EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and European Union list entries

For HMP/THMP with one active ingredient only

Request for information concerning <Herbal substance> from <insert Member State name>

Common name of herbal substance in all EU official languages	
BG (bulgarski): CS (čeština): DA (dansk): DE (Deutsch): EL (elliniká): EN (English): ES (español): ET (eesti keel): FI (suomi): FR (français): HR (hrvatski): HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (Malti): NL (Nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): *IS (íslenska)*: *NO (norsk)*:

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Send a question via our website www.ema.europa.eu/contact

1. Information on medicinal products marketed in <insert Member State name>

Active substance	Indication	Pharmaceutical form Strength (where relevant) Posology Duration of use	Regulatory Status (date, Member State, Type of Marketing authorisation/registration where possible)[1]
To be given according to the declaration guideline (e.g. for the extracts: kind of extract, extraction solvent, DER)		*Only restriction to duration of use may be reported*	*Major brand names preferably to be given to facilitate comparison among MSs by the Rapporteur, can be kept during discussion and shall be deleted at publication stage*
1.			
2.			
3.			

Is data protection applicable on medicinal products containing the herbal substance/preparation?[2] ☐ **Yes** ☐ **No**

Please provide a short statement here or provide details separately

<Include text>

Information on active or analytical marker(s) or constituent(s) with known therapeutic activity (if available)
1.
2.
3.

[1] The information on the regulatory status of the products may preferably include the nature of the marketing authorisation (MA) granted for the product to access the market (MA based on full or mixed application, MA based on bibliographic application as per Article 10a of Directive 2001/83/EC (WEU), traditional use registration, etc.) to establish the period of medicinal use;
for TU: at least 30 years of medicinal use including at least 15 years in the EU;
for WEU: at least 10 years of MA in the EU.

[2] Regulatory data protection is usually not applicable for WEU authorisations (Article 10a). However, it has to be considered for WEU authorisations in case a new therapeutic indication has been granted during the year before the establishment of the Community monograph on basis of significant pre-clinical or clinical studies (Article 10.5) as well as for full MA (Article 8.3). If products on the market have been authorised according to Article 8.3 or new indications have been granted according to Article 10.5, Member States should inform rapporteur if data protection is applicable.

Risks (adverse drug effects, literature, PSUR)
1.
2.
3.

Were pharmacovigilance actions taken on medicinal products containing the herbal substance/preparation? ☐ **Yes** ☐ **No**

Please provide a short statement here or provide details separately

<Include text>

Where available provide information on the following aspects with reference to the specified herbal preparation

Use in children and adolescents

<Include text or provide details separately>

Contraindications

<Include text or provide details separately>

Special Warnings and precautions for use

<Include text or provide details separately>

Drug interactions and other forms of interaction

<Include text or provide details separately>

Fertility, pregnancy and lactation

<Include text or provide details separately>

Overdose

<Include text or provide details separately>

Effects on ability to drive or operate machinery or impairment of mental ability

<Include text or provide details separately>

Safety in other special situations

<Include text or provide details separately>

2. Information on relevant combination medicinal products marketed in <insert Member State name>

'Relevant' is understood here as combinations useful to the purpose of establishing the intended monograph.

1. <*insert Product name*> <*insert Pharmaceutical form*> containing <*insert text*> Indication: <*insert text*> Posology: <*insert text*> On the market since <*insert date*>.
2. <*insert Product name*> <*insert Pharmaceutical form*> containing <*insert text*> Indication: <*insert text*> Posology: <*insert text*> On the market since <*insert date*>.
3. <*insert Product name*> <*insert Pharmaceutical form*> containing <*insert text*> Indication: <*insert text*> Posology: <*insert text*> On the market since <*insert date*>.
Risks (adverse drug effects, literature, PSUR)
1.
2.
3.

3. Information on other relevant products marketed in <insert Member State name>

Include any other relevant information on products available on the market which are neither authorised nor registered as medicinal products (e.g. medical devices, food/dietary supplements, cosmetics).

1. <*insert Product name*> <*insert short description of the product/form*> containing <*insert text*> Indication (health or cosmetic claims): <*insert text*> or <*not available*> Posology (strength, dosage or use instructions): <*insert text*> or <*not available*> On the market since <*insert date*>.
2. <*insert Product name*> <*insert short description of the product/form*> containing <*insert text*> Indication (health or cosmetic claims): <*insert text*> or <*not available*> Posology (strength, dosage or use instructions): <*insert text*> or <*not available*> On the market since <*insert date*>.
3. <*insert Product name*> <*insert short description of the product/form*> containing <*insert text*>

Indication (health or cosmetic claims): <*insert text*> or <*not available*> Posology (strength, dosage or use instructions): <*insert text*> or <*not available*> On the market since <*insert date*>.

4. Additional comments:

Date: