



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication initiative HMPC feedback

Joint PCWP/HCPWP meeting, 1-2 April 2025

Presentation by An LÊ-HMPC member



Key objectives on communication initiative

HMPC work plan 2023-2025

- Identify topics to focus on and bring together similar initiatives already set up by regulatory agencies of Member States : what to communicate, how, to whom?

Websites

Survey among NCA's websites

- Update Assessment Report Summary for the Public (ARSP) for new or revised Herbal monographs

criteria

New draft ARSP template

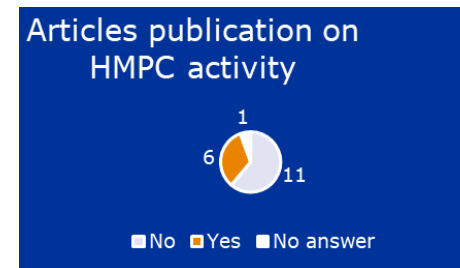
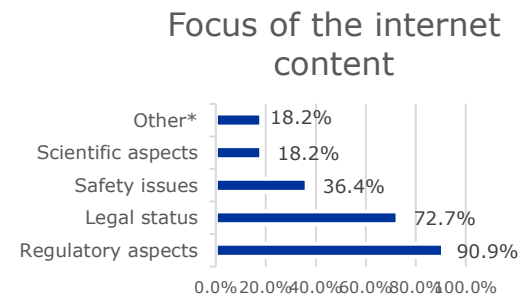
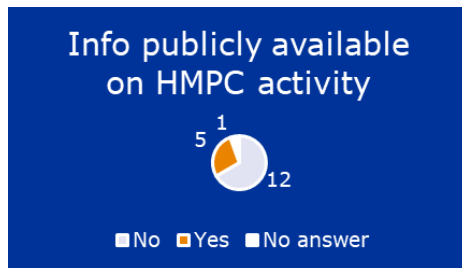
- Explore achievable opportunities to publish information on the differences between the status of the products in cooperation with relevant groups/bodies



Survey about NCA's website information

Compare existing national initiatives

- Survey : **15** questions , **18/28** answers from member states:

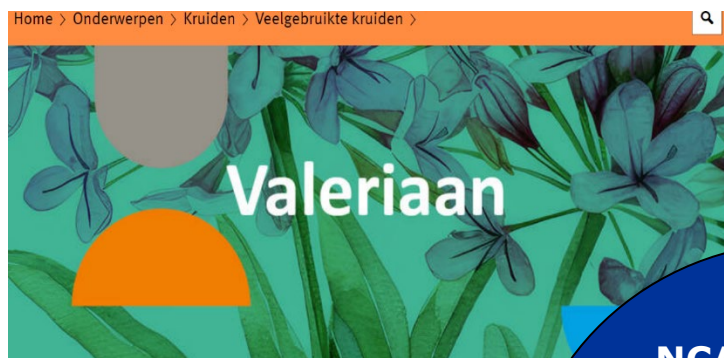




Survey about NCA's website information

Compare existing national initiatives: results

- Limited Information** on herbal in the NCA's websites: **7/11** give information on herbals
- The target audience consists mainly of **applicants for regulatory or legal status** on HMPs (90,9%), **specific information for patients or healthcare professionals** (54%), **safety or scientific** information (36%)
- Limited scientific communication on HMPC activities (**5/18**) only through conferences or publications to scientific community but **less to the general public**.
- The reporting process is specific for HMPC and not comparable with other EMA committees (41,2%)



Valeriaan (*Valeriana officinalis* L.)

Valeriaan (*Valeriana officinalis* L.)

Valeriaan of *Valeriana officinalis* L. is een plant die voorkomt in Europa en Azië. De wortel van de plant wordt gebruikt in kruidenmiddelen. Let op bij het gebruik van kruidenmiddelen met valeriaan. Er kan een wisselwerking ontstaan.

► Interactie informatie voor artsen en apothekers

Gebruik van valeriaan

Valeriaan is goedgekeurd als kruidengeneesmiddel tegen:

- nervositeit en slaapproblemen

Er bestaan ook supplementen en homeopathische geneesmiddelen waar valeriaan in zit. Hiervan is het gezondheidseffect niet officieel aangetoond.

**NCA's websites
strategies:
inform on the best
use of HMPs,
safety,
interactions,
status**





New ARSP Template

National experiences, other surveys, regulatory

General trends:

- **quick, clear and readable** information
- **lay and direct language** as much as possible to **patients** (colours and logos were requested)
- focus on **types of preparations** for medicinal use
- clarify the difference between **efficacy and traditional use** for herbals
- split “risks” in **two sections (interactions, side effects...)**
- regroup the **regulatory information** of the different ARSP sections
- information concerns **only medicinal products** (not herbal products with other regulatory statuses)

Draft template endorsed by HMPC (March 2025)+ Valerian example.

Lay language should be considered as patient-friendly wording as define in the QRD template – Annex III.B.



What is new in the Template

Current publication ARSP Valerian roots 2016

Overview

This is a summary of the scientific conclusions reached by the [Committee on Herbal Medicinal Products \(HMPC\)](#) on the medicinal uses of valerian root. The [HMPC](#) conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing valerian root.

This summary is not intended to provide practical advice on how to use medicines containing valerian root. For practical information about using valerian root medicines, patients should read the [package leaflet](#) that comes with the medicine or contact their doctor or pharmacist.

