in which the registration of traditional medicinal products is deliberately restricted to herbal products. The IVAA agrees with the view that other medicinal products may acquire similar status due to longstanding traditional use, without as yet fulfilling the requirements of full marketing authorisation or an authorisation under the requirements of "well-established use" - as is the case with anthroposophic medicinal products in particular, all of which have a long-standing tradition within the European Union.

The IVAA appreciates the detailed and correct description of anthroposophic medicine in §5.1. of the report, its approach to the healing process as well as its medicinal products, their substances and modes of administration including parenteral applications.

The IVAA stresses that the characteristics of anthroposophic medicinal products should have consequences for the registration procedures for these products. Any regulatory system should take into account the specific features of these medicinal products and the specific therapeutic approach of anthroposophic medicine.

The IVAA wishes to highlight the following obstacles to anthroposophic medicinal products qualifying for marketing authorisation or simplified registration under the Community's current legal framework:

Composition of the product

In addition to herbal substances or preparations, anthroposophic medicinal products may also contain substances and preparations derived from mineral, metal, or animal material.

- The IVAA therefore greatly appreciates suggestions to enlarge the scope of Directive 2004/24/EC to include other than herbal substances/preparations, such as minerals, metals, animal substances and preparations of those substances.

Route of administration

According to Directive 2004/24/EC, traditional herbal medicinal products must be administered orally, externally or via inhalation.

- The IVAA stresses that limiting administration to oral, external or inhalation inevitably excludes the majority of anthroposophic medicinal products from the scope of the Directive 2004/24/EC, even if the scope were enlarged to other than herbal medicinal products.
- Parenteral application of anthroposophic medicinal products is a major part of anthroposophic medicine, and has proven to be safe in more than 80 years of use.² As mentioned above, anthroposophic medicine is practised in hospital settings and in the treatment of major disorders, where a quick and reliable mode of administration – under the supervision of a physician – is mandatory.

Unsupervised use, and use with indications

The present version of Dir 2004/24/EC, “Traditional herbal medicinal products”, addresses medicinal products primarily intended for use without the supervision of a physician for minor indications.

- The majority of anthroposophic medicinal products used in anthroposophic medicine – with the exception of medicines designed for self-medication – are prescribed by fully trained physicians. The restriction of simplified registration for unsupervised use therefore excludes the majority of anthroposophic medicinal products from such procedure.
- Anthroposophic medicine is practised in general and specialised medical practice in 18 EU member states. Additionally, anthroposophic medicine is practised in hospitals, therapy centres and homes for the elderly in 6 member states and in Switzerland. In Germany and Switzerland it is even used in local and university hospitals. Anthroposophic medicine has been shown to offer effective and safe treatment for major diseases in all medical fields, including treatment of cancer, asthma, rheumatic and cardiovascular disease.^{1,2} It is therefore evident that the restriction allowing only simplified registration for “minor indications” excludes anthroposophic medicinal products from such procedure.

² Baars EW et al. 2005

7. Proposals

In summary, the IVAA's proposals are based on the following considerations:

- Widening of the scope of the regulation for traditional herbal medicinal products, as suggested in the report, will, in the EU's current legal framework, still not cover the majority of anthroposophic medicinal products. These represent anthroposophic medicine's most effective means of treating patients in acute and chronic conditions, including major diseases. This will prevent doctors who practise anthroposophic medicine from treating patients in accordance with its underlying principles.
- The special nature of anthroposophic medicinal products as a highly differentiated medical system with more than 1000 medicinal products makes it almost impossible for anthroposophic medicinal products to meet the documentation requirements necessary for applying for ordinary marketing authorisation, or authorisation under "well-established use". Such authorisation necessitates clinical studies based on large groups of identical patients. On the other hand it should be noted that the "Whereas no. 4..." of Directive 2004/24 EC specifically described the aim of finding a solution to safeguard these remedies, which derive from a solid tradition within the EU.
- Anthroposophic medicine has been proven to be reasonably effective.¹
- Anthroposophic medicine has been proven to be reasonably safe, also when applied parenterally.²

In view of the above, the IVAA presents the following proposals, with the aim of safeguarding the anthroposophic medical system and its medicinal products in relation to availability for patients and doctors, and free circulation across the European Union.

- 1. The scope of Dir 2004/24/EC should be enlarged to other than herbal substances or preparations of substances, to include minerals, metals, and animal products, preparations of those substances and compounds of those substances.**
- 2. Within Dir 2004/24/EC or as separate regulation within Dir 2001/83/EC an extra group of the AMP should be defined with the following features:**
 - **Prescription – only intended for use under the supervision of a physician.**
 - **Intended for any indication including major medical conditions.**
 - **Intended for parenteral use as injections.**
- 3. A qualified expert in anthroposophic medicine should be included on the HMPC's group of experts.**

Hollola, 24 July 2007

On behalf of the IVAA board



Peter Zimmermann
President of the IVAA

Bibliography:

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