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Committee on Herbal Medicinal Products (HMPC)

Template for HMPC Assessment Report Summary for the Public (ARSP)

Final

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Assessment Report Summary for the Public (ARSP)

Note: All instruction notes (in green) must be deleted before finalising the ARSP.

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

<Plant, plant part> = <X>

Insert the English name of the plant and the part of the plant described in the EU herbal monograph.

<Botanical name, plant part>

Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.

Other names:

Insert 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 <X>. It summarises the Committee's recommendations <or reflections> on the use of <X>.

The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing <X>. When a Member State authorises a medicine containing <X>, detailed instructions on how to take it will be available in the package leaflet that comes with the medicine.

The information in this summary report concerns herbal medicinal products containing <X> which are only authorised when they comply with the strict pharmaceutical quality and other requirements for herbal 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 is <X> and what do <X> herbal medicines contain?

<X> is the common name for the <plant part> of the plant <plant name>.

For 'aerial parts', replace 'aerial' with 'above-ground' parts.

For 'roots', replace with 'underground' parts.

Medicinal products with <X> contain ...

Insert the raw material as described in the EU herbal monograph but simplified:

<Comminuted herbal substance (reduced into tiny pieces) the <plant part>, <Powdered herbal substance>, <Juice>, <Essential oil>, <Dry, soft or liquid extract>. <Extracts are obtained by putting the plant material in a solvent (such as <ethanol, or methanol> or ...) to dissolve compounds and form a <dry, soft or liquid> extract. The solvent is then <partially or completely> evaporated to obtain a <soft or dry> extract>. <The solvent is then completely evaporated to obtain a dry extract>.

Insert the dosage form, the route of administration as in the EU herbal monograph, in lay language:

Herbal medicines containing this/these <X> preparation<s> are usually available <as herbal tea> <in solid forms><in liquid forms><in semi-solid forms>

<to be drunk> for oral use in case of an herbal tea; <to be taken by mouth> for oral use; <to be applied to the skin> for cutaneous use; <to be applied for absorption through the skin> for transdermal use; <to be inhaled> for inhalation.>

What are the medicinal uses of <X>?

For WEU monographs insert:

<<X> preparation<s> <is> <are>used for the treatment of <insert the indications described in the WEU monograph>. This is based on clinical studies which showed efficacy when used this way...>.

For TU monographs insert:

<<X> preparation<s> has traditional medicinal use for <insert the indications described in the TU monograph>. 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 < X>?

You can find detailed instructions on how to take <X> medicines and who can use them in the package leaflet that comes with the medicine.

Insert the recommendations for use described in the "Contraindications", "Special warnings and precautions for use", "Fertility, pregnancy and lactation" and "Effects on ability to drive and use machines" of the EU herbal monograph as follows:

<Do not use <X> for children <and adolescents under 18 year> <under 12 of age> <between A and B <years><months> of age> [or any other relevant subsets, e.g. weight, gender] because <of the risk of [...]><of the lack of adequate data>.>

<Do not use <X> if you are pregnant or breast feed your child.>

<Do not use <X> if you are allergic to the plant<and><to other [insert genus name] species
><and><to other plants of the [insert botanical family name] family.>

<Do not drive or operate machinery when using <X> medicines as it may have an influence on your ability to drive and use machinery. *[Describe effects where applicable.]*>

<Do not use <X> <when you are known with>< if there is> *[Insert specific pathologies like 'heart or kidney disease'...] or symptoms like 'inflammation of the skin with subcutaneous swelling' ...]*>.

< If your symptoms <persist longer than [x days/weeks]><or><worsen after [x days/weeks]>during the use of the medicinal product, you should consult a doctor or a pharmacist.>

What you need to know before taking <X> with other medicines?

Insert the information described in the section "Interactions with other medicinal products and other forms of interaction" of the EU herbal monograph in the way of the patient package leaflet as follows:

<Do not use <X> together with other medicinal products like *<quote the INN, group of products....>* because it may result the <loss of its effect><side effect>... >

Precise those for which the combination should be avoided and those for which the combination would require some precaution (e.g. dose adjustment...) as follows:

<You must not use <X> together with *<insert the products contraindicated as described in section 4.3>*

<You have to consult your medical doctor or inform your pharmacist before using <X> if:

Insert different therapeutic situations as follows:

- You are under treatment with *<quote the product>*, the dose may have to be adjusted/reduced ...
- You take hormonal contraceptive with <X>, it may lead to increase... Consequently, you should take additional contraceptive measures.

< No interactions with other medicines when using <X> have been described in the literature, at the time of assessment.>

What are the risks associated with <X> medicines?

<You may experience some side effects with <X> medicines.> <No side effects have been reported with <X> medicines at the time of assessment.>

<You may get:

<insert "undesirable effects" described in the EU herbal monograph, in the same order and with sufficiently patient-friendly description of the sign and symptoms (QRD template annexe III.B.4.)>

The frequency of these undesirable effects is <not known >< very common, it may affect more than 1 in 10 people >< common, it may affect up to 1 in 10 people >< uncommon, it may affect up to 1 in 100 people >< rare, it may affect up to 1 in 1,000 people><very rare, it may affect up to 1 in 10,000 people>.

How does <X> work as a medicine?

For WEU monographs, use the following standard sentences:

<The efficacy of a specific preparation<s> of <X> in treating <insert indication(s)> <is> <are> based on <its><their> 'well-established use'. This means that there is documented evidence of their medicinal use covering at least 10 years in the EU with published clinical studies to support the efficacy and safety when used for <describe the use>.

Briefly describe the main clinical studies that support the WEU (i.e. not applicable to TU monographs):

<In its assessment, the HMPc considered a number of clinical studies where <X> has been compared with placebo (a dummy treatment) or other treatments in the <insert indication(s)>. The results showed that <X> was more effective than <placebo> <and> <as effective as> other medicines in <insert indication(s)>.

Insert the mechanism of action described in the WEU monograph when known, summarised in lay language (not applicable to TU monographs):

<The way <X> works in <insert indication(s)> is not fully known, but based on data from <some> studies, it is thought to <insert as appropriate>.

Specify each preparation when different indications are described in the monograph. The other preparations are excluded.

If useful, insert information on the benefits of the treatment. Information could relate to signs and symptoms of the target disease and encourage adherence to the treatment, e.g. for long-term and prevention treatment or prevention of disease complications, if established. The timing of the effect may also be described.

For TU monographs, use the following standard sentences:

The HMPc conclusions on the use of these <X or X preparation> medicines for <relief of> <insert indication(s)> are based on their 'traditional use'. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU).

How are herbal medicines containing <X> approved in the EU?

Any applications for the licensing of medicines containing <X> have to be submitted to the national authorities responsible for medicinal products. Before approval, the national authorities assess the quality, safety and efficacy of the herbal medicine. The HMPc conclusions are taken into account when evaluating applications for the licensing of herbal medicines.

Information on approved <X> medicines in EU Member States may be obtained from the relevant national authorities.

Further information

Further information on the HMPC scientific assessment of <X> medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <https://www.ema.europa.eu/en/medicines>.