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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

FINAL

**STRUCTURE OF THE LIST OF HERBAL SUBSTANCES¹, PREPARATIONS² AND
COMBINATIONS THEREOF**

DISCUSSION IN HMPC	January 2005 March 2005
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	15 May 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 August 2005
ADOPTION BY HMPC	20 September 2005
AGREED BY ORGANISATIONAL MATTERS DRAFTING GROUP	14 June 2006
ADOPTION BY HMPC	13 July 2006

¹ The term “herbal substance” should be considered equivalent to the term “herbal drug” as defined in the European Pharmacopoeia

² The term “herbal preparation” should be considered equivalent to the term “herbal drug preparation” as defined in the European Pharmacopoeia

STRUCTURE OF THE LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS THEREOF

Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004³, amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use

Article 16h indicates that:

“A Committee for Herbal Medicinal Products is hereby established. That Committee shall...have the following competence:

(a) as regards simplified registrations, to:

...

- prepare a draft list of herbal substances, preparations and combinations thereof as referred to in Article 16f (1);

...”.

Article 16f (1) reads as follows:

1. A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product.

List of substances, preparations and combinations thereof

- Scientific content
- Administrative data

³ Published in the Official Journal of the EU on 30 April 2004

List of herbal substances, preparations and combinations thereof

- Scientific content
- Administrative data

Scientific content

- Scientific name of the plant according to the binomial system (genus, species, variety, author)
- Botanical family
- Common name in all EU official languages, where relevant
- Herbal substance(s) or Herbal preparation(s) or Combination(s)
- European Pharmacopoeia monograph reference if exists / reference to another Pharmacopoeia
- Indication
- Type of tradition (e.g. European, Chinese, Ayurveda or others)
- Specified strength (dose range)
- Specified posology (per population group)
- Route of administration (oral, external or inhalation) – expressed in Standard Terms
- Duration of use or any restrictions on the duration of use
general statement (specific data when available to appear in monograph)
- Any other information necessary for the safe use

All ADRs references

Use of SPC sections' titles / requirements from Guideline on SPC to apply

- 4.3 Contra-indications⁴
- 4.4 Special warning and precautions for use
- 4.5 Interactions with other medicinal products and other forms of interaction
- 4.6 Pregnancy and lactation
- 4.7 Effects on ability to drive and use machines
- 4.8 Indesirable effects
- 4.9 Overdose

Pharmaceuticals particulars: [If necessary]

⁴ hypersensitivity and allergic potential to be both covered

Administrative data

- **Status**
Under evaluation
Valid (date of HMPC Opinion, date of European Commission Decision)
Suspended (date of HMPC Opinion, date of European Commission Decision)
Revoked (date of HMPC Opinion, date of European Commission Decision)
Variations/Extensions
- **Numbering**
documentation of past versions with modifications tracking system
- **Cross-reference to EU Number in EuroPharm Database for licensed medicines containing same herbal substance/preparation/combination**
- **Rapporteur/CoRapporteur**
- **Cross-reference to Assessment Report**
- **Bibliographic References and unpublished data used in Assessment Report**

References

Directive 2004/24/EC of the European Parliament and the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.