EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Origanum dictamnus* L., herba

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HMPC decision on review of monograph *Origanum dictamnus* L., herba adopted on 09 July 2013	13 January 2021
Call for scientific data (start and end date)	From 01 April 2021 to 30 June 2021
Adoption by Committee on Herbal Medicinal Products (HMPC)	26 January 2022

Review of new data on *Origanum dictamnus* L., herba

Periodic review (from 2014 to 2021)

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 Scopus, PubMed. Keywords: "*origanum dictamnus*", "dittany of crete", "dittany".
- ☐ 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

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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

18 countries responded negatively to the request for a market overview on monoproducts containing Origani dictamni herba.

According to the response from DE, since 1976 there had been 3 herbal teas with Origani dictamni herba as only active substance on the German market. They disappeared from the market in December 1991 resp. in December 1992 because no application for marketing authorisation according Section 109a in connection with/or Section 105 German Medicinal Products Act had been submitted.

During the review, 32 (Scopus) new references not yet available during the first/previous assessment were identified.

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

Ten references were considered to be relevant for the assessment, among which four referred to combination products marketed in Greece containing herbal preparations from Origanum dictamnus and other plants such as Thymbra capitata (Pirintsos *et al.,* 2020, Anastasaki *et al.,* 2019, Tseliou *et al,.* 2019, Duijker *et al.,* 2015), so finally six remaining references focused on chemistry (mostly phenolic content of water as well other polar extracts and essential oils) and on antioxidant as well as

antimicrobial activities of preparations from Origanum dictamnus alone (Tair *et al.,* 2014, Skotti *et al.,* 2014, Koutelidakis *et al.,* 2016, Takis *et al.,* 2016, Varsani *et al.,* 2017, Paloukopoulou *et al.,* 2021- under press).

No revision is considered required because there are no new data/findings of relevance to justify a revision of the monograph.

References

a) References relevant for the assessment:

Anastasaki M, Bertsias A, Pirintsos SA, Castanas E, Lionis C. Post-market outcome of an extract of traditional Cretan herbs on upper respiratory tract infections: A pragmatic, prospective observational study. *BMC Compl Altern Med* 17(121) 2017, Article number 466

Duijker G, Bertsias A, Symvoulakis EK, Moschandreas J, Malliaraki N, Derdas SP, *et al.* Reporting effectiveness of an extract of three traditional Cretan herbs on upper respiratory tract infection: Results from a double-blind randomized controlled trial. *J Ethnopharmacol* 2015, 163:157–1662

Koutelidakis AE, Andritsos ND, Kabolis D, Kapsokefalou M, Drosinos EH, Komaitis M. Antioxidant and antimicrobial properties of tea and aromatic plant extracts against bacterial foodborne pathogens: A comparative evaluation. *Curr Topics Nutr Res* 2016, 14(2):133–142

Paloukopoulou C, Govari S, Soulioti A, Stefanis I, Angeli A, Matheeussen A*, et al.* Phenols from *Origanum dictamnus* L. and *Thymus vulgaris* L. and their activity against Malassezia globosa carbonic anhydrase. *Natural Product Research* 2021 (under press)

Pirintsos SA, Bariotakis M, Kampa M, Sourvinos G, Lionis C, Castanas E. The therapeutic potential of the essential oil of *Thymbra capitata* (L.) Cav., *Origanum dictamnus* L. and *Salvia fruticosa* Mill. and a case of plant-based pharmaceutical development. *Frontiers in Pharmacol* Vol 1124 2020, Article number 522213

Skotti E, Anastasaki E, Kanellou G, Polissiou M, Tarantilis PA. Total phenolic content, antioxidant activity and toxicity of aqueous extracts from selected Greek medicinal and aromatic plants. *Industr Crops Prods* 2014, 53:46–54

Tair A, Weiss EK, Palade LM, Loupassaki S, Makris DP, Ioannou E, *et. al. Origanum* species native to the island of Crete: *In vitro* antioxidant characteristics and liquid chromatography-mass spectrometry identification of major polyphenolic components. *Nat Prod Res* 2014, 28(16):1284–128718

Takis PG, Oraiopoulou ME, Konidaris C, Troganis AN. ^{1}H-NMR based metabolomics study for the detection of the human urine metabolic profile effects of *Origanum dictamnus* tea ingestion. *Food Funct* 2016, 7(9):4104–4115

Tseliou M, Pirintsos SA, Lionis C, Castanas E, Sourvinos G. Antiviral effect of an essential oil combination derived from three aromatic plants (*Coridothymus capitatus* (L.) Rchb. f., *Origanum dictamnus* L. and *Salvia fruticosa* Mill.) against viruses causing infections of the upper respiratory tract. *J Herb Med* 2019, 17-18, Article number 100288

Varsani M, Graikou K, Velegraki A, Chinou I. Phytochemical analysis and antimicrobial activity of *Origanum dictamnus* traditional herbal tea (decoction). *Nat Prod Commun* 2017, 12(11):1801–1804

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 not to revise the monograph, assessment report and list of references on *Origanum dictamnus* L., herba, by consensus.