

HOMEOPATHIC MEDICINAL PRODUCT WORKING GROUP (HMPWG)

**HMPWG REPORT ON THE REGULATORY STATUS OF
HOMEOPATHIC MEDICINAL PRODUCTS FOR HUMAN USE IN EU AND
EFTA COUNTRIES**

2016

Adoption of content of the survey by HMPWG	September-December 2015
Collection of data	March-December 2016
Discussion in HMPWG and agreement	November 2016
Adoption of the document for publication by HMPWG by written procedure	February 2017
To be sent to HMA-MG for final endorsement	March 2017

<p style="text-align: center;">HMPWG REPORT ON THE REGULATORY STATUS OF HOMEOPATHIC MEDICINAL PRODUCTS FOR HUMAN USE IN EU AND EFTA COUNTRIES</p>
--

Preamble

In 2016, the HMPWG discussed the opportunity to share information on homeopathic medicinal products in EU and EFTA countries.

A questionnaire was developed and circulated to HMPWG members with the aim of obtaining information about the regulatory status of homeopathic medicinal products in the EU and EFTA countries and the state of implementation of Directive 2001/83/EC as amended by Directive 2004/27/EC ('the Directive').

The following report has been compiled from the data collected and has been agreed by the HMPWG.

The report consists of four sections as follows:

- I. Questions on the marketing of homeopathic and anthroposophic medicinal products
- II. Questions on implementation of Directive 2001/83/EC as amended by Directive 2004/27/EC (the Directive)
- III. Questions on the specific national regulatory status of homeopathic medicinal products
- IV. Questions on the national experience of registering/authorising homeopathic medicinal products

I. QUESTIONS ON THE MARKETING OF HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINAL PRODUCTS

1. Are homeopathic medicinal products marketed in your country?

Austria	Yes
Bulgaria	Yes
Belgium	Yes
Croatia	Yes
Cyprus	No
Czech Republic	Yes
Denmark	Yes
Finland	Yes
France	Yes
Germany	Yes
Greece	Yes
Hungary	Yes
Ireland	Yes
Italy	Yes
Latvia	Yes
Liechtenstein	Yes, with Swissmedic MA
Lithuania	Yes
Luxemburg	Yes
Malta	No
Norway	Yes
Portugal	Yes
Romania	Yes
Slovakia	Yes
Slovenia	Yes
Sweden	Yes
Switzerland	Yes
The Netherlands	Yes

2. Are anthroposophic medicinal products marketed in your country?

Austria	Yes
Bulgaria	No
Belgium	Yes
Croatia	No
Cyprus	No
Czech Republic	No
Denmark	Yes
Finland	Yes
France	Yes, but not under the denomination of anthroposophic medicinal products, as some homeopathic medicinal products manufactured according to a homeopathic process can be used in anthroposophic therapy and are marketed. They are registered as homeopathic medicinal products.
Germany	Yes
Greece	No
Hungary	No
Ireland	No
Italy	Yes, but they are considered as homeopathic medicinal products
Latvia	No
Liechtenstein	Yes, with Swissmedic MA
Lithuania	Yes
Luxemburg	Not Officially
Malta	No
Norway	Yes
Portugal	Yes, anthroposophic medicinal products manufactured according to a homeopathic manufacturing method are marketed/registered as Homeopathic medicinal product
Romania	No
Slovakia	No
Slovenia	No
Sweden	Yes, a few anthroposophic medicinal products are registered as traditional herbal medicinal products and a few authorized as herbal medicinal products. However, most of these products have not been assessed, registered or authorized by the agency, since the Swedish government have authorized them directly in accordance with 4 chap.

	10§ of the Medicinal Products Act (SFS 2015:315), allowing certain anthroposophic medicinal products to be sold without authorisation or registration
Switzerland	Yes
The Netherlands	Yes as homeopathic medicinal products (art. 14 and 16), or as traditional herbal medicinal products (art. 16a)

II. QUESTIONS ON IMPLEMENTATION OF DIRECTIVE 2001/83/EC AS AMENDED BY DIRECTIVE 2004/27/EC (THE DIRECTIVE)

3. When was the Directive, implemented in your country with regard to homeopathic medicinal products?

Austria	21 October 2003
Bulgaria	13 April 2007
Belgium	With the publication of the Royal Decree on 14 December 2006
Croatia	July 2013
Cyprus	14 April 2016
Czech Republic	The Directive has been implemented (with regard to homeopathic medicinal products) to date 5 June 2003.
Denmark	October 2005
Finland	7 November 2005
France	The Directive 2001/83 has been implemented on 21 December 2001.
Germany	29 August 2005
Greece	24 January 2006
Hungary	18 November 2005
Ireland	2007 (Current legislation) (A registration scheme was previously provided for in 1998)
Italy	On 06 July 2006 with National Legislative Decree n. 219/2006
Latvia	2006
Liechtenstein	2010
Lithuania	10 July 2007
Luxemburg	-
Malta	The Directive was transposed to the Medicines Act of Malta (including reference to homeopathic medicinal products on the 21 November, 2003
Norway	<p>The Directive was implemented into the Norwegian law in 2010, however there is a transition period until 12.01.2017 where all anthroposophic and homeopathic medicinal products that are registered in at least one country within the EEA/EU can be sold in Norway without any registration.</p> <p>As of 12.01.2017 all homeopathic medicinal products on the Norwegian market must be registered.</p>
Portugal	The Directive was implemented in 2006 (Decree – Law 176/2007). Before we had a Decree-law (D.L 94/95, de Maio) which implemented nationally the Directive 92/73/CEE

Romania	The Directive was implemented in 14 April 2006 (Law no. 95/2006)
Slovakia	2004
Slovenia	In April 2006 when Medicinal Products Act, ZZdr-1 (Official Gazette of the Republic of Slovenia No. 31/06) entered into force.
Sweden	<p>The specific amendments in directive 2004/27 were implemented in 2006 through LVFS 2006:12. The simplified registration as described in article 13(2) and 14-15 of Directive 2001/83/EC was implemented in 2003, by amendments to the Code of Statutes from 1997 (LVFS 2003:2).</p> <p>Pursuant to sections 2 and 17 of the Medicinal Products Ordinance (1992:1752), the Medical Products Agency's Code of Statutes: "Medical Products Agency's provisions and guidelines (LVFS 1997:9) on the registration of certain homeopathic products" were effective already in 1997.</p>
Switzerland	The directive is not applicable in Switzerland
The Netherlands	1996

4. Is the simplified registration procedure described in the Directive presently applied in your country?

Austria	Yes
Bulgaria	Yes
Belgium	Yes
Croatia	Yes
Cyprus	Yes
Czech Republic	Yes
Denmark	Yes
Finland	Yes
France	Yes
Germany	Yes
Greece	Yes
Hungary	Yes
Ireland	Yes
Italy	Yes
Latvia	Yes
Liechtenstein	Yes, but we have no national registered products
Lithuania	Yes
Luxemburg	On demand of the MAH we simply take over national registrations from neighbouring countries (France, Belgium, Germany)
Malta	Yes
Norway	See answer to question 3. As of 5 January this year it is possible to register homeopathic medicinal products as described in the directive under article 14.
Portugal	Yes
Romania	Yes
Slovakia	Yes
Slovenia	Yes
Sweden	Yes
Switzerland	No, this registration procedure is not applied in Switzerland.
The Netherlands	Yes

5. Is the simplified registration procedure, as outlined in article 14.1 mandatory for all old and existing products marketed before 1993 or do you still have old notified products in your country?

Austria	No. There are still old notified products, but most of them will be authorized acc. to article 16.2
Bulgaria	No. Currently there are no homeopathic medicinal products approved before 1993 on the market in Bulgaria
Belgium	No, all the homeopathic medicinal products on the market had to be notified to the FAMHP in 2003. Based on this list of notified homeopathic products the applicants had to submit an application for a demand of registration (art. 14) or authorization (art. 16). In 2003 more around 18000 products were notified. After an update of the list in 2014, around 5600 products remained notified.
Croatia	We don't have old notified products in Croatia
Cyprus	Not applicable, since we do not have products on the market
Czech Republic	<p>Yes. In early nineties we had notified homeopathic products; nevertheless, within the first renewal they were reassessed according to the new legislation. Till now some of the products were withdrawn on the request of the applicant; some of them were not renewed (the applicants did not apply for the renewal), some of them ceased due to sunset clause.</p> <p>Currently we do not have any notified homeopathic product.</p>
Denmark	Not mandatory. Older products still notified
Finland	No renewal procedure planned for those homeopathic medicinal products registered before 1993. All other requirements are identical for all old and existing products.
France	Yes, but some old products (unitary stocks and MA) are still marketed and under assessment through a validation procedure.
Germany	The old market has been completely reviewed.
Greece	Yes
Hungary	There were not homeopathic medicinal products in Hungary before 1993
Ireland	Yes it is mandatory, there are no pre 1993 notified products.
Italy	<p>Registration procedure is not mandatory for all the old and existing products.</p> <p>All the products on the domestic market before the implementation of Directive (National Decree) are notified products. The notification consisted in an <i>ope legis</i> authorization that permitted to these old products to be still on the market even without a formal authorization</p>

	under transitional provisions. These products are without the scope of the procedure outlined in article 14.1 but under domestic procedure
Latvia	Latvia has never had MA of homeopathic products before 1993
Liechtenstein	We have no national products marketed before 1993
Lithuania	Renewal procedure in accordance of Directive was mandatory after accession of EU
Luxemburg	We still have old
Malta	There are no such products
Norway	It is mandatory for all products that are intended to be on the market after 12.01.2017.
Portugal	Simplified registration is mandatory although some old products are on the market due to a transitional period
Romania	There are no homeopathic medicinal products approved before 1993.
Slovakia	Yes. All the products (except for 2 homeopathic products) were notified before the implementation of the Directive (according to the National Decree, and before 1997)
Slovenia	We do not have old notified products. First homeopathic medicinal products were registered in 2011.
Sweden	Yes, the simplified registration procedure, as outlined in article 14.1 is mandatory for products with the characteristics described therein.
Switzerland	In Switzerland we have our own legislation for homeopathic and anthroposophic medicinal products.
The Netherlands	Mandatory for all homeopathic medicinal products since 1996

6. Do you apply article 24 of the Directive to homeopathic medicinal products approved under articles 14 and 16 in your country?

Austria	Yes
Bulgaria	Yes
Belgium	Yes
Croatia	Yes
Cyprus	Yes
Czech Republic	Yes
Denmark	Yes
Finland	Yes
France	No. The authorization is valid for a period of 5 years but the renewal is unlimited afterwards.
Germany	Yes, but the registration/authorization is valid for a period of 5 years and the renewal is unlimited afterwards
Greece	Yes
Hungary	Yes regarding the renewal, no regarding the sunset close
Ireland	Yes
Italy	Yes
Latvia	Yes
Liechtenstein	No
Lithuania	Yes
Luxemburg	Please refer to question 4
Malta	Yes, if the need arises
Norway	We intend to apply article 24 to homeopathic medicinal products
Portugal	Yes
Romania	Yes
Slovakia	Yes
Slovenia	Yes
Sweden	Yes
Switzerland	In Switzerland we have our own legislation for homeopathic and anthroposophic medicinal products.
The Netherlands	Yes

III. QUESTIONS ON THE SPECIFIC NATIONAL REGULATORY STATUS OF HOMEOPATHIC MEDICINAL PRODUCTS

7. What was the regulatory status of homeopathic medicinal products before the implementation of the Directive?

Austria	Authorised or registered acc. to Austrian law
Bulgaria	Marketing authorization
Belgium	Registered or "declared" (a kind of notification procedure)
Croatia	Until 2013, we had procedure very similar to registration of homeopathic products without indication, and homeopathic medicines with indication were authorized in accordance with rules similar to stated in the Directive 2001/83/EC.
Cyprus	Not applicable
Czech Republic	Homeopathic medicinal products have been registered according to the Czech legislation in force at the time of registration.
Denmark	Directives 92/73 and 92/74 was implemented in July 1994 and introduced the simplified registration procedure. Before 1994 only labelling requirements existed for HMP falling under the definition of certain HMP
Finland	Homeopathic medicinal products with granted marketing authorisations came under the group "Herbal remedies". Homeopathic medicinal products with registrations came under the group "Homeopathic products"
France	Homeopathic medicinal products have been authorized under visa or marketing authorization.
Germany	These products were on the market according to the German Medicinal Products Act as authorized, registered or old notified products.
Greece	As allopathic
Hungary	Before year 2005 in Hungary the homeopathic medicinal products were subjects of registration procedure (that means marketing authorization procedure) and that procedure from a regulatory point of view corresponds to the Directive 2001/83/EC
Ireland	Homeopathic products were on the market and had been covered by legislation since 1998 but there was no system for licensing in place before 2002 and so homeopathic products were unregulated before that.
Italy	These products were on the market as notified products (see Q 5 response).

