16 January 2019
EMA/HMPC/554879/2018
Committee on Herbal Medicinal Products (HMPC)

# Addendum to Assessment report on *Phaseolus vulgaris* L., fructus sine semine

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|---|---|
| Rapporteurs | E Skukauska/B Jansone |
| Peer-reviewer | B Kroes |

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| HMPC decision on review of monograph on *Phaseolus vulgaris L.*, fructus sine semine adopted on date 12 November 2013 | 30 January 2018 |
| Call for scientific data (start and end date) | From 1 March 2018 to 31 May 2018 |
| Agreed by Working Party on European Union monographs and list (MLWP) | September 2018 |
| Adoption by Committee on Herbal Medicinal Products (HMPC) | 16 January 2019 |

## Review of new data on *Phaseolus vulgaris L., fructus sine semine*

### Periodic review (from 2013 to 2018)

Scientific data (e.g. non-clinical and clinical safety data, clinical efficacy data)

☐ Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases)

☒ Scientific/Medical/Toxicological databases: search period was set from April 2012 to April, 2018. Using the key words "*Phaseolus vulgaris, pods"* and "*Phaseolus vulgaris* L., fructus sine semine" 9 relevant references and 22 references not supporting assessment were detected. All together using keywords "*Phaseolus vulgaris, pods"* and "*Phaseolus vulgaris* L., fructus sine semine" 506 hits were found (6 of them were significant and included in the reference list as relevant) in Scopus, in PubMed database 49 hits were found (3 of them were significant and already found in Scopus database and included in the list of reference as relevant), in Science direct 722 hits were found (1 of them was significant, already found in Scopus and in PubMed

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and was included in the reference list as relevant); in Google Scholar were found 3 significant publications.

☐ Other

Regulatory practice

☒ Old market overview in AR (i.e. products fulfilling 30/15 years on the market)

☒ New market overview (including pharmacovigilance actions taken in member states)

☐ Referral

☐ Ph.Eur. monograph

☐ Other

Consistency (e.g. scientific decisions taken by HMPC)

☐ Public statements or other decisions taken by HMPC

☐ Consistency with other monographs within the therapeutic area

☐ Other

**Availability of new information (i.e. likely to lead to a relevant change of the monograph)**

| *Scientific data* | Yes | No |
|---|---|---|
| New non-clinical safety data likely to lead to a relevant change of the monograph | ☐ | ☒ |
| New clinical safety data likely to lead to a relevant change of the monograph | ☐ | ☒ |
| New data introducing a possibility of a new list entry | ☐ | ☒ |
| New clinical data regarding the paediatric population or the use during pregnancy and lactation likely to lead to a relevant change of the monograph | ☐ | ☒ |
| New clinical studies introducing a possibility for new WEU indication/preparation | ☐ | ☒ |
| Other scientific data likely to lead to a relevant change of the monograph | ☐ | ☒ |
| *Regulatory practice* | Yes | No |
| New herbal substances/preparations with 30/15 years of TU | ☐ | ☒ |
| New herbal substances/preparations with 10 years of WEU | ☐ | ☒ |
| Other regulatory practices likely to lead to a relevant change of the monograph | ☐ | ☒ |
| Referrals likely to lead to a relevant change of the monograph | ☐ | ☒ |
| New / Updated Ph. Eur. monograph likely to lead to a relevant change of the monograph | ☐ | ☒ |
| *Consistency* | Yes | No |
| New or revised public statements or other HMPC decisions likely to lead to a relevant change of the monograph | ☐ | ☒ |
| Relevant inconsistencies with other monographs within the therapeutic area that require a change of the monograph | ☐ | ☒ |
| Other relevant inconsistencies that require a change of the monograph | ☐ | ☒ |

**Summary and conclusions on the review**

During the review 31 new references not yet available during the previous assessment were identified.

No references were provided by Interested Parties during the Call for data.

