European Medicines Agency
Evaluation of Medicines for Human Use

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OVERVIEW OF COMMENTS RECEIVED ON 'COMMUNITY HERBAL MONOGRAPH ON *EQUISETUM ARVENSE* L., HERBA' (EMEA/HMPC/394894/2007)

Table 1: Organisations providing comments on the draft Community herbal monograph on *Equisetum arvense* L., herba, as released for consultation on 31 October 2007 until 15 February 2008.

	Organisation
1	Kooperation Phytopharmaka, Germany
2	The Association of the European Self-Medication Industry (AESGP)

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Table 2: Discussion of comments

GENERAL COMMENTS TO DRAFT DOCUMENT		
SPECIFIC COMMENTS ON TEXT		
SECTION TITLE		
Paragraph no. line no.	**Comment and Rationale**	**Outcome**
2. Qualitative and quantitative composition ii) Herbal preparations:	• Dry aqueous extract (DER_{native} 6-8:1) and combinations thereof with dried herbal substance. Rationale: This corresponds to the preparation Zinnkraut-Kräutertabletten, marketed in Germany by SALUS Haus GmbH & Co. KG since 30 June 1978. • Powdered herbal substance Rationale: Powdered equisetum is authorised as traditional herbal medicinal product in *inter alia* France and Spain.	The monograph should describe preparations of Equiseti herba. It was decided by the HMPC that combinations - including those of different preparations from the same plant species - are not covered by the monograph. Therefore, the proposal is not accepted. It is suggested to apply for such a product with an individual application. The preparation is listed under ii) Herbal preparations: a) comminuted herbal substance.
4.1 Therapeutic indications	Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. **Traditional herbal medicinal product used to facilitate urinary and digestive elimination functions.** **Traditional herbal medicinal product used as an adjuvant to slimming diet.** **Rationale:** A number of references (listed in annex) attest of the traditional use in the following indications: - facilitation of urinary and digestive elimination functions - adjuvant to slimming diet	The indication "to facilitate urinary elimination functions" is subsumed in the wording "as an adjuvant in minor urinary complaints." There is lack in the majority of literature demonstrating a traditional use in the indication "to facilitate digestive elimination functions". Pharmacological studies on this topic are -not available. In so far the efficacy of Equiseti herba is not plausible for this indication. The pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience for the indication "as an adjuvant to slimming diet". The use of diuretics for obesity / overweight is obsolete. See also II.1.2 in the Assessement Report.

4.2. Posology and method of administration	• Dry aqueous extract (6-8:1) and combinations thereof with dried herbal substance corresponding to 1102 mg of the herbal substance 3 times daily. 1 coated tablet is equivalent to 1102 mg (= 150 mg + 952 mg) herbal substance. 1 single dose is equivalent to 1102 mg herbal substance. 1 daily dose is equivalent to 3306 mg herbal substance. Rationale: This corresponds to the preparation Zinnkraut-Kräutertabletten, coated tablets, marketed in Germany by SALUS Haus GmbH & Co. KG since 30 June 1978 with the indication "Traditionally used to support the excretory function of the kidneys". One coated table contains powdered herbal substance 150 mg and aqueous dry extract (DER_{native} 6-8:1) 136 mg. • powdered herbal substance: 190-500 mg Rationale: Powdered equisetum is authorised as traditional herbal medicinal product in different countries at two different single doses: 190 mg/capsule (Spain) and 250 mg/capsule (France). The single dose may be 1 or 2 capsules. • dry extract (4-7:1) extraction solvent: water: 185-200 mg. The daily dose is 2-3 times	See comments above. There was no further material to prove the tradition of these products. The member states did not mention such products during the request for information. There is no rationale for the proposed posology. There was no adequate information provided and the 30-years tradition was not confirmed by France or Spain.
Duration of use	• The sentence should be rephrased as follows: "If the symptoms persist ~~after one week~~ during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted" Rationale: Draft community herbal monographs for herbal preparations having the same therapeutic indication as Equiseti herba (Betulae folium and	The herbal substance is traditionally used over a period of 2 to 4 weeks. Having regard to the particularities of the indication "…an adjuvant in minor urinary complaints" the specification of the duration of use, before consulting a doctor if the symptoms persist, is considered to contribute to the safety of the use. It is suggested not to cancel the formulation "after one week".

	Solidaginis virgaureae herba) do not specify a specific duration before consulting a doctor if symptoms persist, which looks more realistic.	
Undesirable effects	Based on a literature search, no information has been found which could support possible "mild gastrointestinal complaints". It is proposed to delete "mild gastrointestinal complaints". The sentence would thus read: "mild ~~gastrointestinal complaints and~~ allergic reactions (e.g. rash) have been reported."	The wording is based on the BfArM case nr. 97001924. See also II.3.3.1 in the Assessment Report.