Latvia	Simplified registration procedure only.
Liechtenstein	PLs. note that Liechtenstein is also part of the Customs Union with Switzerland. The Swiss legislation applied and applies within this Customs Union
Lithuania	Marketing authorization
Luxemburg	As other medicines sold only through pharmacies but prescription free
Malta	No provisions were taken as no products were considered for application
Norway	As described above, according to Norwegian law, all homeopathic medicinal products registered in at least one other EEA/EU country may be sold in Norway.
Portugal	Homeopathic products were classified as homeopathic pharmaceutical product (art 14) and homeopathic medicinal products (art 16)
Romania	Registered as homeopathic medicinal products (Marketing authorization) – similar procedure of registration as indicated in Directive 2001/83/EC in accordance with the old national law No 336/2002 on medicinal products which has been voluntarily harmonized with the Directive
Slovakia	Homeopathic medicinal products have been registered according to the Czechoslovak legislation (till 1993), after separation (Czech Republic, Slovak Republic) according to Directive (from 2004).
Slovenia	Slovenia had no homeopathic medicinal products on the market before 2011.
Sweden	Before 1994, when a registration procedure was first implemented, the homeopathic products were considered as food supplements.
Switzerland	<ul style="list-style-type: none"> • Before 2002 mandatory authorisation only for pharmaceutical specialities (specific brands and indication): One of the first registration of homeopathic/anthroposophic products with indication was given in 1934. • In 2002 the Law on Therapeutic Products enacted. Since then Switzerland has a mandatory authorisation also for Homeopathic/anthroposophic products without indication. • A special guidance for the homeopathic/anthroposophic products was provided in 2002 • In 2006 the Ordinance on Complementary and Herbal medicinal products enacted.
The Netherlands	Not registered nor notified, if they were labelled as “homeopathic medicinal product”, based on National Regulation for homeopathic medicinal products from 1992

8. Do you have specific national rules for authorized/registered homeopathic medicinal products for old and existing products marketed before 1993 (If so, please specify)?

Austria	No
Bulgaria	No
Belgium	No
Croatia	No
Cyprus	No
Czech Republic	The first homeopathic products were registered in 1992 according to the Czech legislation in force at the time of registration. Homeopathic preparations had to fulfil definition of the homeopathic product according to the legislation, nosodes were not accepted, and the route of administration was limited to oral and external use.
Denmark	Notification procedure
Finland	No
France	All medicinal products, which have been authorized and marketed prior to January 18th 1994, have been subject to a MA or a registration. The dossiers have been submitted according to a calendar running from 2001 to the end of 2015. A lot of them are still currently under assessment.
Germany	The assessment of the old notified products has been completed.
Greece	No
Hungary	No
Ireland	No
Italy	Yes, there is a specific national rule for these products. According to art. 20 of Legislative Decree n. 219/2006 the homeopathic medicinal products already marketed before the deadline of 6/6/1995 should be all subjected to the national procedure. They can all access to this procedure even if they do not requirements under art. 14(1), second intend - except for therapeutic indications. The procedure is considered a renewal of the <i>ope legis</i> authorisation.
Latvia	No
Liechtenstein	No
Lithuania	No
Luxemburg	No
Malta	No
Norway	All products must be registered before 12.01.2017 if intended to be on the marked after 12.01.2017.
Portugal	No

Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	There are no specific rules for products marketed before 1993. All products, which are actually on the market are treated in the same way
The Netherlands	No

9. Have you implemented article 16.2 of the Directive regarding homeopathic medicinal products? (If so, please specify the specific national rules)

Austria	<p>Yes</p> <p>No preclinical/clinical data required</p> <p>Required: toxicological evaluation, justification of homeopathic use, evidence on the specific homeopathic efficacy</p>
Bulgaria	<p>Yes</p> <p>For homeopathic medicinal products under Art. 16 (Marketing authorization with indications):</p> <p>The Marketing Authorisation Holder (MAH) does not submit results from preclinical and clinical trials for homeopathic medicinal products if MAH can prove the indications, using bibliographic data from scientific literature, established safe homeopathic use of the medicinal product or of the homeopathic stocks within its composition concerned.</p> <p>In these cases, bibliographic data must indicate:</p> <ol style="list-style-type: none"> 1. The homeopathic nature of the raw materials and their traditional administration, in the presence of the indication applied for; 2. The non-harmful nature of the homeopathic medicinal product, in terms of the level of dilution of each of its ingredients. <p>For homeopathic medicinal products under Art. 14 (Registration without indication):</p> <p>In simultaneous submission of documentation for the registration of a group of homeopathic medicinal products with indications, the applicant presents a list of the group of medicines.</p> <p>Grouping of homeopathic medicinal products in applications is carried out according to the origin of the starting materials (plant, chemical, biological, mineral, nosodes or other), formulation and purpose of use.</p>
Belgium	Yes
Croatia	No
Cyprus	No
Czech Republic	<p>Yes, we have. According to the Czech law the homeopathic medicinal products registered according to 16.2 should fulfil following points:</p> <ul style="list-style-type: none"> • they are intended for oral or external use for treatment of less serious symptoms or diseases where supervision of physician is not needed • non-clinical and/or clinical studies are not mandatory if the

	<p>applicant is able to demonstrate safety of homeopathic stocks by data published in scientific literature</p> <ul style="list-style-type: none"> justification of homeopathic use and indications for the homeopathic medicinal product can be provided by reference to publications acknowledged in member states with traditional homeopathic practice or by results of research so called homeopathic proving.
Denmark	No
Finland	Yes. However, no marketing authorisations granted at the moment under the article 16.2 of the Directive regarding homeopathic medicinal products. Indications 'Used as a homeopathic medicinal product' or 'Used as an anthroposophic medicinal product' might be acceptable (case-by-case evaluation).
France	<p>Yes.</p> <p>For a homeopathic medicinal product subject to an MA, considering its specificities, the applicant is exempted from producing all or part of the pharmacological, toxicological and clinical results, if he can demonstrate, by thoroughly referring to accepted publications in the traditional medicinal use in France, that the homeopathic use of this product or its composing stocks are well established and provide all guarantees of safety.</p>
Germany	<p>Yes.</p> <p>According to Section 22 (3) of the German Medicinal Products Act specific scientific documents may be presented for homeopathic medicinal products. Furthermore, the medical experience gained by the homeopathic school of therapy must also be taken into consideration.</p> <p>These are:</p> <ul style="list-style-type: none"> - Monographs of Commission D - "Criteria for cognition-based data on clinical indications in homeopathy" (2002) - Scientific literature - Opinions of experts associations - Reports from authorized homeopathic medicinal products
Greece	No
Hungary	No
Ireland	Yes homeopathic medicinal products for the treatment of mild self-limiting conditions can be authorized under article 16.2. (See Addendum 1 for specific details)
Italy	No
Latvia	No

Liechtenstein	No
Lithuania	Yes. Rules for granting marketing authorization for medicinal products (approved by the order No V-596 of the Health minister of the Republic of Lithuania on 10 July 2007).
Luxemburg	Please refer to question 4
Malta	No, we do not have any specific national rules
Norway	No, and we do not plan to do so.
Portugal	No
Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	No
The Netherlands	Yes

10. If you still have notified products, are there plans to make the simplified procedure mandatory for these products?

Austria	No (see question #5)
Bulgaria	Not applicable
Belgium	No
Croatia	Not applicable
Cyprus	Not applicable
Czech Republic	We do not have notified products any more.
Denmark	No concrete plans
Finland	All homeopathic medicinal products have been divided into Article 14 and Article 16 products according to the valid Directive. Labelling texts have also been updated according to the valid Directive. Valid national variation procedure (corresponding to the EU variation regulation) exists. No renewal procedure planned for those homeopathic medicinal products registered before 1993.
France	Yes.
Germany	The assessment of the old notified products has been completed.
Greece	Yes
Hungary	We do not have notified products (all are registered)
Ireland	We do not have notified products except those already under assessment under the National Rules according to article 16.2.
Italy	Yes, these products have to be formally authorised before the deadline of 31/12/2018.
Latvia	We do not have such products
Liechtenstein	Not applicable
Lithuania	We do not have notified products
Luxemburg	No
Malta	No, we have no products
Norway	Not applicable.
Portugal	Not applicable
Romania	Not applicable
Slovakia	Yes (4 notified homeopathic medicinal products in this time)
Slovenia	We do not have notified products
Sweden	Not applicable, see question 5
Switzerland	We have “special simplified authorization procedures” for homeopathic and anthroposophic medicinal products without indication. Only for a small number of products a full documentation is required.

Normally it is either possible to get a simplified authorization based on a reduced dossier or an application procedure.

The applicable procedure depends on a risk assessment which was made by Swissmedic. The outcome was the “List of homeopathic and anthroposophic substances (HAS List)”.

The HAS list consist of substances for which Swissmedic has the proof that their use can be seen as traditional within homeopathy or anthroposophy and potencies for which safety has been proven to the extent that all or certain documentation on quality and security doesn’t need to be submitted.

Application Procedure: Based on the HAS list for each substance and dosage form only basic information, i.e. declaration of manufacturing method and starting material, must be submitted electronically. An additional documentation (master dossier) is only required for certain substances of animal or human origin, for medicinal products administered parenterally or applied either on or in the eye.

Reduced dossier: Some documents must be submitted for each product. But the number of the quality and safety documentation is reduced to a minimum.

There are no efforts to change this system. On the contrary: Currently we are working on changes of the Law on Therapeutic Products. The aim of the new law is to enable simplified procedures for more medicinal products.

The Netherlands

No

11. Do you have specific fees for the different procedures regarding registration and post-registration (variations and renewals, e.g.) for homeopathic medicinal products? If so, please provide a list.

Austria	<p>Yes</p> <p>Registration without indication</p> <p>National procedure, single stock: 402 €, more than one stock: 1407 € RMS: 4020€, CMS: 807€</p> <p>Annual fee (lifecycle): national: 25€, RMS: 603€, CMS: 302€</p> <p>Authorisation with indication (national procedure): single stock 1005€, more than one stock: 3518 €</p> <p>Annual fee (lifecycle): single stock: 603€, more than one stock: 302€</p>																	
Bulgaria	<p>Yes</p> <p>For the procedure of registration of a homeopathic medicine product the fees are:</p> <ul style="list-style-type: none">- for a homeopathic medicinal product according to the origin of the starting materials (plant, chemical, biological, mineral, etc.) - 1000 leva;- for a group of homeopathic medicines according to the origin of the starting materials (up to 250 positions in the group of plant, chemical, biological, mineral, etc.) - 6000 leva;- for a group of homeopathic medicines according to the origin of the starting material (from 251 to 500 positions in the group of plant, chemical, biological, mineral, etc.) - 8000 leva;- for a group of homeopathic medicines according to the origin of the starting material (over 500 positions in the group of plant, chemical, biological, mineral, etc.) - 10 000 leva; <p>Note: 1 euro ~ 1.95 leva (BGN)</p> <p>- For a renewal of registration the fee is 50 percent of the fees defined under the previous article.</p>																	
Belgium	<p>Yes. The fees are currently under review. The new fees will be implemented as soon as the Royal Decree has been published. (within the next months).</p> <p><u>Registration:</u></p> <table><tr><td rowspan="4">SIMPLIFIED - ART 14</td><td>1 stock</td><td>€</td><td>365,00</td></tr><tr><td>up to 5 stocks</td><td>€</td><td>2.594,85</td></tr><tr><td>extra stock</td><td>€</td><td>365,00</td></tr><tr><td>cross reference</td><td>€</td><td>30,79</td></tr></table>					SIMPLIFIED - ART 14	1 stock	€	365,00	up to 5 stocks	€	2.594,85	extra stock	€	365,00	cross reference	€	30,79
SIMPLIFIED - ART 14	1 stock	€	365,00															
	up to 5 stocks	€	2.594,85															
	extra stock	€	365,00															
	cross reference	€	30,79															

	FULL - ART 16	1 stock	€ 776,03
		up to 5 stocks	€ 4.650,00
		extra stock	€ 365,00
		cross reference	€ 30,79

Post-registration:

The cost will be covered by a taxation. Tax 0.2% on turnover HoMP (min. 12.5€) excluding MA.

