The European Agency for the Evaluation of Medicinal Products
Post-authorisation Evaluation of Medicines for Human Use

London, 3 March 2004
Doc. Ref: EMEA/CPMP/HMPWP/1156/03

WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL CONCEPT PAPER ON THE IMPLEMENTATION OF DIFFERENT LEVELS OF SCIENTIFIC EVIDENCE IN CORE-DATA FOR HERBAL DRUGS

DISCUSSION AT HMPWP	February 2003
RELEASE FOR CONSULTATION BY THE EMEA	May 2003
DEADLINE FOR COMMENTS	August 2003
RE-DISCUSSION AT HMPWP	November 2003 February 2004
PUBLICATION OF FINAL PROPOSAL	March 2004

The views presented in this document are those of the HMPWP, which has been created as a forum for exchange of experience in the field of herbal medicinal products. This document is released for the purposes of transparency and has no legal force with respect to Directive 2001/83/EC.

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Final concept paper on the implementation of different levels of scientific evidence in core-data for herbal drugs

Introduction

In the HMPWP "Draft Points to Consider on the Evidence of Safety and Efficacy Required for Well-established Herbal Medicinal Products in Bibliographic Applications" (EMEA/HMPWP/23/99), the levels of evidence (from Ia to IV) and the grading of recommendations (Grade A, B or C) were given as they have been taken from the US Agency for Health Care Policy and Research (AHCPR, 1994) and WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine, WHO/EDM/TRM/2000.1, WHO Geneva, 2000.
The Therapeutic Goods Administration (TGA), Australia, has issued similar recommendations: "Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods", describing three levels of scientific evidence (high, medium and general levels of evidence) and giving possible claims for the different levels of evidence. (Guidelines for Levels and Kinds of Evidence to Support Indications and Claims, TGA, October 2001)

The present document aims at adapting the recommendations from the above-mentioned guidelines to the European situation and to explain the current approach of the working party in drafting core data for herbal drugs.

Minimum requirements for different levels of evidence related to certain claims acceptable for indications to be approved in marketing authorisations referring to Article 10(1)(a)(ii) of CD 2001/83/EEC ("Well-established use")

A) MAJOR CLAIMS: MINIMUM REQUIREMENTS FOR HIGH LEVEL OF EVIDENCE (Level Ia, Ib; Grade A)

The claims
- "For the treatment, cure or management of any serious disease or disorder" and
- "For the prevention of any serious disease or disorder"

should be reserved for **products with high level of evidence** only .

B) MEDIUM CLAIMS: MINIMUM REQUIREMENTS FOR MEDIUM LEVEL OF EVIDENCE (Level IIa, IIb, III; Grade B)

For **products with medium level of evidence** the following claims may be acceptable:
- Reduction of the risk of a disease / disorder
- Reduction in frequency of a discrete event
- Aids/assists in the management of a named symptom / disease / disorder
- Relief of symptoms of a named disease or disorder

C) MINOR CLAIMS: MINIMUM REQUIREMENTS FOR GENERAL LEVEL OF EVIDENCE (Level IV, Grade C)

For **products with general level of evidence** the following claims may be acceptable:
- Relief or management of symptoms of a minor, self-limiting disease / disorder that does not require medical intervention for diagnosis or monitoring
- Description of a pharmacological action related to management of symptoms of a minor, self-limiting disease / disorder that does not require medical intervention for diagnosis or monitoring

If general evidence is submitted to support such claims, additional supporting evidence, e.g. pharmacological data, may be necessary for acceptance.