What is valerian root?



What are the HMPC conclusions on its medicinal uses?



How does valerian root work as a medicine?



What evidence supports the use of valerian root medicines?



What are the risks associated with valerian root medicines?



How are valerian root medicines approved in the EU?



HMPC - committee feedback PCWP-HCPWP



National names,



Types of preparations, efficacy, interest of using the medicines, precautions of use



New sections on side effects and interactions



Regulatory specific section



How would Valerian ARSP look like in 2025?

Valerian root

Valeriana officinalis L., *radix*

Other names: [Insert the link to the common name table in all member states language here](#)



Introduction

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of Valerian root. This summary is not intended to provide practical advice on how to use medicines containing Valerian root. You can find detailed instructions on how to take Valerian root medicines and who can use them in the package leaflet that comes with the authorised medicine.

The information in this summary report concerns medicinal products containing Valerian root which comply with the strict pharmaceutical quality and other requirements for medicinal products. They are approved by the competent authorities to be placed on the market as medicinal products. Other products, like food, food supplements, cosmetic products or medical devices do not follow the same criteria and regulatory requirements as medicinal products and are excluded from this summary.

What Valerian root preparations are used in medicines?

Valerian root is the common name for the underground parts of the plant *Valeriana officinalis* L.

Medicinal products with valerian contain the roots dry and comminuted (reducing into tiny pieces), the powder, the juice of the fresh root, the dry or liquid extracts of the roots. Extracts are obtained by putting the plant material in a solvent (such as ethanol or methanol) to dissolve compounds and form a liquid extract. The solvent is then completely evaporated to obtain a dry extract.

Herbal medicines containing comminuted valerian root are usually available as **herbal tea** to be drunk, or as **bath additives**. The other herbal preparations of valerian root are available in **solid or liquid form** to be taken by mouth.

What are the medicinal uses of Valerian root?

The efficacy of a **specific dry ethanolic valerian root extract** has been demonstrated in clinical studies for the treatment of the relief of **mild nervous tension and sleep disorders**.

Other valerian root preparations have traditional medicinal use for the relief of **mild symptoms of mental stress and to aid to sleep**. Traditional medicinal use means that the use in the specified indication is exclusively **based upon long-standing medicinal use and not based on results from clinical studies**.

When is it not recommended to use Valerian root?

Do not use Valerian root medicines for children under **12 years** of age.

Do not use Valerian root medicine when you are **pregnant** or if you **breast feed** your children.

Do not bathe with valerian root medicines if you have **open wounds, skin problems, high fever, severe infections and severe heart and circulation problems**

Do not **drive or operate machinery** when using valerian root medicine as it may have an influence on your ability to drive and use machinery.

If your mild nervous tension and sleep disorders persist or worsen after **2 weeks** during the continuous use of the medicinal product, you should consult a doctor or a pharmacist.



How would Valerian ARSP look like in 2025?

What you need to know before taking Valerian root with other medicines?

No interactions with other medicines have been described up till now.

What are the risks associated with Valerian root medicines?

You may experience some side effects with Valerian root medicines.
You may get nausea and abdominal cramps.

How are herbal medicines approved in the EU?

Like for other medicines in the EU, companies must submit an application to the national authorities responsible for medicinal products before marketing a herbal medicine. Before approval, the national authorities assess the quality, safety and efficacy of the herbal medicine. For traditional herbal medicines, the medicinal use is plausible and safe based on documented medicinal use for at least 30 years (including at least 15 years within the EU), and not based on results from clinical trials. The HMPC conclusions are taken into account when evaluating applications for the licensing of herbal medicines.

Information on approved Valerian root medicines in EU Member States may be obtained from the relevant national authorities.

Further information

Further information on the HMPC scientific assessment of Valerian root medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.europa.eu/Find medicine/Herbal medicines for human use, here

How does Valerian root work as a medicine?

The efficacy and safety of a specific preparation of valerian root in **treating the relief of mild anxiety and sleep disorders** is based on its 'well-established use'. This means that there is a **documented medicinal use for at least 10 years in the EU and published clinical studies to support the efficacy and safety**.

The way valerian root medicines work is not fully known as no constituent with known therapeutic activity or active marker can be recognised, but from some clinical studies Valerian root and its preparations seem to improve sleep structure with a gradual onset of efficacy. It is thought that effects on the brain leading to relaxation and sleepiness might play a role.

The benefit of using valerian root medicine for the treatment of the relief of mild nervous tension and sleep disorders has been shown up to **2 to 4 weeks** of treatment.

The traditional use of valerian root is described for the **relief of mild symptoms of mental stress and to aid to sleep**. This means **that the use is plausible and safe based on documented medicinal use for at least 30 years (including at least 15 years within the EU), and not based on results from clinical studies**.



Feed back from PCWP/HCPWP

HMPC May 2025 meeting

- Comments on the new ARSP template dedicated to the patients?
- Comments on specific herbal ARSP, once, or on a regular basis?
- Identify other needs: improve presentation, publications, newsletters, format ...?
- Explore best practice for communication on interactions between (T)HMPs and other medicinal products.
 - How to draft specific information on interaction section for healthcare professionals?
- Any other topics of interest?



**We are looking forward to
hearing your comments, ideas ,
views....**

