



London, 12 March 2009
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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

FINAL

**PROCEDURE FOR THE APPOINTMENT BY THE HMPC OF A RAPPORTEUR¹
RESPONSIBLE FOR**
- **A SCIENTIFIC EVALUATION OR**
- **THE ESTABLISHMENT OF A COMMUNITY HERBAL MONOGRAPH AND/OR
COMMUNITY LIST ENTRY**

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
REVISION AGREED BY ORGANISATIONAL MATTERS DRAFTING GROUP	10 February 2009
REVISION ADOPTED BY HMPC	12 March 2009

¹ Where relevant, the HMPC could decide on the appointment of two Rapporteurs
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PROCEDURE FOR THE APPOINTMENT BY THE HMPC OF A RAPPORTEUR RESPONSIBLE FOR:

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Legal framework and scope of the procedure

Reference to the appointment by the HMPC of a Rapporteur is made in particular in

- Article 62.1 (Title IV) of Regulation (EC) No 726/2004 and
- Article 6 of the HMPC Rules of Procedure (EMEA/HMPC/139800/2004 Rev.2).

Reference to the work as Rapporteur is also found in section III of the Mandate, objectives and rules of procedure for the HMPC Working Party on Community Monographs and Community List (MLWP) (EMEA/HMPC/379153/2005 Rev.2).

This procedure does not cover the appointment of (Co-)Rapporteurs responsible for the evaluation of an application in a referral procedure according to Article 16c(1)(c) or Article 16c(4) of Directive 2001/83/EC as amended.

General principles to be considered

1. All HMPC members (including co-opted members) and alternates can act as Rapporteur.
2. The appointment is made on the basis of objective criteria, which will allow the use of the best available expertise in the EU on the relevant scientific area.
3. The appointment is made by the HMPC.

Mechanism of appointment

1. Members and alternates are invited to express their preferences regarding certain Rapporteurships orally during the HMPC meeting at which Rapporteurs are appointed or in writing in advance of the meeting. Proposals for Rapporteurship for monographs/list entries are often discussed in MLWP meetings and transmitted to the HMPC for formal appointment.

2. Criteria used for the appointment of Rapporteurs

The appointment of Rapporteurs is made on the basis of objective criteria, which will allow the use of the best available expertise in the EU on the relevant scientific area. The members and alternates' expertise, past experience in the assessment of relevant herbal substance class and the delegations workload are duly taken into account.

Whenever possible, the appointment may also take into consideration other factors such as the distribution of Rapporteurships between delegations.

Monitoring of Rapporteurship distribution

The HMPC secretariat endeavours to publish regularly overviews of Rapporteurship distribution, in particular:

Distribution of HMPC assessment work related to Community herbal monographs/Community list entries (Annex to 'Overview of status of HMPC assessment work – priority list')

Distribution of HMPC assessment work related to development of guidance in the areas of quality, safety & efficacy, pharmacovigilance and organisational matters