EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Action Plan for Herbal Medicines 2010-2011

Key trends and new issues

- The issues raised in the European Commission's Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products need to be addressed. In particular, improvement concerning the genotoxicity data situation shall be sought.
- A possible extension of the scope of Directive 2004/24/EC has been proposed by the European Commission and is supported by the Herbal Medicinal Products Committee (HMPC), i.e. the simplified registration procedure could be opened to other traditional products of a long standing tradition in the EU, including certain products of animal origin.
- The Member States will face the end of the transition period by which they shall apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products already on the market on 30 April 2004.
- Regular reports on the uptake of the traditional use registration scheme in the Member States shall be undertaken, in cooperation with the CMD-h.
- Any international request for collaboration in the field of herbal medicines and alternative treatments needs to be addressed, in close collaboration with the European Commission.

Objectives

In order to address the aforementioned key trends and new issues the following objectives should be achieved.

Objective 1: To improve the output of the Committee on Herbal Medicinal Products, in particular by increasing the quality and number of Monographs and List entries

The following shall be addressed:

1. In collaboration with stakeholders, **adjust the priority list** of herbal substances, preparations and combinations thereof for assessment to the **needs of the market operators** and **allocate Member States resources accordingly.**

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2. Implement in 2011 the **orientation concerning the genotoxicity data situation**[1] discussed and to be chosen in 2010. Possible options include the use by the HMPC of unpublished data available on a national level and a labelling transparent with regard to genotoxicity information.

3. Implement the HMPC policy for the **systematic assessment of the need for revision** of final Community herbal monographs, aiming that they remain up to date (scientific state of the art). *Pending sufficient resources at HMPC/MLWP level.*

4. Implement changes to the **working methodology** of the HMPC, its Working Party (WP) and Drafting Groups (DGs) as well as to their interaction, to improve the quality and timely delivery of monographs and list entries and related documents.

5. Achieve the **expected number of monographs and list entries** to be established:

   Community herbal monographs
   - Final: 20
   - Released for public consultation: 20

   Community list entries:
   - Transmitted to the European Commission: 10*
   - Released for public consultation: 10*

   ** pending success concerning the genotoxicity data situation*

Objective 2: To respond to any actions arising from the end of the transition period by which Member States shall apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products

Articles 2 & 3 of Directive 2004/24/EC of 31 March 2004

Article 2

1. The Member States shall take the necessary measures to comply with this Directive by 30 October 2005. They shall forthwith inform the Commission thereof. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. For the traditional herbal medicinal products as referred to in Article 1, which are already on the market on the entry into force of this Directive, the competent authorities shall apply the provisions of this Directive within seven years after its entry into force. [= 30 April 2011]

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*. [= 30 April 2004]

[1] See Annex 1: extract from the European Commission Communication COM(2008)584 on experience acquired as a result of the application of Directive 2004/24/EC's provisions.

The following shall be addressed:

1. Collaborate with the European Commission on guidance on complex legal issues raised by Directive 2004/24/EC such as the inclusion of some **interpretative guidance** on Directive 2004/24/EC in the **Notice to Applicants.**

2. Contribute to discussions by the HMPC serving as a **platform for exchange of information** between the Member States.

Objective 3: To report on the uptake of the traditional use registration scheme

The following shall be addressed:

1. In collaboration with the CMD-h, **publish** and update on a 6-monthly basis an **overview of applications received, under evaluation and registrations granted per Member State** (name of product, herbal substance, preparation or combination thereof used and the therapeutic indication(s) granted).

2. Explore the possibility to include traditional use registrations in the EU database on medicinal products.

3. In collaboration with the CMD-h, **report on the impact** of published Community herbal monographs upon assessment of marketing authorisations and traditional use registrations granted by the Member States.

4. Investigate the need for **revision of scientific guidance** (guidelines, Questions & Answers, etc.) published by the HMPC for adaptation to the latest developments in the herbal sector.

Objective 4: To respond to the possible extension of the scope of the simplified registration procedure

1. Contribute to the preparation of a possible extension of the scope[2], when requested by the European Commission.

Objective 5: To respond to any European Commission's request for enhanced co-operation between the Agency and EFSA in the area of health claims for food containing herbal ingredients and for clarification of the borderline with medical devices

1. Establish an ad hoc group at the level of the HMPC to prepare scientific contribution.

Note: In addition, the HMPC will contribute to ongoing DG SANCO activities in the area of risk assessment, risk management and emerging risks (with other Scientific Committees of the Agency).

[2] See Annex 1: extract from the European Commission Communication COM(2008)584 on experience acquired as a result of the application of Directive 2004/24/EC's provisions.

Annex 1

Extract from the '**Communication from the Commission to the Council and the European Parliament concerning the 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'** (COM(2008)584). The document, prepared on the basis of Article 16i of Directive 2001/83/EC, has been adopted and transmitted to the Council and the European Parliament.

The document was published on 1 October 2008.

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/archives/2008_en.htm

Section 2.5 Genotoxicity data issue

"In order to ensure the successful application of the Directive, the issues relating to genotoxicity demand careful scientific and legal consideration. As stated in the HMPC report, the systematic request for genotoxicity data has made the proposal of list entries difficult since these data are generally not available. It has probably also contributed to the small number of applications received so far. Consequently, **a request for genotoxicity data to assess traditional herbal medicinal products should be made on a case-by-case basis when there is a specific concern for safety, as required by the relevant provisions in the legislation**. This ensures the protection of public health while allowing the registration of traditional herbal medicinal products. A more restrictive approach would create the risk that the products concerned will end up being marketed under another classification (and not as medicinal products), without the necessary quality, safety and efficacy controls applicable under pharmaceutical legislation."

Section 4 Summary and conclusions

"…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**. … 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."

Endorsed by the European Medicines Agency Management Board, 18 March 2010.

Endorsed by Heads of Medicines Agencies, 13 April 2010.

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