11 March 2010
EMA/HMPC/710724/2009
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on draft 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products / traditional herbal medicinal products' (EMEA/HMPC/CHMP/CVMP/287539/2005 Rev.1)

Final

Table 1: Organisations that commented on the draft guideline as released for public consultation

Organisations and/or individuals	
AESGP	Association Européenne des Spécialités Pharmaceutiques Grand Public

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SCIENCE MEDICINES HEALTH

Table 2: Discussion of comments

General comments

Interested party	Comment and Rationale	Outcome
AESGP	We take the benefit of this revision to communicate some minor comments on specific items which are not correct from our point of view or which should be clarified.	

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
6.2.2. Quantified extracts	AESGP	**6.2.2. Quantified extracts – Example Ginkgo extract (line 357, 364)** In both these cases, the term "and quantified" should be added after "refined" because this term is part of the complete declaration.	(1) Not agreed. The type of the extract is not a necessary part of the declaration. This goes for quantified extracts as well as for standardised and other extracts.

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6.2.3.Other extracts	AESGP	**6.2.3. Other extracts – Example c – Tinctures (line 420)** From our point of view, the declaration of the equivalent amount of herbal dry is not correct. It should read: "equivalent to 200 mg Valerian root" instead of "equivalent to 200 - 250 mg Valerian root because in case of tinctures the decisive quality parameter is the ratio **drug to solvent** and not the ratio **drug to tincture**, in this case 1 : 5. This corresponds to 200 mg herbal drug.	(2) Not agreed. There was agreement during the preparation of the guideline, that the declaration of tinctures in finished products by using 'Drug to extraction solvent ratio' should no longer be supported because it is not directly comparable with the declaration of other preparations, where the DER is used.
6.3.3. Other herbal preparations	AESGP	**6.3.3. Other herbal preparations– Example Myrrh tincture (line 489)** For the same reason as under 6.2.3. the declaration of Myrrh tincture should read: "equivalent to 5.0 mg Myrrh" instead of "equivalent to 5.5 - 6.3 mg Myrrh".	(3) Not agreed. There was agreement during the preparation of the guideline, that the declaration of tinctures in finished products by using 'Drug to extraction solvent ratio' should no longer be supported because it is not directly comparable with the declaration of other preparations, where the DER is used.