Croatia

Yes

National procedure:			
Marketing authorisation		30 000 kn	(cca 4000 euros)
Registration- simplified procedure for monocomponent product	4000 kn		(cca 500 euros)
Registration- simplified procedure for multicomponent product	7000 kn		(cca 900 euros)
Variations to a marketing authorization for a medicinal product			
Minor variation (IA and IB)			
1. IA		2.500,00	(cca 300 euro)
2. IB		3.500,00	(cca 450 euro)
3. Authorization for introduction of, or change to, a summary of pharmacovigilance system for every additional authorization in grouping of variations		500,00	(cca 70 euro)
Major variation (II)			
4. simple		3.500,00	(cca 450 euro)
5. complex		6.000,00	(cca 800 euro)
6. very complex		10.000,00	(cca 1300 eur)
7. Authorization for the same variation in an additional strength or pharmaceutical form (charged for both minor and major variations)		500,00	(cca 70 euro)
8. Decision on variations to a decision on a marketing authorization for a medicinal product/Refusal of authorization of variations to the marketing authorization for a medicinal product (charged for both minor and major variations)		1.000,00	(cca 130 euro)
3.2. Other variations			
1. Variation to labelling and/or package leaflet, including variation of a mock-up of inner and outer packaging, that does not require changes in the summary of product characteristics		1.000,00	(cca 130 eur)
2. Dossier upgrade including minor variations		9.000,00	(cca 1200 euros)
3. Dossier upgrade including major variations		15.000,00	(cca 2000 euros)
4. Dossier upgrade for an additional pharmaceutical form of strength		2.000,00	(cca 260 eur)
5. Transfer of a marketing authorization for a medicinal product		3.000,00	(cca 400 eur)
Withdrawal of a marketing authorization for a medicinal product			
Withdrawal of a marketing authorization for a medicinal product at the applicant's request, and in case the medicinal product has not been placed on the market within three years of the authorisation being granted		2.000,00	(cca 260 eur)

Cyprus

There are no specific fees for homeopathic medicinal products.

Czech Republic

National procedures:

R-001 national marketing authorisation of a homeopathic product (with indication) – 250 000,- CZK

R-002 national marketing authorisation of a homeopathic product through a simplified procedure (specific for homeopathic products) – 200 000,- CZK

R-010 national renewal of homeopathic products (specific for homeopathic products) – 35 000,- CZK

R-008 national type IA variation (for all MPs) – 6 000,- CZK

R-040 national type IB variation (for all MPs) – 15 000,- CZK

R-007 national type II variation (for all MPs) – 70 000,- CZK

CMS procedures:

R-028 CMS marketing authorisation of a homeopathic product through a simplified procedure (specific for homeopathic products) – 90 000,- CZK

R-035 CMS renewal (for all MPs) – 80 000,- CZK

R-034 CMS type IA variation (for all MPs) – 4 000,- CZK

R-033 CMS type IB variation (for all MPs) – 10 000,- CZK

	<p>R-032 CMS type II variation (for all MPs) – 50 000, - CZK</p> <p>RMS procedures:</p> <p>R-042 RMS marketing authorisation of a homeopathic product through a simplified procedure (specific for homeopathic products) – 310 000, - CZK</p> <p>R-026 RMS renewal (for all MPs) – 200 000, - CZK</p> <p>R-025 RMS type IA variation (for all MPs) – 12 000, - CZK</p> <p>R-024 RMS type IB variation (for all MPs) – 25 000, - CZK</p> <p>R-023 RMS type II variation (for all MPs) – 100 000, - CZK</p>
Denmark	http://laegemiddelstyrelsen.dk/en/licensing/fees/
Finland	<p>a) Marketing authorisation for homeopathic medicinal product (HMP) with medical indication: first marketing authorisation application 13 000€, next pharmaceutical forms or strengths 8000€/application; FI as CMS: first marketing authorisation application 10 000€, next pharmaceutical forms or strengths 6000€/application</p> <p>b) Marketing authorisation for HMP without medical indication (including extension applications): 2100€/application</p> <p>c) Registration for HMP (including extension applications): 1-5 stocks in the HMP 950€/application, more than 5 stocks in the HMP 1200€/application</p> <p>d) If FI as RMS, additional process fee: 12 000€/application</p> <p>e) Variations: same fee for all type of medicinal products</p> <p>f) Annual fee for authorized or register HMP: 200€/product</p> <p>g) Renewal when FI is RMS: 2000€/product</p> <p>h) Fees for vet HMPs respectively (somewhat lower)</p>
France	<p>Yes.</p> <p>1) Registration procedure</p> <ul style="list-style-type: none"> • Products marketed prior to January 18th 1994 (validation procedure): <ul style="list-style-type: none"> - Single stock: 760€ - Compound consisting of 2 to 5 stocks: 1256€ - Compound consisting of more than 5 stocks: 3800€ • Products marketed after January 18th 1994 (new products): <ul style="list-style-type: none"> - Single stock: 1768€ - Compound consisting of 2 to 5 stocks: 2478€ - Compound consisting of more than 5 stocks: 7600€ • Variation: 496€ • Renewal: 1500€

	<p>2) Marketing authorisation</p> <ul style="list-style-type: none"> • Products marketed prior to January 18th 1994 (validation procedure): 1400€ • Products marketed after January 18th 1994 (new products): 14000€ • Variation: 1400€ • Renewal: 5000€ 								
Germany	See http://www.bfarm.de/SharedDocs/Downloads/DE/Service/Gebuehren/AMG-KostV2015.pdf?__blob=publicationFile&v=4								
Greece	Simplified 8000€; Variation 500€ minimum								
Hungary	Yes, see attachment								
Ireland	<p>Yes</p> <p>Simplified Registrations.</p> <p>–Single stock 678€</p> <p>Two or more stocks 1,016€</p> <p>National Rules Authorisations</p> <p>Single stock 1,016€</p> <p>Two or more stocks 1,500€</p> <p>Variation 339€</p> <p>(For full information See Addendum 2)</p>								
Italy	<p>Yes, see the list below:</p> <table> <tr> <td>Marketing authorization for Homeopathic medicinal products pursuant to Art. 16 of Directive 2001/83/EC</td> <td>€ 39.600,00</td> </tr> <tr> <td>Registration procedure Homeopathic medicinal products pursuant to Art. 14 of Directive 2001/83/EC</td> <td>To be defined</td> </tr> <tr> <td>Extensions pursuant to Annex I to Commission Regulation (EC) No 1234/2008 - reduced fee for all quality extensions for which no new clinical data are submitted. For homeopathic medicinal products the fee covers up to a maximum of 10 dilutions, if referred to a homeopathic medicinal product containing only one active substance, and up to 8 homeopathic active substances, if referred to a homeopathic medicinal product containing two or more active substances, and/or for each additional pharmaceutical form and up to 3 presentations.</td> <td>€ 9.187,20</td> </tr> <tr> <td>Renewal fee – for each homeopathic medicinal product according to art. 20 of Legislative Decree 219/06 - for each SINGLE REMEDY including all its dilutions and pharmaceutical forms</td> <td>€ 800,00</td> </tr> </table>	Marketing authorization for Homeopathic medicinal products pursuant to Art. 16 of Directive 2001/83/EC	€ 39.600,00	Registration procedure Homeopathic medicinal products pursuant to Art. 14 of Directive 2001/83/EC	To be defined	Extensions pursuant to Annex I to Commission Regulation (EC) No 1234/2008 - reduced fee for all quality extensions for which no new clinical data are submitted. For homeopathic medicinal products the fee covers up to a maximum of 10 dilutions, if referred to a homeopathic medicinal product containing only one active substance, and up to 8 homeopathic active substances, if referred to a homeopathic medicinal product containing two or more active substances, and/or for each additional pharmaceutical form and up to 3 presentations.	€ 9.187,20	Renewal fee – for each homeopathic medicinal product according to art. 20 of Legislative Decree 219/06 - for each SINGLE REMEDY including all its dilutions and pharmaceutical forms	€ 800,00
Marketing authorization for Homeopathic medicinal products pursuant to Art. 16 of Directive 2001/83/EC	€ 39.600,00								
Registration procedure Homeopathic medicinal products pursuant to Art. 14 of Directive 2001/83/EC	To be defined								
Extensions pursuant to Annex I to Commission Regulation (EC) No 1234/2008 - reduced fee for all quality extensions for which no new clinical data are submitted. For homeopathic medicinal products the fee covers up to a maximum of 10 dilutions, if referred to a homeopathic medicinal product containing only one active substance, and up to 8 homeopathic active substances, if referred to a homeopathic medicinal product containing two or more active substances, and/or for each additional pharmaceutical form and up to 3 presentations.	€ 9.187,20								
Renewal fee – for each homeopathic medicinal product according to art. 20 of Legislative Decree 219/06 - for each SINGLE REMEDY including all its dilutions and pharmaceutical forms	€ 800,00								

	<p>Renewal fee – for each homeopathic medicinal product according to art. 20 of Legislative Decree 219/06 - for each COMBINATION Homeopathic Product including all its principles and pharmaceutical forms € 1.200,00</p> <p>Renewal fee - for each strength associated with a pharmaceutical form for which renewal is sought; regarding to homeopathic this medicinal products to ten dilutions associated with a pharmaceutical form € 3.062,40</p> <p>Variation to a Registration procedure for Homeopathic medicinal products pursuant to Art. 16 of Directive 2001/83/EC and for Homeopathic medicinal products pursuant to Art. 14 of Directive 2001/83/EC</p> <p>Type IA Variation € 660,00</p> <p>Type IB Variation € 1.531,20</p> <p>Type II Variation € 9.187,20</p>
Latvia	There is significantly lower price for registration and renewals of homeopathic medicine
Liechtenstein	Not applicable
Lithuania	Yes. Please find attachment “Lithuania addendum 5”.
Luxemburg	No
Malta	Yes in the Legal Notice Medicines Authority Fees Regulations.
Norway	<p>Registration: 4000 NOK – one fee covers all dilutions of one pharmaceutical form of a specific homeopathic medicinal product</p> <p>Type I variation: No fee</p> <p>Type II variation: 2000 NOK</p> <p>Renewal: 2000 NOK - one fee covers all dilutions of one specific homeopathic medicinal product.</p>
Portugal	<p>We have a special ordinance (Portaria 94/2009 de 28 de Janeiro) at : https://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_III/130_Port_94_2009.pdf</p>
Romania	http://www.anm.ro/anmdm/_/Tarife%20APP_%20Autorizare Reinnoire Variatii Activitati%20conexe%20RO.pdf
Slovakia	<p>New marketing authorisation – the national procedure:</p> <ul style="list-style-type: none"> - Fee for the new marketing authorisation (complete/total) of a homeopathic medicinal product with approved therapeutic indication – 8000 € - Fee for the new marketing authorisation (simplified registration procedure) of a homeopathic medicinal product without approved therapeutic indication – 6400€

New marketing authorisation – MRP/DCP-CMS:

- Fee for the new marketing authorisation (complete/total) of a homeopathic medicinal product with approved therapeutic indication – 5000 €
- Fee for the new marketing authorisation (simplified registration procedure) of a homeopathic medicinal product without approved therapeutic indication – 4000 €

New marketing authorisation – MRP/DCP-RMS:

- Fee for the new marketing authorisation (complete/total) of a homeopathic medicinal product with approved therapeutic indication – 9000 €
- Fee for the new marketing authorisation (simplified registration procedure) of a homeopathic medicinal product without approved therapeutic indication – 7500 €

Renewal marketing authorisation:

- the national procedure – 5 000 €
- DCP/MRP-CMS – 4 000 €
- DCP/MRP-RMS – 5 000 €

Variation – type II:

- the national procedure – 4 000 €
- DCP/MRP-CMS – 3 200 €
- DCP/MRP-RMS – 5 000 €

Variation – type IA, IB:

- the national procedure – 200 €
- DCP/MRP-CMS – 200 €
- DCP/MRP-RMS – 200 €

(286/2012 Z.z.)

