WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL POSITION STATEMENT ON CHAMOMILLA CONTAINING HERBAL MEDICINAL PRODUCTS

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RELEASE FOR CONSULTATION</td>
<td>July 2003</td>
</tr>
<tr>
<td>DEADLINE FOR COMMENTS</td>
<td>October 2003</td>
</tr>
<tr>
<td>RE-DISCUSSION IN THE HMPWP</td>
<td>April 2004</td>
</tr>
<tr>
<td>PUBLICATION OF FINAL DOCUMENT</td>
<td>May 2004</td>
</tr>
</tbody>
</table>

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Introduction

In 1992, the CPMP Herbal Medicinal Products Working Party (HMPWP) examined literature on the risk of anaphylactic reactions associated with the consumption of herbal medicinal products containing *Chamomilla recutita* (L.) Rauschert. Following consultation with the CPMP Pharmacovigilance Working Party, the HMPWP prepared a proposal for the amendment of the labelling of *Chamomilla recutita* containing herbal medicinal products to reflect recent findings.

Recommendation

The following amendment to the SPC of *Chamomilla recutita* containing herbal medicinal products is proposed:

Under section 4.8 Undesirable effects

“Hypersensitivity reactions to (german) chamomille (e.g. contact dermatitis) are very rare. Some cases of anaphylactic shock or asthma have been reported. Cross reactions may occur even in people with allergy to compositae (e.g. artemisia/mugwort)”.

References

- Anaphylaxis to camomile: clinical features and allergen cross-reactivity (*Reider N et al.* (2000) Clinical and Experimental Allergy: 30; 1436-1443)
- Asthma bronchiale durch inhalation mit Echter Kamille (Chamomilla recutita) (*Senff H et al.* (1989) Allergologie: 12(2); 51-53)