20 May 2014
EMA/HMPC/679424/2013
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on draft Community herbal monograph on *Panax ginseng* C.A. Meyer, radix (EMA/HMPC/321233/2012)

Final

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on Panax ginseng C.A. Meyer, radix as released for public consultation on 16 April 2013 until 15 July 2013

	Organisations and/or individuals
1	AESGP, Christelle Anquez-Traxler (c.anquez@aesgp.eu)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Table 2: Discussion of comments

GENERAL COMMENTS		
Interested party	**Comment and Rationale**	**Outcome**
AESGP	AESGP in principle welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for panax ginseng-containing products, should facilitate mutual recognition in Europe.	

SPECIFIC COMMENTS ON TEXT			
Section number and heading	**Interested party**	**Comment and Rationale**	**Outcome**
2. Qualitative and quantitative composition	**AESGP**	The herbal preparation D) does not only contain 4% ginsenosides but is adjusted to this amount. The wording should be modified as follows: D) Dry extract ($DER_{genuine}$ 3-7:1), extraction solvent ethanol 40% V/V, **adjusted** to 4% ginsenosides (sum of Rb_1, Rb_2, Rc, Rd, Re, Rf, Rg_1, Rg_2)	Not endorsed. The term “adjusted” may indicate a process of standardisation or quantification of extracts. In principle, standardisation or quantification is only acceptable if constituents with therapeutic activity are known or are generally accepted to contribute to the therapeutic activity. Currently the efficacy of ginseng preparations is not supported by clinical studies in order to suggest well-established use. Therefore, in accordance with HMPC guidance documents standardisation or quantification of ginseng extracts cannot be accepted. Furthermore, the herbal preparation D has been reported differently by member states, with some referring to a standardised preparation and others just stating a content of 4% ginsenosides. In order to avoid

			confusion it was decided to use the term “containing”. This wording has also been used before in a similar case in the course of the establishment of the Community herbal monograph on *Arctostaphylos uva-ursi* (L.) Spreng., folium (EMA/HMPC/573460/2009 Rev.1)
3. Preparation form	**AESGP**	This paragraph describes the different preparations and dosage forms with an accepted traditional use. The herbal preparations B, C and E are marketed in solid dosage forms as well as in liquid dosage forms for oral use. This is in line with the table in the Assessment Report which lists the preparations available in national markets. E.g. preparation B is listed under “Germany” in position 10, preparation C in positions 28, 43 and 56 as well as preparation E in positions 17, 25, 40, 41 and 49. Therefore it has to be specified in paragraph 3, 4th sentence: "Herbal preparation**s B, C,** D**, E** in solid and liquid dosage forms". As a consequence, the 2nd sentence should read as follows: "Herbal preparations ~~B, C, E,~~ F, K, L in solid dosage forms".	Endorsed. The documents have been changed accordingly.