24 November 2015
EMA/HMPC/624379/2015
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Hedera helix* L., folium (EMA/HMPC/586888/2014)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Hedera helix* L., folium as released for public consultation on 28 January 2015 until 15 May 2015.

	Organisations and/or individuals
1	Wroclawskie Zaklady Zielarskie Herbapol S.A., Poland

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Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
None		

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
4.2. Posology and method of administration	Wroclawskie Zaklady Zielarskie Herbapol S.A.	We suggest changing the description of the posology in the population of "Children between 6-11 years of age" in the subsection "a)" in the following manner: "Single dose: 11-35 mg, two to three times daily Daily dose: 33-70 mg (Note: Maximum daily dose for ethanol-containing finished products: 34 mg; corresponding to 210 mg herbal substance)." The posology proposed in the monograph for the preparation "a)" appears to be a typing mistake. The subsection "a)" corresponds to the herbal preparation "Dry extract (DER 4-8:1), extraction solvent ethanol 24-30% m/m" for which posology was suggested on the basis of the consolidated data for the following marketed preparations: 1. dry extract (4-8:1), extraction solvent ethanol 30% 2. dry extract (5-7.5:1), extraction solvent: ethanol 30%	Endorsed In the monograph and the AR the maximal single dose for children between 6-11 years of age was changed from 32.5 to 35 mg.

Section number and heading	Interested party	Comment and Rationale	Outcome
		The posology of the second preparation was given in the Assessment Report and falls within the range of 11.2 mg to 35 mg in the population of children aged 6-11 years (see p. 15 of Draft Assessment Report, EMA/HMPC/586887/2014, for the upper limit), and not 11.2 mg to 32.5 mg as currently stated in the summarizing row on p.16 of the Assessment Report. Therefore, the error in the monograph seems to be taken from incorrect data in the Assessment Report. The posology of the preparation "dry extract (5-7.5:1)" should be fully integrated and accurately represented in the monograph, since this preparation appears to bring the vast majority of clinical data for the monograph. Additionally, in the population of children aged 6-11 years as well as in other patient groups (i.e. adults) the single dose of 35 mg dry extract seems a logical consequence of the adopted maximum daily doses (105 mg [3 x daily 35 mg] – adults; 70 mg [2 x daily 35 mg] – 6-11 y.). Moreover, in the population of children aged 6-11 years the single dose of 35 mg of the dry extract (5-7.5:1) applied twice daily meets the recommendations on maximum daily dosages of the herbal substance for ethanol-free ivy preparations outlined on p. 78 of the Assessment Report (6-12 years: 437 mg in 2-3 daily dosages). References: 1. EMA. Assessment report on *Hedera helix* L., folium. EMA/HMPC/586887/2014, London 2014	