EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2020
EMA/HMPC/489234/2020
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Solanum dulcamara* L., stipites

Rapporteur(s)	E Svedlund
Peer-reviewer	R Länger

HMPC decision on review of monograph *Solanum dulcamara* L., stipites adopted on 15 January 2013	15 January 2013
Call for scientific data (start and end date)	From 1 April 2020 to 30 June 2020
Adoption by Committee on Herbal Medicinal Products (HMPC)	18 November 2020

Review of new data on *Solanum dulcamara* L., stipites

Periodic review (from 2013 to 2020)

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

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

The EudraVigilance database was searched on 1/9/2020 using the key words 'solanum dulcamara', 'solani dulcamarae', 'woody nightshade'

☒ Scientific/Medical/Toxicological databases

The following databases were searched on 8/9/2020 using the key word 'solanum dulcamara' and publication year up to 2011: PubMed; Cochrane; Embase

☐ 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

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☒ Ph.Eur. monograph

There is no 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

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 45 new references in PubMed and 65 new references in Embase database not yet available during the first/previous assessment were identified.

0 references were provided by Interested Parties during the Call for data.

0 references were considered to be relevant for the assessment.

0 references justify a revision of the monograph.

No new safety issues have been identified from reports in the EudraVigilance database up to 1 September 2020.

In the first assessment report published in 2013, there are information on medicinal products on the German market since 1990 and 1991 that today should have fulfilled the 30 years of TU. However, the market authorisation for these medicinal products ended in 2013 and therefore there are no new herbal substances/preparations with 30/15 years of TU that will trigger a revision of the monograph.

In conclusion, no revision is considered required because no new data/findings of relevance for the content of the monograph were found.

References

a) References relevant for the assessment:

None.

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

The HMPC agreed notto revise the monograph, assessment report and list of references on *Solanum dulcamara* L., stipites, by consensus.