18 July 2017
EMA/HMPC/48689/2017
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Allium sativum* L., bulbus EMA/HMPC/7685/2013)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Allium sativum* L., bulbus as released for public consultation on 25 July 2016 until 31 October 2016.

	Organisations and/or individuals
1	LABOFARM (Pharmaceutical Laboratory), Poland

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Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
LABOPHARM	We welcome the preparation of a Community draft monograph on *Allium sativum* L., bulbus (EMA/HMPC/7685/2013), however we propose to take into consideration the following specific comments. We are a manufacturer of herbal medicinal product Tabletki z czosnku Labofarm, that contains powdered Allium sativum bulbus in the dose of 300 mg. This product has been on the market since July 1990 (26 year on the market). This information was omitted in the draft of Assessment report on *Allium sativum* L., bulbus (EMA/HMPC/7686/2013), in the point: Information on medicinal products marketed in the EU/EEA, Table 1: Overview of data obtained from marketed medicinal products. We propose to add information about this medicinal product. See: Marketing Authorisation of medicinal product Tabletki z czosnku Leki współczesnej terapii. Preparaty roślinne. Varia (Drugs in contemporary therapy. Herbal preparations. Varia) SPC of Tabletki z czosnku Labofarm	Endorsed. This product was added in the AR as a herbal medicinal product on the Polish market since 1990.

Specific comments on text

<table>
<tr><th>Section number and heading</th><th>Interested party</th><th>Comment and Rationale</th><th>Outcome</th></tr>
<tr><td>4.2. Posology and method of administration</td><td>LABOPHARM</td><td>We propose to add:
Indication 2)
Adolescents, adults and elderly
d) Powdered herbal substance
single dose: 300 mg
Daily dose: 900 mg divided into 3 doses

Justification:
Draft Assessment report on Allium sativum L., bulbus (EMA/HMPC/7686/2013) contains information about products on the market in the EU/EEA Member States. In the Table 1: Overview of data obtained from marketed medicinal products is the following information:

<table>
<tr><th>Active substance</th><th>Indication</th><th>Pharmaceutical form</th><th>Regulatory status</th></tr>
<tr><td>Dried powder (+oil)</td><td>For oral use in adults and elderly: for the treatment of the symptoms of common cold and cough</td><td>300 mg (+ 0.001 ml). 3 tablets daily</td><td>1987 United Kingdom</td></tr>
</table>

Currently this product has 29 years tradition. We suppose that when the monograph is in final status, the product will reach 30 years of</td><td>Not endorsed.
This product is on the UK market for 30 years. Nevertheless, it corresponds to a combination product. Allium is present as actives substances in both forms as powder as well as essential oil. Furthermore, it has been confirmed that another herbal preparation (Echinacea) is also present in this herbal medicinal product. Consequently this product was removed from the AR.</td></tr>
</table>

Section number and heading	Interested party	Comment and Rationale	Outcome
		tradition. Therefore, we believe that this product can be included in the final version of the monograph. Omission of garlic powder in the indication: Traditional herbal medicinal product used for the relief of the symptoms of cold, because of the lack of a few months to achieve 30 years of tradition may result in moving from the status of the medicinal product to the status of dietary supplement, and that was not the objective of Directive/24/2004/EC.	