Slovenia

Yes. Please see Article 19:

http://www.jazmp.si/fileadmin/datoteke/dokumenti/Razno/EN_Pravilnik_o_pristojbinah_na_podrocju_zdravil_Ur_l_65-11_clean.pdf

Article 19

(Fees for homeopathic medicinal products)

Fees relating to the issue, renewal, variation, transfer and cessation of marketing authorisation for a homeopathic medicinal product shall be as follows:

1. for the issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains a single homeopathic principle, associated with one pharmaceutical form – NP.....100 points
2. for the issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains two to three homeopathic principles, associated with one pharmaceutical form – NP.....300 points
3. for the issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains up to three homeopathic principles,

-
- associated with one pharmaceutical form – MRP/DCP-CMS.....50 points
4. issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains up to three homeopathic principles, associated with one pharmaceutical form – MRP/DCP-RMS.....4000 points
5. for the issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains more than three homeopathic principles, associated with one pharmaceutical form – NP.....400 points
6. for the issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains more than three homeopathic principles, associated with one pharmaceutical form – MRP/DCP-CMS.....60 points
7. for the issue of marketing authorisation for a homeopathic medicinal product in a simplified procedure, which contains more than three homeopathic principles, associated with one pharmaceutical form – MRP/DCP-RMS.....4400 points
8. additional fees for the issue of marketing authorisation for a homeopathic medicinal product referred to in items 1, 2 and 5 of this article, for each additional pharmaceutical form within the application.....60 points
9. additional fees for the issue of marketing authorisation for a homeopathic medicinal product referred to in items 3 and 6 of this article, for each additional pharmaceutical form within the application.....20 points
10. additional fees for the issue of marketing authorisation for a homeopathic medicinal product referred to in items 4 and 7 of this article, for each additional pharmaceutical form within the application.....1750 points
11. for renewal or variation of marketing authorisation for a homeopathic medicinal product referred to in items 1, 2, 3, 5 and 6 of this article.....30 points
12. for renewal or variation of marketing authorisation for a homeopathic medicinal product referred to in items 4 and 7 of this article.....1000 points
13. fees for the transfer or cessation of marketing authorisation at the request of the marketing authorisation holder shall be the same as the fees referred to in Article 16 of these Rules
14. fees for the issue of marketing authorisation for a homeopathic medicinal product in accordance with paragraph 1 of Article 14 of the Act on medicines shall be the same as fees referred to in Article 10 of these Rules.

The value of 1 point is 5 Eur.

Sweden

List from the Swedish Medical Product Agency's website:
<https://lakemedelsverket.se/english/product/Homeopathic-products/Fees/>

Application type (for complete information see SFS 2010:1167)	FEES (SEK)	FEES (EUR)
Approval of registration for homeopathic medicinal products (see Chapter 2, § 6)		
<i>The fee covers a single-component product, single-component products in a dilution series, or a combined product.</i>		
National application	4 000	433 EUR
Application concerning a recognition of a registration of a homeopathic medicinal product through the DCP or MRP when Sweden is CMS	2 000	216 EUR
Renewal application	Included in the annual fee	
Additional fee for application of a registration of a homeopathic medicinal product through the DCP or MRP when Sweden is requested as RMS (see Chapter 3, § 4)		
<i>In addition to the fee below, the fee as described above should also be paid for (in accordance with Chapter 2, § 6)</i>		
Fee for registration of a homeopathic medicinal product	4 000	433 EUR
Variation of an existing registration (see Chapter 3, § 7)		
<i>The fee covers a single-component product, single-component products in a dilution series, or a combined product.</i>		
Variation type II national application	2 000	216 EUR
Variations type 1A and type 1B within all procedures	Included in the annual fee	
Annual fees (see Chapter 4, § 1)		
Homeopathic medicinal product (a single-component product, single-component products in a dilution series, or a combined product)	250	27 EUR

Switzerland Homeopathic and anthroposophic medicinal products without indication:
Simplified procedure with full documentation: 1500,- CHF
Reduced dossier: 500,- CHF
Application procedure after notification of a basic company dossier (1000,- CHF):
200,- CHF for an amount of 20 applications.
If a master dossier is necessary: 1000,- CHF

The Netherlands	Applications for homeopathic medicinal products:		
	Products with an indication, or other than for oral or external use:	€ 2.400	
	Products without an indication, and for oral or external use:	€ 1.200	
	Application via DCP/MRP with NL=RMS	€ 2.800	

12. As Commission regulation (CE) No. 1234/2008 of November 2008 is not applicable to the simplified registration of homeopathic medicinal products, how do you handle the variation procedures?

Austria	According to national legislation.
Bulgaria	As the variations for the products with MA
Belgium	As other variations.
Croatia	We appoint marketing authorization holders to guideline as help during documentation compilation
Cyprus	Not applicable
Czech Republic	We accept variations concerning homeopathic products and we handle them in the same way as the other medicinal products.
Denmark	They are to be handled as medicinal products with an MA
Finland	National regulation, corresponding to Commission regulation for variations
France	Since January 1st 2016, the decree No. 2015-709 of 22 June 2015 refers to the regulation (CE) No. 1234/2008 of 24 November 2008, regarding variations concerning the registration of homeopathic medicinal products. This rule can therefore be applied by analogy.
Germany	In national procedures they were handled according to Section 29 of the German Medicinal Products Act, the criteria of Commission regulation (CE) No. 1234/2008 are applied. In European procedures they were handled according to Commission regulation (CE) No. 1234/2008 after consulting the CMS.
Greece	As allopathic
Hungary	Same as the variations procedures of the allopathic medicinal products
Ireland	We have a National procedure in which we use the same principles as for other medicinal products.
Italy	In national procedures the regulation (CE) No. 1234/2008, as amended, applied for variations of registered homeopathic medicinal products by analogy to other medicinal products
Latvia	We do not have such products.

Liechtenstein	Not applicable
Lithuania	It is applicable
Luxemburg	Life cycle is automatically linked to the country of origin of the product
Malta	National simplified procedure
Norway	At the moment we are not handling them as no products are registered, but we have information on our website saying that the registration holder is responsible for keeping the registration up to date by submitting variations. Even though the 1234/2008 regulation is not applicable to homeopathic medicinal products we will emphasize that the registration holder is responsible for keeping the registration up to date.
Portugal	They are handled in the same way as the other medicinal products
Romania	As allopathic. For homeopathic products authorized through a simplified procedure, variations in documentation could be approved if appropriate documentation or justifying information will be submitted.
Slovakia	As herbal medicinal products
Slovenia	We do not have much experience with variation procedures to the terms of registration for homeopathic medicinal products (till now we received only 4 variation procedures (3 are still in-progress)). For administrative and quality changes of homeopathic medicinal products we use the same principles as for other medicinal products
Sweden	<p>In large parts, we handle the variations as for other medicinal products. However, we use a simplified application form.</p> <p>The following information is given to the companies on the Swedish Medical Product Agency's website: https://lakemedelsverket.se/english/product/Homeopathic-products/Variations/</p> <p>A change of a registered homeopathic medicinal product may be performed only after permission from the Medical Products Agency (MPA). To simplify the variation application procedure, the application form <u>"Variation application for homeopathic medicinal products"</u> can be used.</p>

Variation applications for homeopathic medicinal products are not regulated by the variation regulation (EC) No 1234/2008 and LVFS 2006:11. However, these regulations may act as support when applying for a variation for homeopathic medicinal products. For examples of changes, conditions and documentation, see [Commission Procedural Guideline](#) and [Application for variation to a marketing authorisation](#) where various changes are listed.

[Application for variation to a marketing authorisation](#) is used by the Medical Products Agency as a basis to assess whether the applicant has categorised the variation of the homeopathic medicine properly. Based on this document, one may determine variations as type IA/IB or type II, and into one of the three categories: administrative, quality or safety.

The time table for the variation procedures of type 1A/1B for homeopathic medicinal products is normally 60 days. For major variations of type II, the time table for the procedure is 120 days.

Variation of an existing registration (see Chapter 3, § 7)	
<i>The fee covers a single-component product, single-component products in a dilution series, or a combined product.</i>	
Variation type II national application	2 000
Variations type 1A and type 1B within all procedures	Included in the annual fee

FEES (EUR)

216 EUR

Switzerland

Only variations for those issues must be submitted, which are part of our special registration procedures for the homeopathic and anthroposophic medicinal products without indication. For these products we have defined special variation procedures

The Netherlands

Likewise normal medicinal products

13. Which preclinical/clinical documentation do you require for authorisation of homeopathic medicinal products with therapeutic indications?

Austria	See question 9
Bulgaria	Similar to the documentation for allopathic medicinal product with justification for any missing information in Module 4 and without Module 5.
Belgium	Full Module 4. Module 5: see question 9
Croatia	Full documentation, WEU, same as for “classic” medicines
Cyprus	Not applicable
Czech Republic	Module 4 (documentation demonstrating safety based on the character/stage of dilution of the homeopathic stock), Module 5 (homeopathic literature, homeopathic provings, clinical trials)
Denmark	Authorisation of an HMP with medical indication is not possible – unless as a normal medicinal product
Finland	No experience. Requirements according to valid guidelines.
France	<p><u>Non-clinical information:</u> Module 4 must include all data on animals, <i>in vitro</i> or <i>in vivo</i>, allowing to define the safety. These data must contain information on herbal drug, stock or compound(s) of stock regarding:</p> <ul style="list-style-type: none"> - Pharmacology (efficacy) and pharmacokinetics, if applicable. - General toxicology after single and repeated administrations. - Genotoxicity and carcinogenicity. - Reprotoxicity (in pups, males and females). - Local tolerance. <p><u>Clinical information:</u> Module 5 must include:</p> <ul style="list-style-type: none"> - A compiling of references (mostly from Materia medica) for each stock - An assessment of the provided bibliographic references proving the homeopathic use of the stocks in the claimed indication. - An assessment of the bibliographic references regarding safety mentioned in the Clinical overview.

Germany	CTD: modules 2, 4 and 5 Furthermore (if applicable): - For combination preparations: assessment of the combination - Assessment for incompatible constituents (homeopathic literature)
Greece	As art 16
Hungary	Same as for the allopathic medicinal products
Ireland	Module 4 to support safety as per National Legislation and Module 5 to Justify the homeopathic use using published literature,(For full information See Addendum 3)
Italy	We do not have authorised homeopathic medicinal products bearing therapeutic indications. Should we have any,, the same requirements of other medicinal products will be needed.
Latvia	It depends on the legal bases that would be chosen by applicant.
Liechtenstein	Not applicable
Lithuania	Please see attachment “Lithuania addendum 6”.
Luxemburg	Same as in the country of origin
Malta	If we had to assess a product, we would require preclinical/clinical bibliographic and scientific documentation on the mother tincture
Norway	We do not have – and will not have – homeopathic medicinal products with therapeutic indications
Portugal	The preclinical documentation has to follow the requirements of module 4, depending on the level of dilution. The therapeutic indication must be justified according to the homeopathic Materia Medica of each component and their association, or with clinical trials
Romania	Same as for allopathic medicinal products with justification for any missing information.
Slovakia	Module 2, 4, and 5
Slovenia	N/A: We do not have implemented article 16.2.

