EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

# Overview of comments received on Community herbal monograph on *Urtica dioica* L., *Urtica urens* L. their hybrids or their mixtures, radix (EMA/HMPC/461160/2008)

**This document was valid from 24 September 2012 until 22 January 2025**

| | Organisations and/or individuals |
|---|---|
| 1 | European Scientific Cooperative on Phytotherapy (ESCOP) |
| 2 | Association of the European Self-Medication Industry (AESGP) |
| 3 | Pharmaceutical Laboratory Labofarm, Poland (LABOFARM) |
| 4 | Polska Rada Leku Roślinnego, Poland (PRLR) |

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Table 2: Discussion of comments

## General comments to draft document

| Interested party | Comment and Rationale | Outcome |
|---|---|---|
| ESCOP | We welcome the preparation of a Community draft monograph on Nettle root and would like to comment as follows. | |
| AESGP | AESGP welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for Urtica radix-containing products, should facilitate mutual recognition in Europe. | |
| LABOFARM | We welcome the preparation of a Community draft monograph on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix (nettle root), however we propose to take into consideration the following specific comments.<br><br>We are a manufacturer of herbal medicinal product URTIX tablets, which contains powdered Urticeae radix in the dose of 330 mg. Product URTIX, 330 mg is on the market from 27.12.2001 (11 year on the market). Product is also registered in Lithuania since 2007. This information was omitted in the draft of Assessment report on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix (nettle root), presenting information from Poland (point: Other products which have been on the market for less than 30 years). | The Assessment Report on Urticae radix has been corrected according to the comment. |
| PRLR | We welcome the preparation of a Community draft monograph on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix (nettle root) however we propose to take into consideration the following specific comments. | |

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## SPECIFIC COMMENTS ON TEXT

| Section number and heading | Interested party | Comment and Rationale | Outcome |
|---|---|---|---|
| 2. Qualitative and quantitative composition | AESGP | We propose to add the following preparation:<br>"Dry extract (DER 6-11:1), extraction solvent methanol 20%". Alternatively, the DER range of extract b), e.g. "DER 6-14.3:1" could be widened, however, the posology is different (see below under 4.2).<br><br>The preparation is marketed in Germany as "Natu-prosta 600 mg uno, Filmtabletten". Package leaflet and expert information are attached. | Proposal is not endorsed. This product has not been on the market for more than 30 years, only since 2001. Thus it cannot be included in the Monograph on Nettle root with traditional use. |
| 2. Qualitative and quantitative composition | LABOFARM | We suggest to add:<br>ii) Herbal preparations<br>f) powdered herbal substance<br>Rationale: Our study of release beta sitosterol showed that the herbal medicinal product Urtix is similar to traditional herbal medicinal products (THMP) containing dry extract with methanol as extraction solvent. Based on sterol quantification results we assess dosage equivalence.<br>See: Expert opinion on traditional use of Urtix, tablets. | Proposal is not endorsed. The product has not been on the market for more than 30 years, only since 2001. National Competent Authorities may decide about acceptance after evaluation of a full set of data to demonstrate comparability. This task could be assigned the HMPC in the case of a referral if suitable data are provided in accordance with the legal procedure. |
| 2. Qualitative and quantitative composition | PRLR | We suggest to add:<br>ii) Herbal preparations<br>f) powdered herbal substance<br><br>Rationale: In the "definition" section of ESCOP Monograph – Urticae radix (Second Edition) monograph, an herbal substance was defined as whole, cut or powdered, dried roots and | The proposal is not accepted. There have not been any products containing powdered herbal substance of Nettle root on the market more than 30 years. No appropriate literature including posology has been provided by the interested party. |