Nine references were considered to be relevant for the assessment. These references include results of non-clinical studies describing the hypoglycemic effect, hypolipidemic, antibacterial activity and antioxidant activity. Other 22 references contain data that concerns only beans (*Phaseolus vulgaris semine*) but not the pods. Taking into account that the composition and therapeutic use of the seeds

preparations are different (for the weight control) from that of the pods, data found in literature on the beans could not be extrapolated to bean pods. The data about the beans themselves are not considered in this review.

No references justify a revision of the monograph.

No revision is considered required because no clinical studies or new safety concerns related to the use of *Phaseolus vulgaris* L., fructus sine semine were found. No new medicinal products containing *Phaseolus vulgaris* L., fructus sine semine as the single active substance, fulfilling the legal requirements of traditional use or WEU were reported during the call for data by Interested Parties or EU member states.

**References**

a) References relevant for the assessment:

Alkofahi AS, Abdul-Razzak KK, Alzoubi KH, Khabour OF. Screening of the Anti-hyperglycemic activity of some medicinal plants of Jordan. *Pak J Pharm Sci* 2017, 30(3):907-912

Almuaigel MF, Seif MA, Albuali HW, Alharbi O, Alhawash A. Hypoglycemic and hypolipidemic effects of aqueous extract of phaseolus vulgaris pods in streptozotocin-diabetic rats. *Biomed Pharmacother* 2017, 94:742-746

Chaurasia S, Saxena R. Antibacterial Activity of Four Different Varieties of Green Beans. *Research Journal of Pharmaceutical, Biological and Chemical Sciences* 2012, 3(3):70-74

Chaurasia S, Saxena R. Evaluation of Total Phenol and Flavonoid Content, Antioxidant and Iron Chelation Activities of Ethanolic Extracts of Green Beans. *Am. J. PharmTech Res* 2014, 4(3):614-624

Ivashko L, Dmytrik V, Raetska Ya. Biochemical parameters of the rats with esophageus burn treated with aquesous extract of phaseolus vulgaris pods. *Biological Markers in Fundamental and Clinical Medicine* 2018, 2(1):14-16

Kyznetsova M.Y, Lavrovska D, Makieieva O, Ostapchenko L. Effect of Aqueous Extract from Phaseolus vulgaris Pods on Lipid Peroxidation and Antioxidant Enzymes Activity in The Liver and Kidney of Diabetic Rats. *J. Appl Pharm Sci* 2015, 5(5):001-006

Kyznetsova M.Y, Savchuk O.M, Halenova T.I, Ostapchenko L.I. Вуглеводний обмін при цукровому діабеті 1-го типу у щурів за умов застосування водного екстракту лушпиння квасолі звичайної. [Carbohydrate metabolism in type 1 diabetic rats under the conditions of the kidney bean pods aqueous extract application]. *Fiziolohichnyĭ zhurnal* 2015, 61(6):96-103

Kyznetsova M.Y, Zhyvolozhnyi A.Y, Lavrovska D.O, Ostapchenko L.I. Effect of aqueous extract from Phaseolus vulgaris pods on cytokine profile of streptozotocin-induced diabetic rats. *Res J. Pharm Bio Chem Sci* 2015, 6(1):1511-1520

Rana Jenish H, Patel Urvi R, Sonia J.Patel, Vijay Lambole, Dhiren P.Shah. Pharmacological activities of Phaseolus Vulgaris: A review. *Int J Pharm Sci* 2016, 7(2):107-115

b) References that justify the need for the revision of the monograph:

None

**Rapporteur's proposal on revision**

☐ Revision needed, i.e. new data/findings of relevance for the content of the monograph

☒ No revision needed, i.e. no new data/findings of relevance for the content of the monograph

**HMPC decision on revision**

☐ Revision needed, i.e. new data/findings of relevance for the content of the monograph

☒ No revision needed, i.e. no new data/findings of relevance for the content of the monograph

HMPC agreed with Rapporteurs position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Phaseoli fructus (sine semine).