Sweden	Full documentation in accordance with art. 8.3.
Switzerland	<p>The requirements are defined in annex 1, Part III and IV of the Ordinance on complementary an herbal medicinal products.</p> <p>Please follow the link</p> <p>https://www.swissmedic.ch/zulassungen/00153/00189/00190/00738/index.html?lang=en&download=NHZLpZeg7t,lnp6lONTU042l2Z6ln1ad1lZn4Z2qZpnO2Y uq2Z6gpJCDdIN9fmym162epYbg2c JjKbNoKSn6A--</p>
The Netherlands	Full preclinical and clinical documentation

14. Do you have any restriction on the therapeutic indications that can be claimed?

Austria	No
Bulgaria	Yes (Control of severe diseases such as: cancer, AIDS, infections etc.)
Belgium	The accepted therapeutic indication depends on the level of evidence provided in Module 5 (see question 9).
Croatia	No
Cyprus	No
Czech Republic	Yes. The indications are limited to less serious symptoms or less serious illnesses not requiring supervision or intervention of a medical doctor
Denmark	Not applicable
Finland	No experience.
France	For pathologies requiring a medical monitoring, the homeopathic medicinal product can only be accepted as adjuvant treatment. In any case, the proof of traditional use of the stock, in the therapeutic indication, has to be demonstrated by the bibliography
Germany	Yes. See paper "Criteria for cognition-based data on clinical indications in homeopathy" (2002) http://www.bfarm.de/DE/Arzneimittel/zul/zulassungsarten/besTherap/amAnthropo/Kriterien.html
Greece	This is the decision of the evaluations board, as yet no restrictions
Hungary	No
Ireland	Yes only indications for mild self-limiting conditions are accepted, (see Addendum 1. Article 11(2)(c) – "...that any such indication shall be suitable for use without the intervention of a registered medical practitioner for diagnostic purposes or for prescription or for the monitoring of treatment,..."). This is decided on a case by case basis.
Italy	No
Latvia	No
Liechtenstein	Not applicable
Lithuania	Homeopathic medicinal products could be used only for light (self-passing) symptoms and conditions. This includes symptoms or the condition, which can be safely facilitated or taken for their prevention without medical supervision or intervention

Luxemburg	No as long as there is a registration elsewhere
Malta	Yes. Only indications for mild conditions are acceptable
Norway	Not applicable
Portugal	Yes they are limited to those indications accepted for OTC acceptable in the Portuguese legislation
Romania	We have not any restriction on the therapeutic indications that can be claimed.
Slovakia	No experience
Slovenia	Not applicable
Sweden	No
Switzerland	There is no restriction related to the therapeutic indication. However, the applicant must provide the evidence for it. But depending on the indication the products will be only available on prescription
The Netherlands	No

15. Do you have additional requirements for the labeling of homeopathic medicinal products?

Austria	Yes They have to contain the label “homeopathic medicinal product”, if they are registered acc. to article 14 “homeopathic medicinal product (without approved therapeutic indication)”
Bulgaria	No
Belgium	“Homeopathic Medicinal Product” should be mentioned on the labels
Croatia	Yes
Cyprus	No
Czech Republic	No
Denmark	No
Finland	No
France	No. For the products following the registration procedure, the labelling is the one provided for in article 69 of the Directive 2001/83/CE. The warnings mostly concern the excipients. For the products following the MA procedure, the labelling is the one of a standard MA, with mentions adapted for homeopathic medicinal products.
Germany	Yes. <ul style="list-style-type: none"> - “Homeopathic Medicinal Product” should be mentioned on the labels for registered products. For authorized products the homeopathic nature of the product should be indicated. - Therapeutic indication: “The indication is based on the homeopathic drug picture. This includes...” - Warnings and precautions: Differential diagnostic information: Advice for the patient to consult the doctor if the symptoms of the disease persist or become more severe. - Interactions: “Common information: The effect of a HMP may be influenced generally by harmfully factors in the way of life and by consuming irritating substances

or luxury foodstuffs.

If you are taking any other medicines, please inform your doctor.”

- Duration of application:

“HMP should not be used over a longer period without the advice of a doctor.”

- Side effects:

“Common information:

When using a HMP the existing symptoms can initial aggravate. In this case you should stop taking the medicine and ask your doctor.”

Greece	No
Hungary	No
Ireland	No
Italy	Yes, we have additional requirements regarding the excipients. A national guideline on “Excipients in the label” is in-progress.
Latvia	No
Liechtenstein	Not applicable
Lithuania	No
Luxemburg	Language has to be official in Luxembourg : German and/or French
Malta	No
Norway	At the moment we do not check labeling of homeopathic medicinal products. During the registration these will be handled in the same way as other medicinal products, with some exceptions.
Portugal	Yes, ethanol, sucrose and lactose have to be mentioned in the labelling
Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	Yes, they must be labelled as homeopathic medicinal products. There are also requirements concerning the specific declaration of the active components etc. The rules of labeling of homeopathic medicinal products are defined in the AMZV – an ordinance which is not available in English
The Netherlands	No

16. If anthroposophic medicinal products are marketed in your country, are they labelled as homeopathic medicinal products or as anthroposophic medicinal products?

Austria	They are labelled as homeopathic medicinal products according to anthroposophic tradition
Bulgaria	Not applicable
Belgium	They are label as homeopathic medicinal product but the anthroposophic tradition is mentioned in the indication
Croatia	We don't have anthroposophic medicinal products marketed in Croatia
Cyprus	Not applicable
Czech Republic	We do not have any anthroposophic medicinal product.
Denmark	They are labelled as medicinal products.
Finland	On the labelling 'Homeopathic medicinal product' is replaced by 'Anthroposophic medicinal product'
France	No, they are labelled as homeopathic medicinal products.
Germany	In case of marketing authorization they are labelled as anthroposophic medicinal products, in case of registration they are labelled as homeopathic medicinal products for anthroposophic use.
Greece	No
Hungary	Not applicable
Ireland	All products are homeopathic only no anthroposophic products on the market.
Italy	According to art. 20 of Legislative Decree 219/06 the anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are subject to the same procedure of homeopathic medicinal products. with regard to the registration and marketing authorization.
Latvia	It could be in case the anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorization, in the same way as homeopathic medicinal products.
Liechtenstein	Swiss medicinal products are marketed according to Swiss legislation (labelled as anthroposophic medicinal products).
Lithuania	Anthroposophic

Luxemburg	Not applicable
Malta	Most probably as homeopathic medicinal products
Norway	If a product is registered as a homeopathic product, it will also be labelled in accordance with the rules for labelling homeopathic products. Anthroposophic medicinal products that are not registered as a homeopathic product nor has a marketing authorization will only be sold through a special exception arrangement. The use and effect/side effects of these products are the responsibility of the prescriber and all these products are labelled with a sticker saying that the products have not been assessed by NoMA prior to being sold.
Portugal	They are labelled as homeopathic medicinal products
Romania	Not applicable
Slovakia	Not applicable
Slovenia	Not applicable
Sweden	They are labelled as anthroposophic medicinal products.
Switzerland	They are labelled as anthroposophic medicinal products
The Netherlands	Some of them are labelled as “homeopathic medicinal product used according the principles of anthroposophic medicine.”

17. In the past ten years, have you received any reports of adverse reactions to homeopathic products or stocks?

a. If yes, did the reports lead to any modifications of the authorised or registered products?.

Austria	Yes a. No
Bulgaria	Yes a. No
Belgium	Yes a. No
Croatia	No
Cyprus	No
Czech Republic	Yes a. No
Denmark	No reports on AR have been received the past 10 years.
Finland	Yes a. No
France	Yes. a. Yes, type IB-C.I.3.A variation: "Change in the SPC, Labelling or the Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR"
Germany	Yes. Adverse reactions have been reported to the BfArM Pharmacovigilance System. a. Yes. If the adverse reactions are plausible, e. g. drug intolerance or allergic symptoms, these reactions are mentioned in the package leaflet of the homeopathic medicinal products. In case of high risks of severe adverse reactions a national graduated plan can be initiated.
Greece	No
Hungary	Yes a. No
Ireland	No
Italy	Yes, They are registered in the "Italian surveillance system of natural health products". a. No
Latvia	Yes a. No

Liechtenstein	No
Lithuania	Yes a. No
Luxemburg	No
Malta	No
Norway	No
Portugal	-
Romania	Yes a. No
Slovakia	No
Slovenia	Yes a. No
Sweden	No reports from health care, only a few reports directly from patients. a) No
Switzerland	Yes a. If there were adverse reactions, the package insert of the product will be adapted. If the adverse reaction is in connection with a particular substance, the list HAS will be adapted too.
The Netherlands	No

18. Do you apply the parallel import procedure to homeopathic medicinal products in your country?

Austria	It can be applied, no application yet
Bulgaria	In principal, YES, but only for products with marketing authorization-with indication (no such cases till now).
Belgium	Yes
Croatia	We didn't receive any request for parallel import of HMP
Cyprus	No
Czech Republic	Yes.
Denmark	Basically yes, no experience so far
Finland	Basically yes, no experience so far
France	Yes
Germany	Yes
Greece	No
Hungary	Until now no such type of procedures (but the possibility exists)
Ireland	This issue has not arisen.
Italy	Currently not
Latvia	We apply the same parallel import procedure
Liechtenstein	No
Lithuania	Yes
Luxemburg	No
Malta	Yes if the need arises depending on the product and in line with our parallel import regulations. As there are currently no marketing authorisations for homeopathic medicinal products in Malta, there cannot be parallel import for any product
Norway	At the moment homeopathic medicinal products are not parallel imported (or exported) in Norway. What will happen once the registration procedure is up and running, we do not know.
Portugal	Yes. We even have 1 homeopathic medicinal product authorised via normal full marketing authorisation and via parallel import authorization
Romania	Yes, homeopathic products can be subject to parallel import. For the moment there are no requests.

Slovakia	No
Slovenia	According to the legislation it can be applied but we have not received any application yet.
Sweden	Yes, in principle. But so far we have never received an application for parallel import of a HMP.
Switzerland	No
The Netherlands	Yes

IV. QUESTIONS ON THE NATIONAL EXPERIENCE OF REGISTERING/AUTHORISING HOMEOPATHIC MEDICINAL PRODUCTS

19. How many homeopathic medicinal products have been registered in your country using the simplified registration procedure referred to article 14 of the Directive? (please, also include figures on withdrawn and procedures in-progress).

