



London, 24 October 2005
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OVERVIEW OF COMMENTS RECEIVED ON
'Structure of the list of herbal substances, preparations and combinations thereof'
(EMEA/HMPC/100824/2005)

Table 1: Organisations that commented on the document as released for consultation

	Organisation
1.	Laboratoires Servier

Table 2: Discussion of comments

Line no or section and paragraph no	Comment and rationale	Outcome / Proposed change
Page 3/4	Specified posology: it should allow for a range as it is the case for the strength	This is already possible with the current wording
Page 3/4	<p>Route of administration: "external use" is not defined in the current Standard terms list (December 2004) nor in the ICH M5 EWG "Routes of administration controlled vocabulary"</p> <p>The appropriate term should be "topical use" as expressed in the ICH M5 draft, even if in the 2004/24/EC Directive on traditional herbal medicinal products (article 16 bis §1.c) "external use" is used but not defined.</p> <p>Topical medicinal products are defined in the CPMP guideline "Excipients in the label and package leaflet of medicinal products for human use" (CPMP/463/00. July 2003) § Excipients in the labelling:</p> <p><i>"Topical medicinal products can be taken to include those medicinal products applied externally to the skin, respiratory products delivered to the lung by inhalation and any medicinal product delivered to the oral, nasal, rectal and vaginal mucosae, i.e where the delivery may be local or transdermal."</i> Using the "topical use" expression avoids a comprehensive Routes of administration list <i>i.e</i> encompassing the auricular, buccal, cutaneous, dental, nasal, oral, oropharyngeal, rectal, inhalational, sublingual, gingival, laryngeal, laryngopharyngeal, oromucosal routes (14 routes). Most of these routes are used by current herbal drug preparations through the European Community.</p>	Decision that the document should retain reference to "external use" as referred to in Directive 2001/83/EC as amended.