



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

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

**FINAL POSITION PAPER ON CAPSICUM / CAPSAICIN
CONTAINING HERBAL MEDICINAL PRODUCTS**

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Final Position paper on Capsicum / capsaicin containing herbal medicinal products

INTRODUCTION

Following publication of the Opinion of the EU Scientific Committee on Food on capsaicin* (ref. SCF/CS/FLAV/FLAVOURS/8 ADD1 Final, dated 28 February 2002), the Working Party on Herbal Medicinal Products discussed whether action in relation to herbal medicinal products containing capsaicin/*Capsicum* species would be necessary.

Capsaicin is the main amide-derived alkaloid or capsaicinoid of the plant genus *Capsicum*. It is normally present in conjunction with a number of other capsaicinoids, including dihydrocapsaicin. The Ph.Eur. Monograph for *Capsicum* (*Capsici fructus*) (ref 1859) indicates that *Capsicum* is either the dried fruits of *Capsicum annuum* L. var. *minimum* (Miller) Heiser or small fruited varieties of *Capsicum frutescens* L. and should contain a minimum 0.4% total capsaicinoids expressed as capsaicin.

ASSESSMENT

Upon review of the Opinion from the Scientific Committee on Food, it can be concluded that the available data do not allow for the establishment of a no adverse event level [NOAEL] and as such make it impossible to extrapolate the data to possible exposure through the consumption of herbal medicinal products containing *Capsicum* and/or capsaicin for oral use.

In addition, the existing pharmacovigilance data for authorised products varies considerably from one Member State to another and, while this is likely a function of under-reporting in some countries, this data is inadequate to establish any real risk associated with herbal medicinal products containing *Capsicum*/capsaicin for oral use. It is clear that the regulation of herbal medicinal products of this nature also varies from Member State to Member State with many herbal products available without a product authorisation or as food supplements.

HMPWP RECOMMENDATION

Based on the available data, no pharmacovigilance action is recommended at this time in relation to herbal medicinal products containing *Capsicum* / capsaicin.

* http://europa.eu.int/comm/food/fs/sc/scf/index_en.html