Austria	2851 registered, 3805 withdrawn, 13 in progress
Bulgaria	1323
Belgium	So far, none are registered. Procedures in progress: 54
Croatia	1 registration in progress
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	59 homeopathic medicinal products have been registered after the Directive was implemented in the Czech legislation. 208 homeopathic medicinal products have been renewed according to the Directive.
Denmark	None HMP have been registered until now
Finland	1 registration which has been withdrawn
France	Total: 860 In-progress: 990
Germany	Since 1979: 2417 have been registered according to Section 38 German Medicinal Products Act, 394 of them have been registered after 28.08.2005 1076 are on the market Withdrawn applications: 1341 In progress: 26 Since 1993: 3470 have been registered according to Section 105 German Medicinal Products Act (old products), 2613 of them are on the market

Greece	30 registered, 1 in progress
Hungary	785
Ireland	Total 121 (Registered 98, In-progress 13, withdrawn 10)
Italy	4 procedures have been withdrawn by the applicant after the assessment 28 procedures have been rejected
Latvia	MA -0
Liechtenstein	0
Lithuania	39 medicinal products
Luxemburg	Not counted, depends on the origin
Malta	None so far
Norway	0
Portugal	599
Romania	7 medicinal products granted; 2 medicinal products procedures in-progress
Slovakia	2 (total 2 685 – old authorisation, before 1997)
Slovenia	99
Sweden	<p>Directive 2001/83/EC was implemented through LVSF 2003:2 that came into force may 2003.</p> <p>Before that, 234 HMPs were registered (of which 143 have been withdrawn).</p> <p>After the implementation 1250 HMPs were registered (of which 261 have been withdrawn)</p> <p>Today (2016-05-13) we have:</p>

	1080 registered products 404 withdrawn registrations 5076 withdrawn applications (withdrawn before/during assessment, never registered) 1 in progress
Switzerland	19 – 22: Inapplicable But we can give the numbers for our procedures: with indication: about 700 without indication: <ul style="list-style-type: none"> • “normal” simplified authorization: about 10 • Reduced dossier: about 900 • application procedure: about 12'000
The Netherlands	Article 14: 2632 homeopathic medicinal products.

20. How many homeopathic medicinal products have been authorised according to article 16.1 of the Directive 2001/83/EC (please, also include figures for withdrawn and procedures in-progress)

Austria	None
Bulgaria	None
Belgium	None
Croatia	2 authorization in progress according to the Directive 2001/83/EC. (4 products, which are still on market, were authorized before implementation of Directive 2001/83/EC in 2013.).
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	None
Denmark	None
Finland	None
France	Since 2001, according to articles 16.1 and 16.2, we've received 375 submissions, of which 260 have been assessed (including 67 authorisations) and 115 are still in-progress.
Germany	None
Greece	None
Hungary	21 authorised, 3 applications were withdrawn during the authorization procedure (due to the lack of proper nonclinical and clinical documentation)
Ireland	Total 14. Authorised 0, In-progress 14
Italy	None
Latvia	MA –100; withdrawn-0; in-progress-0
Liechtenstein	None
Lithuania	No information
Luxemburg	See question 19
Malta	None so far
Norway	None
Portugal	42

Romania	30 medicinal products granted; 7 withdrawn; 16 medicinal products procedures in-progress
Slovakia	None
Slovenia	None
Sweden	None
Switzerland	None
The Netherlands	None

21. How many homeopathic medicinal products have been authorised according to article 16.2 of the Directive?

Austria	520 authorised, 163 withdrawn, 25 in progress
Bulgaria	80
Belgium	9 products authorized 14 products withdrawn 60 products in progress
Croatia	None
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	4
Denmark	None
Finland	None
France	See question 20.
Germany	Since 1988: 292 have been authorized according to Section 21 German Medicinal Products Act, 36 of them have been authorized after 28.08.2005 185 are on the market Since 1993: 1510 have been authorized according to Section 105 German Medicinal Products Act (old products), 1053 of them are on the market
Greece	None
Hungary	None
Ireland	One
Italy	None
Latvia	MA –8
Liechtenstein	None
Lithuania	102 medicinal products
Luxemburg	See question 19

Malta	None so far
Norway	None
Portugal	None
Romania	None
Slovakia	None
Slovenia	None
Sweden	Not applicable (Sweden has not implemented article 16.2).
Switzerland	None
The Netherlands	Article 16.2: 442 homeopathic medicinal products

22. How many homeopathic medicinal products are authorised/registered according to article 13 of the Directive under specific national rules? (please, also include figures for withdrawn and procedures in-progress)

Austria	None
Bulgaria	None
Belgium	None
Croatia	None
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	None
Denmark	None
Finland	Registration granted before 1993, no renewal: 506
France	None
Germany	National rules especially transition frameworks have been defined in the German Medicines Act.
Greece	None
Hungary	None
Ireland	None
Italy	344 procedures are in-progress.
Latvia	None
Liechtenstein	None
Lithuania	22 medicinal products. All withdrawn
Luxemburg	See answer to question 19
Malta	None so far
Norway	None
Portugal	None
Romania	None
Slovakia	None
Slovenia	None
Sweden	None
Switzerland	None
The Netherlands	None

23. Currently have you completed the review and registration/authorization of all homeopathic medicinal products already on the market before the implementation of the Directive in your country?

Austria	No
Bulgaria	Yes
Belgium	No
Croatia	Yes
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	See answer to question No. 5
Denmark	No
Finland	No renewal procedure for registrations granted before 1993
France	No
Germany	Yes
Greece	No
Hungary	Yes (see answer to question 7)
Ireland	Review Yes, Registration Yes, Authorisation No, applications are under assessment.
Italy	No, currently, 4 products have completed the procedure
Latvia	Not yet
Liechtenstein	Not applicable, see answer to question 5
Lithuania	Yes
Luxemburg	Depends on the country of origin
Malta	Not applicable, as there are no products on the market
Norway	No. However all homeopathic medicinal products that are not registered by 12.01.2017 will lose market access.
Portugal	-
Romania	Yes
Slovakia	No
Slovenia	Not applicable
Sweden	Yes, except for the anthroposophic products with authorisation from the Swedish government (see question 16).
Switzerland	Inapplicable
The Netherlands	Yes

24. Are there any major obstacles for the registration of homeopathic medicinal products in your country? (If so, please, specify)

Austria	No
Bulgaria	No
Belgium	No
Croatia	No
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	No. However, the rules which have to be followed are mentioned in answer to the question number 9.
Denmark	Not applicable
Finland	No
France	No, no major obstacles other than: <ul style="list-style-type: none"> - the lack of resources to process and assess the dossiers increasing the delay of validation, - the content of the dossiers, often not documented enough.
Germany	No
Greece	No
Hungary	In case of registration according to article 14 there are no obstacles, in case of registrations according to article 16.1 we are following the Directive 2001/83/EC
Ireland	No
Italy	No
Latvia	No
Liechtenstein	No
Lithuania	No
Luxemburg	No
Malta	Not applicable
Norway	As we haven't received any applications yet, we do not know.
Portugal	No
Romania	No major obstacles. It can be mentioned the content of the dossier which is not enough documented
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	No
The Netherlands	No

25. Have you acted as Reference Member State (RMS) in any mutual recognition procedures involving homeopathic medicinal products?

Austria	No
Bulgaria	No
Belgium	No
Croatia	No
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	No
Denmark	No
Finland	No
France	A RMP could be planned for 2017 in France.
Germany	Yes
Greece	No
Hungary	No
Ireland	No
Italy	No
Latvia	No
Liechtenstein	No
Lithuania	No
Luxemburg	No
Malta	No
Norway	No
Portugal	No
Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	Inapplicable
The Netherlands	No

26. Have you been involved as a Concerned Member State (CMS) in any mutual recognition procedures related to homeopathic medicinal products?

Austria	No
Bulgaria	No
Belgium	No
Croatia	No
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	No
Denmark	No
Finland	No
France	No
Germany	No
Greece	No
Hungary	No
Ireland	No
Italy	No
Latvia	No
Liechtenstein	No, for MRP/DCP approved medicinal products we have an agreement with Austria.
Lithuania	No
Luxemburg	No
Malta	No
Norway	No
Portugal	No
Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	Inapplicable
The Netherlands	Yes

27. Have you acted as Reference Member State (RMS) in any decentralized procedures application related to homeopathic medicinal products?

Austria	No
Bulgaria	No
Belgium	No
Croatia	No
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	No
Denmark	No
Finland	No
France	No
Germany	Yes
Greece	No
Hungary	No
Ireland	No
Italy	No
Latvia	No
Liechtenstein	No
Lithuania	No
Luxemburg	No
Malta	No
Norway	No
Portugal	No
Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	Inapplicable
The Netherlands	No

28. Have you been involved as a Concerned Member State (CMS) in any decentralized procedures application related to homeopathic medicinal products?

Austria	Yes
Bulgaria	No
Belgium	No
Croatia	No
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	No
Denmark	No
Finland	No
France	No
Germany	No
Greece	No
Hungary	No
Ireland	No
Italy	Yes, in 1 procedure.
Latvia	No
Liechtenstein	No, see point 26
Lithuania	No
Luxemburg	No
Malta	No
Norway	No
Portugal	Yes, in one application
Romania	No
Slovakia	No
Slovenia	No
Sweden	No
Switzerland	Inapplicable
The Netherlands	No

29. How many renewal applications for homeopathic medicinal products approved under articles 14 and 16 have you received?

Austria	2587
Bulgaria	1237
Belgium	1
Croatia	10
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	267
Denmark	None
Finland	None so far
France	410
Germany	2745
Greece	None
Hungary	art.14: 710, art.16.1: 47
Ireland	Article 14 only - 25
Italy	None
Latvia	106
Liechtenstein	None
Lithuania	111 applications
Luxemburg	Not counted as life cycle depends on country of origin
Malta	Not applicable
Norway	None
Portugal	None
Romania	29 renewal applications for homeopathic medicinal products
Slovakia	None
Slovenia	18
Sweden	1089
Switzerland	Inapplicable
The Netherlands	Several, but cannot provide a figure

30. How many renewal applications for homeopathic medicinal products approved under articles 14 and 16 have you received that are either granted or pending?

Austria	1926 granted 654 pending
Bulgaria	12
Belgium	1 granted
Croatia	None
Cyprus	Questions 19-30 are not applicable since there are no homeopathic products on our market
Czech Republic	267
Denmark	None
Finland	None
France	Granted: 347 Pending: 63
Germany	Granted: 2023 Pending: 39
Greece	None
Hungary	see answer to question 29 (none pending)
Ireland	25
Italy	None
Latvia	106
Liechtenstein	None
Lithuania	114 applications
Luxemburg	Not counted as life cycle depends on country of origin
Malta	Not applicable
Norway	None
Portugal	Art 14: 190 approved; Art 16: 2 approved
Romania	17 renewal applications for homeopathic medicinal products are granted and 12 pending
Slovakia	None
Slovenia	18
Sweden	1089 granted, 0 pending
Switzerland	Inapplicable
The Netherlands	Several, but cannot provide a figure

31. Are there any manufacturing sites of homeopathic medicinal products authorized in your country according to article 40 of the Directive? If so, how many?

Austria	Yes, ~10
Bulgaria	No
Belgium	4
Croatia	No
Cyprus	We have on manufacturing facility but is for manufacturing of homeopathic raw materials and not finished products.
Czech Republic	Yes. There are three manufacturing sites of homeopathic medicinal products authorized in the Czech Republic.
Denmark	2-3
Finland	None
France	7.
Germany	170
Greece	1
Hungary	No
Ireland	1
Italy	8 manufacturing sites
Latvia	1 -licence of manufacturers
Liechtenstein	We had one site, but the license was withdrawn in 2007.
Lithuania	Yes, 2 sites (UAB „Aconitum“ ir UAB „Santonika“).
Luxemburg	None
Malta	Not applicable
Norway	No
Portugal	No
Romania	1
Slovakia	No
Slovenia	1
Sweden	2
Switzerland	about 20
The Netherlands	Yes, GMP Inspection is responsibility of Inspection.

Ireland Addendum n.1

National Rules

Excerpted from Statutory Instrument 540 of 2007

Authorisation of homeopathic medicinal products under national rules.

11. (1) Notwithstanding the provisions of Regulations 9 and 10 insofar as those provisions relate to the requirements for pre-clinical tests and clinical trials, the Board may grant a marketing authorisation in respect of a homeopathic medicinal product other than a product referred to in Article 14.1 of the 2001 Directive.

(2) For the purposes of obtaining an authorisation in accordance with this Regulation and subject to paragraph (3), the applicant shall demonstrate to the satisfaction of the Board—

- (a) that the product is a homeopathic medicinal product which conforms with the principles and characteristics of homeopathy as practised in the State;
- (b) that the indication sought is appropriate to such a homeopathic medicinal product;
- (c) that any such indication shall be suitable for use without the intervention of a registered medical practitioner for diagnostic purposes or for prescription or for the monitoring of treatment;
- (d) that the efficacy of the product shall be established on the basis of evidence that the particular class of homeopathic medicinal product has been in use in the State as a homeopathic treatment for the indication sought; and
- (e) that the safety of the homeopathic medicinal product has been established in the manner set out in paragraph (3).

