09 July 2025
EMA/HMPC/5153/2025
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Plantago lanceolata* L., folium (EMA/HMPC/887979/2022)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Plantago lanceolate* L., folium as released for public consultation on 24 July 2024 until 15 November 2024.

	Organisations and/or individuals
1	AESGP - Association of the European Self-Medication Industry
2	German Pharmaceutical Industry Association (BPI), Germany
3	Dr. Theiss Naturwaren GmbH, Germany

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Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	Comment on the draft monograph (EMA/HMPC/887979/2022) about 2.Qualitative and quantitative composition In the former version of the monograph (EMA/HMPC/437858/2010 Corr.), the herbal preparations included (d) Liquid extract (DER 1:0.8-1.2); extraction solvent: ethanol 20-40% V/V; Why this preparation changes to Liquid extract (DER 1:1); extraction solvent: ethanol 25-35%? In the assessment report on plantaginis lanceolatae folium – Revision 1 (EMA/HMPC/887981/2022), in section 2.1.1, table 1 presenting Overview of data obtained from marketed medicinal products in EU/EEA member states, highlights the presence of Liquid extract (1:1), extraction solvent: ethanol 20% (m/m) with regulatory status AT, THMP, 2010 and DE, WEU, at least 1976; Plantaginis Extractum fluidum (DER 1:1), extraction solvent: ethanol 20% (m/m) with regulatory status CZ, THMP, on the market since 1999, switched to TUR 04/2011; liquid extract from Plantaginis lanceolatae herba (1:1); extraction solvent: ethanol 20%(m/m) with regulatory status DE, WEU, 2005; Liquid extract from Plantago lanceolata, folium (0.9- 1.1:1); extraction solvent: ethanol 20% (m/m) with regulatory status LT, THMP, 1995; liquid extract (0.7-1.3:1); extraction solvent: ethanol 20% (m/m) with regulatory status PL, THMP, 1996. The requirement of Article 16c (c) of Directive 2001/83/EC documenting medicinal use throughout a period of at least 30 years preceding	During the revision, all submitted data has been reviewed. While the extracts with extraction solvent ethanol 40% (V/V) were included in a separate entry j), and thus the upper limit for d) is now 35% (V/V). At the same time, the lower value was corrected because a transmission error in the first version of the monograph stated extracts with ethanol 20% (V/V), while the extracts submitted (market overview) were produced with ethanol 20% (m/m) (=24.6% (V/V). This has been corrected, which leads to "ethanol 25-35% (V/V)".

Interested party	Comment and Rationale	Outcome
	the date of application, including at least 15 years within the EU has been fulfilled for the Liquid extract (1:1), extraction solvent: ethanol 20% (m/m). However, in the section 2.3, this information about the liquid extract with solvent extraction ethanol 20% V/V has been omitted in table 3, instead the liquid extract (DER 1:1); extraction solvent: ethanol: 25-30% (V/V) was hold. It has to be noted that in table 1, liquid extract (1:0.9-1.1); extraction solvent: ethanol 35% (V/V) with regulatory status DE, WEU, at least 1976; liquid extract (1:1); extraction solvent: ethanol 35% (V/V) with regulatory status DE, THMP, at least 1976, and liquid extract (1:1); extraction solvent: ethanol 24.6% (V/V) with regulatory status DE, WEU, at least 1976; liquid extract (1:1); extraction solvent: ethanol 25% (V/V) with regulatory status DE, WEU, at least 1976 exist. Therefore, the overall table (table 3) should have included the liquid extract (DER 1: 0.9-1.1); extraction solvent: ethanol: 20-35% (V/V) instead.	

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	The former version of the monograph included (d) Liquid extract (DER 1:0.8-1.2); extraction solvent: ethanol 20-40% V/V Proposed change (if any): Based on the assessment report, the active substance, liquid extract (DER 1:1); extraction solvent: ethanol 20% is in use in DE since at least 1976. (d)Liquid extract (DER 1: 0.9-1.1);	Partially agreed. As seen from the Overview of data obtained from marketed medicinal products in EU/EEA member states in the Assessment report, no product with extraction solvent ethanol 20% (V/V) exist. The extraction solvent ethanol 20% (m/m) from existing products represent ethanol 24.6% (V/V).

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		extraction solvent: ethanol: 20-35% (V/V); not to 40% because a new item have been added covering the ethanol 40% (j) Liquid extract (DER 1:0.8-1.2), extraction solvent: ethanol 40% V/V.	Due to a Polish product, the DER can be broadened to 1:0.9-1.1 instead of 1:1.
2. Qualitative and quantitative composition	Dr. Theiss Naturwaren GmbH	1. The former version of the monograph specified the herbal preparations (d) as Liquid extract (DER 1:0.8-1.2); extraction solvent: ethanol 20-40% V/V. In the current draft monograph the herbal preparations (d) is now specified as Liquid extract (DER 1:1), extraction solvent: ethanol 25-35% V/V. Proposed change (if any): Based on the assessment report the herbal preparation d) should be specified as Liquid extract (DER 0.9-1.1:1), extraction solvent: ethanol 24-35% V/V. Rationale: The assessment report on plantaginis lanceolatae folium – Revision 1 (EMA/HMPC/887981/2022), table 1 in section 2.1.1 (Overview of data obtained from marketed medicinal products in EU/EEA member states) (Page 9-11), shows the presence of various medicinal products using the extraction solvent ethanol 20% (m/m). Therefore, the extraction solvent ethanol of herbal preparation d) should be specified as at least "ethanol 24 - 35% V/V". 2. The assessment report on Plantaginis lanceolatae folium – Revision 1 (EMA/HMPC/887981/2022), table 1 in section 2.1.1	Agreed. According to the relevant ethanol tables, ethanol 20% (m/m) corresponds to ethanol 24.6% (V/V). According to the rounding rules, this is actually given as 25% (V/V). However, to avoid any problems in procedures, the value is changed to 24% (V/V). DER see above.

Section number and heading	Interested party	Comment and Rationale	Outcome
		(Overview of data obtained from marketed medicinal products in EU/EEA member states), shows the presence of a medicinal product using Liquid extract from Plantago lanceolata, folium (0.9-1.1:1); extraction solvent: ethanol 20% (m/m). Therefore, the DER of herbal preparation d) should be specified as "0.9-1.1:1" or an herbal preparation covering Liquid extract from Plantago lanceolata, folium (0.9-1.1:1); extraction solvent: ethanol 20% (m/m) should be added.	
4.2. Posology and method of administration	BPI	Cutaneous use (Indication 3) *Children from 3 years of age, adolescents, adults and elderly:* Preparation a) as macerate in 150 ml of cold water *Children from 3 years of age, adolescents, adults and elderly:* Single dose: 1.4 g Dosage frequency: 3-4 times daily *Daily dose: 4.2-5.6 g* Proposed change (if any): The age information is double. The second age information should be deleted.	Agreed.
4.2 Posology and method of administration	Dr. Theiss Naturwaren GmbH	Why is the proposed minimum single dose and minimum daily dose of preparation d) for children 5-11 years of age (single dose: 1.2 - 1.3 g / daily dose: 2.5 - 3.9 g) higher than for Adolescents, adults and elderly (single dose: 0.4 - 2.6 g / daily dose: 1.2 - 5.6 g)?	This information is incorrect and has already been unfortunately included in the first version of the monograph.

Section number and heading	Interested party	Comment and Rationale	Outcome
			After double-checking the correct SD and DD according to products on the market (table 1 of the AR), the posology is now displayed in the monograph correctly.