

05 June 2018
EMA/HMPC/627591/2017
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Polypodium vulgare* L., rhizoma

Rapporteur(s)	Gro Fossum
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HMPC decision on review of monograph <i>Polypodium vulgare</i> L., rhizoma adopted on 06 November 2008	05 April 2016
Call for scientific data	From 15 July 2016 to 15 October 2016
Agreed by Working Party on European Union monographs and list (MLWP)	March 2018
Adoption by Committee on Herbal Medicinal Products (HMPC)	05 June 2018

Review of new data on *Polypodium vulgare* L., rhizoma

Periodic review (from 2009 to 2017)

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

- ☒ Pharmacovigilance data (e.g. data from EudraVigilance, Vigibase, national databases): The World Health Organisation's Uppsala Monitoring Centre (WHO-UMC): 2 case reports
- ☒ Scientific/Medical/Toxicological databases: Toxline (6 hits); Pubmed/Embase (18 hits)
- ☒ Other relevant scientific data: SciFinder/Medline (8 hits)

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)

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

Summary and conclusions on the review

During the review eight new references not yet available during the first assessment were identified.

No reference was provided by Interested Parties during the Call for data.

No reference was considered to be relevant for the assessment.

No revision is considered required because only eight new articles were found in a SciFinder search, where seven articles referred to different botanical and phyto-chemical characteristics of *Polypodium vulgare* L. One indian experimental biology study described the pharmacodynamic *in vivo* effects of aqueous extract of the root of *Polypodium vulgare* L. on perfused frog heart, anaesthetised dogs and rabbit small intestine after exposure to various drugs such as pentobarbitone, pentylenetetrazol. None of the data included in the new references could be considered relevant.

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 position 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 not to revise the monograph, assessment report and list of references on *Polypodium rhizoma* by consensus.