(3) For the purpose of this Regulation and subject to subparagraph (4), the safety of the homeopathic medicinal product shall be demonstrated—

- (a) by reference to relevant published literature or original data having regard to the proposed route of administration and the dilution involved; or
- (b) in the case of stocks derived from substances commonly used in food, by means of a statement setting out the homeopathic nature of the product and the absence of any change to the route of exposure for the substance concerned; or
- (c) in the case of an active principle used in allopathic medicinal products, by establishing that the dilution of the stocks is at least 1 in 10,000 of the mother tincture or not more than one hundredth of the smallest dose of the said active principle as used in allopathy; or
- (d) by establishing that the medicinal product contains not more than one part per 10,000 of the mother tincture.

(4) In regard to the active principles referred to in subparagraphs (3)(c) and (d), the Board may refuse to grant an authorisation where it is satisfied that the active principle concerned is toxic and as such would present concerns in regard to the safety of the product. For the purposes of this subparagraph, the Board may publish and update from time to time a list of the substances that it considers to be in this category.

(5) A homeopathic medicinal product that is placed on the market on foot of a marketing authorisation granted in accordance with this Regulation shall, in addition to compliance with the

requirements of Regulation 16 (relating to labelling and package leaflets), be presented in such a manner as to show—

- (a) that the product is a homeopathic medicinal product in respect of which an authorisation has been granted in accordance with this Regulation;
- (b) that any evidence of efficacy on the part of the product has not been based on the outcome of clinical trials;
- (c) that use of the product is only intended for the symptomatic relief of the condition to which the indication specified relates; and
- (d) that the user is advised to consult a doctor or other healthcare professional if the symptoms persist.

Ireland Addendum n. 2

Fees for Registration, Authorisation, Renewal & Variation procedures for homeopathic products registered according to Article 14 and authorised according to Article 16, as published on the HPRA website www.hpra.ie

1.9 Homeopathic product registration and authorisation

1.9.1 New homeopathic applications

Codes* 271-272 are for applications for certificate of registration for homeopathic medical products under the simplified registration scheme. The codes apply to:

- national applications,
- ‘assessment step 1’ of applications in the decentralised procedure where Ireland is the RMS,
- decentralised applications where Ireland is a CMS.

Each pharmaceutical dosage form of a product requires a separate application form and a separate fee irrespective of the stock or potency used. An application for a series of dilutions (potencies) derived from the same stock or stocks are treated as a single application, provided all dilutions are mentioned in the same application.

Codes 273-274 apply to MR applications where Ireland is a CMS.

Code 275 applies to MR applications where Ireland is the RMS. This supplement is for the production and release of the assessment report and the handling and administration of the 90-day mutual-recognition procedure. It is payable in addition to the appropriate national fee HPRA Guide to Fees for Human Products FIN-G0002-19 13/28 (271 or 272), either when the initial national application is made or before the 90-day mutual-recognition procedure begins. Only one supplement is charged for the entire range.

1.9.2 New homeopathic applications national rules scheme

Codes 287-288 apply to new applications for authorisation under the national rules scheme. These fees cover authorisations of homeopathic medicinal products, as provided for under S.I. 540 of 2007, as amended and EU Directive 2001/83/EC, as amended. The national rules scheme covers homeopathic medicinal products that have indications and therefore do not qualify for the simplified registration scheme.

1.9.3 Homeopathic registrations and national rules scheme variations

Code 276 is for national variation applications. For bulk variations for the same change to two or more certificates, authorisations or license, code 277 is the reduced rate fee which applies to the third and subsequent certificate.

Codes 278-279 apply to MR variation applications where Ireland is a CMS.

Code 280 is a supplement fee which applies to MR variation applications where Ireland is the RMS. Only one supplement is charged for the entire range.

Code 204 applies when the cost of multiple variations to the master file exceeds €2,038.

1.10 Maintenance of authorisations or registrations

Codes 251, 266-267 are yearly fees for each MA, which covers all aspects of routine dossier management and maintenance, including the work associated with on-going pharmacovigilance activities. A reduced fee (code 251) is applied to the first ten MAs and fee code 266 is applied to the subsequent MAs. Fee code 267 applies to MAs which are deemed to be dormant.

Dormant authorisations are defined as MAs where the product is not marketed (excluding temporary cessation) as notified to the HPRA by 1 January of each year. Notification can be made by submitting a Marketing Status Notification form.

Where an MA holder has less than 10 dormant authorisations, these will be charged at the dormant rate, the balance up to 10 at the reduced rate and all other authorisations charged at the standard rate.

Where an MA holder has more than 10 dormant authorisations, these will be charged at the dormant rate, and all other authorisations charged at the standard rate. HPRA Guide to Fees for Human Products FIN-G0002-19 14/28

Authorisations or registrations that are withdrawn before 1 May will not be charged a maintenance fee for that year. MAs withdrawn on 1 May and after that date will be charged a full year's fee.

Maintenance fees are payable annually and are invoiced to MA holders during the course of the year.

A reduced annual maintenance fee of €55 (code 249) also applies to homeopathic products.

***Codes are listed on the Fees Application Form (see excerpt below)**

**Homeopathic product registration fees extracted from FIN-F0018 Fee application form for human products v20
(effective from 1 January 2016)**

Fee Code	Type	Price in €	Quantity	Total in €
	1.9 Homeopathic Product Registration and Authorisation			
	1.9.1 New Homeopathic Applications			
271	New National/Decentralised application - Standard fee – single stock	678		
272	New National/Decentralised Application - standard fee – two or more stocks	1,016		
273	New Mutual Recognition Application where Ireland is the CMS - Standard fee single stock	452		
274	New Mutual Recognition Application where Ireland is the CMS - Standard fee – two or more stocks	678		
275	Mutual Recognition/Decentralised RMS Supplement	564		
	1.9.2 New Homeopathic Applications National Rules Scheme			
287	New National Application - standard fee - single stock	1,016		
288	New National Application - standard fee - two or more stocks	1,500		
	1.9.3 Homeopathic Registrations and National Rules Scheme Variations			
276	National variation	339		
277	National variation – reduced rate	170		

278	Mutual Recognition variation CMS	226		
279	Mutual Recognition variation – reduced rate CMS	113		
280	Variation – Mutual Recognition/ Decentralised RMS Supplement	170		
204	Bulk variation for multiple changes to the master file	2,038		

Ireland Addendum n. 3

Preclinical/clinical documentation required for authorisation of homeopathic medicinal products with therapeutic indications. In General the full CTD format is requested with the addition of the following from the National Guideline:

Guide to National Rules Scheme for Homeopathic Medicinal Products for Human Use (Excerpt)

7 SAFETY

The applicant must submit data, together with an expert report, to demonstrate the safety of the homeopathic medicinal product in question. The applicant is reminded that products, including their indications, submitted under the NRS must be suitable for use without the intervention of a medical practitioner for diagnosis, prescription or monitoring of treatment. The safety of the product must be demonstrated in accordance with the Medicinal Products (Control of Placing on the Market) Regulations, (S.I. No.540 of 2007), specifically Article 11, subparagraphs 3 and 4 (See Addendum 1).

8 EFFICACY

While the evidence of efficacy of the product does not have to be based on the outcome of clinical trials, the applicant must submit data as to the efficacy of the homeopathic medicinal product by providing suitable evidence, together with an expert report, demonstrating that the particular class of homeopathic medicinal product has been in use in the State as a homeopathic treatment for the indication sought. Information provided must consist of at least one of the following types of data: - Study reports in relation to the product which is the subject of the application. - Published scientific literature or the results of investigations commonly known as homeopathic provings; which consist of the administration of a substance to a human subject in order to ascertain the symptoms produced by that substance. The applicant must also submit an expert report to include an evaluation of the data, including an explanation as to how the data establishes that the product has a recognised level of efficacy in the therapeutic indication for which authorisation is sought and is sufficient to demonstrate that a homeopathic practitioner in this State would accept the homeopathic use of the product for those indications. A summary of the required efficacy data and the expert report are submitted in Module 2.5 of the application and the supporting efficacy data are submitted in Module 5 of the dossier.

Hungary Addendum n.4

II.	Homeopathic preparations					
II.A.		New authorizations				
II.A.1.				Mono-component medicinal product		
II.A.1.1.					If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	67,500
II.A.1.2.					If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	270,000
II.A.2.				Multi-component medicinal product		
II.A.2.1.					If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	135,000
II.A.2.2.					If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	540,000
II.A.3.				Other		540,000
II.B.		Modification of marketing authorization				
II.B.1.			Type IA-IB			
II.B.1.1.				Mono-component medicinal product		

II.B.1.1.a.					If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	11,700
II.B.1.1.b.					If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	11,700
II.B.1.2.				Multi-component medicinal product		
II.B.1.2.a.					If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	117,000
II.B.1.2.b.					If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	117,000
II.B.1.3.				Other		117,000
II.B.2.			Type II			
II.B.2.1.				Mono-component medicinal product		
II.B.2.1.a.					If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States	23,400
II.B.2.1.b.					If the active constituent indicated does not appear	23,400

					in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		
II.B.2.2.				Multi-component medicinal product			
II.B.2.2.a.					If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		234,000
II.B.2.2.b.					If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		234,000
II.B.2.3.				Other			234,000
II.B.2.3.a.				Submissions lodged under Subsection (4) of Section 3 of Decree No. 30/2005 (VIII. 2.) EüM			130,000
II.B.2.3.b.				Other submissions			26,000
II.B.3.				Changes not effecting the summary of product characteristics, pertaining only to the labeling and the package leaflet [Act XCV of 2005, Subsection (2) of Section 10]			26,000
II.B.4.				Transfer of marketing authorization (succession)			234,000
II.B.5.				In the Hungarian marketing authorization, addition or removal of packaging units that have already been authorized under the mutual recognition procedure			130,000
II.B.6.				Switching to the global identification system			130,000
II.B.7.				Change in the classification of the product			351,000
II.C.			Renewal of marketing authorization				

II.C.1.					Mono-component medicinal product			
II.C.1.1.						If the active constituent indicated appears in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		45,000
II.C.1.2.						If the active constituent indicated does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		180,000
II.C.2.					Multi-component medicinal product			
II.C.2.1.						If the active constituent indicated is the combination of active substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		90,000
II.C.2.2.						If the active constituent indicated (also) contains active substances which does not appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States		350,000
II.C.3.					Other			350,000
II.D.		Annual maintenance of marketing authorization						
II.D.1.				Mono-component medicinal product				90,000
II.D.2.				Multi-component medicinal product				135,000
II.E.		Withdrawal of marketing authorization						27,000

Lithuania addendum n. 5

MARKETING AUTHORISATION FEES (in force since 11 of August 2015)

(the reference to the original document: [Dėl Lietuvos Respublikos Vyriausybės 2000 m. gruodžio 15 d. nutarimo Nr. 1458 „Dėl konkrečių valstybės rinkliavos dydžių ir šios rinkliavos mokėjimo ir grąžinimo taisyklių patvirtinimo“ papildymo](#))