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| | | rhizomes of *Urtica dioica* L., *Urtica urens* L., their hybrids or mixtures of these. The same definition of nettle root (as an herbal substance) was included in a draft Assessment Report (based on DAB 10, ESCOP monographs, WHO monographs). The form of powdered nettle root was also mentioned in point 2.1 of the AR as it was used in Russian folk medicine. The section "Composition of drug" in the German Commission E monograph on Urticae radix (Bundesanzeiger No. 173 18.09.1986; revisions 1989, 1990 and 1991) was defined as "Stinging nettle root consists of the underground parts of *Urtica dioica* L., *U. urens* L. and/or their hybrids [Fam. Urticaceae] as well as preparations from nettle root at an effective dose".<br><br>See:<br>1. Commission E Monograph (Urticae radix) Bundesanzeiger Nr. 173, 18.09.1986.<br>2. ESCOP Monograph (Second Edition) (Urticae radix - Nettle root). European Scientific Cooperative on Phytotherapy, Thieme, Stuttgart 2003, 528-535. | |
| 4.1. Therapeutic indications | ESCOP | As compared to the former draft public statement published in 2009, we welcome the indication proposed in the HMPC draft monograph because e.g. the treatment of symptoms of BPH (which is a more serious condition) will be permitted in self-medication after consultation of a medical doctor. | |
| 4.1. Therapeutic indications | AESGP | We highly appreciate the wording proposed for the therapeutic indications, in particular the option to treat symptoms of benign prostatic hyperplasia (BPH) after serious conditions have been excluded by a medical doctor.<br><br>From our point of view the wording proposed for the indications corresponds to current scientific data and takes into account | |

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| | | the option to treat more serious conditions such as BPH symptoms after medical consultation and diagnosis ('collaborative concept'). | |
| 4.2 Posology | AESGP | For the above proposed "Dry extract (DER 6-11:1), extraction solvent methanol 20%", the daily dose is 1 tablet daily, i.e. 600.10 mg of the extract, corresponding to 5.1 g herbal drug. As this is different from the dosage that the draft monograph proposes for extract b), it would be useful from our point of view to include this extract separately under 4.2. "Posology". | Proposal is not endorsed. This product has not been on the market for more than 30 years, only since 2001. Thus it can not be included in the Monograph on Nettle root with traditional use. |
| 4.2 Posology | LABOFARM | We propose to add:<br>*Adults, elderly*<br>Single dose:<br>f) Powdered herbal substance: 1.32 g of powdered herbal substance 3 – 4 times daily.<br>**Rationale:** our study of release beta sitosterol showed that the herbal medicinal product Urtix is similar to traditional herbal medicinal products (THMP) containing dry extract with methanol as extraction solvent. Based of sterol quantification results we assess dosage equivalence.<br><br>See: Expert opinion on traditional use of Urtix, tablets. | National Competent Authorities may decide about acceptance after evaluation of a full set of data to demonstrate comparability. This task could be assigned the HMPC in the case of a referral if suitable data are provided in accordance with the legal procedure. |
| 4.2 Posology | PRLR | We propose to add:<br>Adults, elderly<br>Daily dose:<br>f) Powdered herbal substance: 4 - 6 g of powdered herbal substance, 3 – 4 times.<br>**Rationale**: In the dosage section, the ESCOP Monograph (Second Edition) recommends using 4 – 6 g of herbal substance. The same dosage was recommended by the | The proposal is not accepted. There have not been any products containing powdered herbal substance of Nettle root on the market more than 30 years. No appropriate literature including posology has been provided by the interested party. |

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| | | German Commission E monograph on Urticae radix (Bundesanzeiger No. 173 18.09.1986; revisions 1989, 1990 and 1991), which recommends a daily dose of 4 – 6 g nettle root for infusions as well as other galenical preparations for oral use to treat difficulty in urination in Benign Prostatic Hyperplasia (BPH) stages I and II.<br>See:<br>1. Commission E Monograph (Urticae radix) Bundesanzeiger Nr. 173, 18.09.1986.<br>2. ESCOP Monograph (Second Edition) (Urticae radix - Nettle root). European Scientific Cooperative on Phytotherapy, Thieme, Stuttgart 2003, 528-535. | |

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