1. GRANTING MARKETING AUTHORISATION) (reference No 5749)

		Application	NP ¹		MRP/CMS ²		DCP/CMS ²		MRP/RMS ²		DCP/RMS ²	
			Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy
4.38	1.1	Full application (2001/83/EB Article 8(3))	5 413 €		788 €		788 €		6 691 €		11 961 €	
			97 €	5 316 €	97 €	691 €	97 €	691 €	97 €	6 594 €	97 €	11 864 €
4.39	1.2	Well-established use application (2001/83/EB Article 10a)	5 413 €		816 €		816 €		6 691 €		11 961 €	
			97 €	5 316 €	97 €	719 €	97 €	719 €	97 €	6 594 €	97 €	11 864 €
4.40	1.3	Fixed combination application (2001/83/EB Article 10b)	5 426 €		816 €		816 €		6 691 €		11 961 €	
			97 €	5 329 €	97 €	719 €	97 €	719 €	97 €	6 594 €	97 €	11 864 €
4.41	1.4	Generic/hybrid application (2001/83/EB Article 10(1); 10(3); 10(4))	3 199 €		476 €		476 €		4 552 €		8 679 €	
			97 €	3 102 €	97 €	379 €	97 €	379 €	97 €	4 455 €	97 €	8 582 €
4.42	1.5	Informed consent application (2001/83/EB Article 10c)	3 199 €		548 €		548 €		4 552 €		8 679 €	
			97 €	3 102 €	97 €	451 €	97 €	451 €	97 €	4 455 €	97 €	8 582 €
4.43	1.6	Additional strength form applied simultaneously	1095 €		288 €		288 €		1118 €		1940 €	
			97 €	998 €	97 €	191 €	97 €	191 €	97 €	1021 €	97 €	1843 €
4.43-1	1.7	Additional pharmaceutical form applied simultaneously	1575 €		308 €		308 €		1621 €		5 196 €	
			97 €	1478 €	97 €	211 €	97 €	211 €	97 €	1524 €	97 €	5 099 €
4.44	1.8	Extension of Marketing Authorisation	2 578 €		453 €		453 €		2 655 €		3 293 €	
			97 €	2 481 €	97 €	356 €	97 €	356 €	97 €	2 558 €	97 €	3 196 €
4.45	1.9	Marketing Authorisation of simplified registration procedure for homeopathic medicinal products (2001/83/EB Article 14)	837 €		295 €		295 €		968 €		2 049 €	
			97 €	740 €	97 €	198 €	97 €	198 €	97 €	871 €	97 €	1952 €
4.45-6	1.10	Marketing Authorisation of additional potency or pharmaceutical form applied simultaneously for simplified registration procedure for homeopathic medicinal products	434 €		151 €		151 €		612 €		1041 €	
			48 €	386 €	48 €	103 €	48 €	103 €	48 €	564 €	48 €	993 €
4.45-7	1.11	Extension of Marketing Authorisation of simplified registration procedure for homeopathic medicinal products	575 €		196 €		196 €		742 €		1458 €	
			69 €	506 €	69 €	127 €	69 €	127 €	69 €	673 €	69 €	1389 €
4.46	1.12	Marketing Authorisation of homeopathic medicinal products by other registration procedure (2001/83/EB Article 16)	1227 €		-		-		-		-	
			97 €	1130 €								
4.46-3	1.13	Marketing Authorisation of additional potency or pharmaceutical form applied simultaneously for homeopathic medicinal products authorized by other registration procedure	444 €		-		-		-		-	
			48 €	396 €								
4.46-4	1.14	Extension of Marketing Authorisation of homeopathic medicinal products authorized by other registration procedure	799 €		-		-		-		-	
			69 €	730 €								
4.47	1.15	Marketing Authorisation of simplified registration (Community herbal monograph) procedure for traditional herbal medicinal products (2001/83/EB Article 16(a))	1259 €		338 €		338 €		1384 €		5 455 €	
			97 €	1162 €	97 €	241 €	97 €	241 €	97 €	1287 €	97 €	5358 €
4.47-6	1.16	Marketing Authorisation of additional strengths or pharmaceutical form applied simultaneously of simplified registration procedure for traditional herbal medicinal products	592 €		176 €		176 €		749 €		749 €	
			48 €	544 €	48 €	128 €	48 €	128 €	48 €	701 €	48 €	701 €
4.47-7	1.17	Extension of Marketing Authorisation of simplified registration procedure for traditional herbal medicinal products	822 €		247 €		247 €		1035 €		1035 €	
			69 €	753 €	69 €	178 €	69 €	178 €	69 €	966 €	69 €	966 €

Notes: * Fee indicated in point 1.6 have to be paid when simultaneously with the application to supplement marketing authorisation (registration) certificate additional application for other strength is being submitted
*Fee indicated in points 1.10, 1.13, 1.16 have to be paid when simultaneously with the application to supplement marketing authorisation (registration) certificate additional application for other strength and/or other pharmaceutical form is being submitted.

Notes: * Fee indicated in point 1.6 have to be paid when simultaneously with the application to supplement marketing authorisation (registration) certificate additional application for other strength is being submitted

*Fee indicated in points 1.10, 1.13, 1.16 have to be paid when simultaneously with the application to supplement marketing authorisation (registration) certificate additional application for other strength and/or other pharmaceutical form is being submitted.

2. RENEWAL OF MARKETING AUTHORISATION (reference No 5749)												
		Application	NP ⁱ		MRP/CMS ⁱⁱ		DCP/CMS ⁱⁱ		MRP/RMS ^{iv}		DCP/RMS ^v	
4.48	2.1	Renewal of Marketing Authorisation	1043 €		359 €		359 €		1981 €		1981 €	
			97 €	946	97 €	262 €	97 €	262 €	97 €	1884 €	97 €	1884 €
4.49	2.2	Additional strengths or pharmaceutical forms applied simultaneously	344 €		136 €		136 €		563 €		563 €	
			69 €	275 €	31 €	105 €	31 €	105 €	97 €	466 €	97 €	466 €
4.50	2.3	Renewal of Marketing Authorisation of homeopathic medicinal products authorized by simplified registration procedure	395 €		94 €		94 €		691 €		691 €	
			69 €	326 €	31 €	63 €	31 €	63 €	97 €	594 €	97 €	594 €
4.50-6	2.4	Additional strengths or pharmaceutical forms applied simultaneously for Renewal of Marketing Authorisation of homeopathic medicinal products authorized by simplified registration procedure	202 €		59 €		59 €		384 €		384 €	
			49 €	153 €	12 €	47 €	12 €	47 €	49 €	335 €	49 €	335 €
4.51	2.5	Renewal of Marketing Authorisation of homeopathic medicinal products authorized by other registration procedure	581 €		-		-		-		-	
			97 €	484 €								
4.51-1	2.6	Additional strengths or pharmaceutical forms applied simultaneously for renewal of Marketing Authorisation of homeopathic medicinal products authorized by other registration procedure	330 €		-		-		-		-	
			49 €	281 €								
4.52	2.7	Renewal of Marketing Authorisation of traditional herbal medicinal products authorized by simplified registration procedure	581 €		120 €		120 €		1115 €		1115 €	
			97 €	484 €	31 €	89 €	31 €	89 €	97 €	1018 €	97 €	1018 €
4.52-6	2.8	Additional strengths or pharmaceutical forms applied simultaneously for renewal of Marketing Authorisation of traditional herbal medicinal products authorized by simplified registration procedure	323 €		69 €		69 €		615 €		615 €	
			49 €	274 €	12 €	57 €	12 €	57 €	69 €	546 €	69 €	546 €

3. VARIATIONS AND OTHER CHANGES (reference No 5749)									
		Variation / Change	NP ^a			MRP/CMS ^a DCP/CMS ^a		MRP/RMS ^a DCP/RMS ^a	
			Validation	Evaluation of quality, safety and efficacy	additional fee for each additional variation code	Evaluation of quality, safety and efficacy	additional fee for each additional variation code	Evaluation of quality, safety and efficacy	additional fee for each additional variation code
4.53	3.1	Variation Type IA	-	121 €	12 €▼	73 €	12 €▼	200 €	12 €▼
4.54	3.2	Variation Type IB	217 €		12 €▼	196 €	12 €▼	352 €	12 €▼
			97 €	120 €					
4.55	3.3	Variation Type II (except new indication)	613 €		12 €▼	468 €	12 €▼	1284 €	12 €▼
			97 €	516 €					
4.56	3.4	Variation Type II (new indication)	845 €		12 €▼	613 €	12 €▼	1690 €	12 €▼
			97 €	748 €					
4.57	3.5	Change of labeling and package leaflet ▼▼	162 €			158 €		404 €	
4.58	3.6	Change of classification	738 €						
			97 €	641 €					
4.59	3.7	Transfer of Marketing Authorisation ▼▼	284 €						
▼ When the application is being submitted for grouping of variations, additional fee (12 €) has to be paid for each additional variation code not depending on the number of medicine products/strengths/pharmaceutical forms.									
▼▼ One State fee has to be paid for several strengths and / or pharmaceutical forms when at the same time the application (-s) is/are being submitted for identical variation of terms to marketing authorisation or transfer of marketing authorisation rights and when the documentation is common.									

3a. VARIATIONS (WORKSHARING) (reference No 5749)								
			LTU/CMS			LTU/RMS		
			Validation	Evaluation of quality, safety and efficacy	additional fee for each additional medicinal product's name ¹	Validation	Evaluation of quality, safety and efficacy	additional fee for each additional medicinal product's name ¹
4.54-1.1	3a.1	Worksharing (IB)	350 €			450 €		
		-	97 €	253 €	12 € [▲]	97 €	353 €	12 € [▲]
4.54-1.2	3a.2	Worksharing (II)	697 €			1397 €		
		-	97 €	600 €	12 € [▲]	97 €	1300 €	12 € [▲]

[▲] When the application is being submitted for group of medicines products, additional fee (12 €) has to be paid for each additional invented name of medicinal product, not depending on the number of strengths and (or) pharmaceutical forms.

5. PARALLEL IMPORT (reference No 5749)				
			Validation	Evaluation of documents
4.63	5.1.	Application for licence of parallel import	73 €	268 €
4.64	5.2.	Application for change of parallel import conditions*		133 €

* One State fee has to be paid for several strengths and / or pharmaceutical forms when at the same time the application (-s) is/are being submitted for identical variation of terms to marketing authorisation and when the documentation is common.

¹ NP – national procedure

² MRP / CMS – mutual recognition procedure; CMS – LT as Concerned Member State

³ DCP / CMS – decentralized procedure; CMS – LT as Concerned Member State

⁴ MRP/RMS – mutual recognition procedure; RMS – LT as Reference Member State

⁵ DCP/RMS – decentralized procedure; RMS – LT as Reference Member State

Lithuania addendum n. 6

PRE-CLINICAL REQUIREMENTS

9. The applicant must provide the preclinical information (data) of the active substance (s) from which (s) manufactured provided by registered homeopathic medicine homeopathic stock, the toxicological properties (toxicity, genotoxicity, toxicity to reproduction and development, local tolerance).

10. Registration file Module 2, the pre-clinical expert, corresponding to the requirements of paragraph 12 of the Rules, ready for the pre-clinical evaluation, which must be assessed in accordance with paragraph 11 of Schedule information (data), and explain how this information (data) proves acceptable homeopathic medicinal product safety. If the security of showing information (data) is presented, ikiklinikiniame evaluation of the confirmation that the homeopathic medicinal product meets one of the criteria of paragraph 12 of Schedule, and if applicable Description 12.4, further explains why it is not present toxicological information.

11. Registration file Module 4 provides non-clinical studies of scientific information (data) (eg., Research reports, scientific articles copies), which should be sufficient to demonstrate that the homeopathic medicinal product is safe. If necessary, it may additionally be provided in forms other than scientific information (data). If the product meets Description 12.4 thereof, contain information (data), reasoned that a preparation of homeopathic dilution of the raw materials to such an extent that the toxicological information is not

12. The applicant can not to report a homeopathic medicinal product submitted for registration under the special procedure for registration of security, if it meets at least one of the following criteria:

12.1. It is an oral homeopathic medicine, made of materials used in food;

12.2. made of the homeopathic stock, which is not of biological origin and not part of the lower potency homeopathic medicines or other non-prescription medicines included in the Republic of Lithuania Register of medicinal products, composition;

12.3. made of mineral or vegetable (non-biological) origin of the homeopathic stock, the dilution of greater than 1/1023;

12.4. If the product is made of the homeopathic stock, which dilution of less than stated in the Description 12.3 point, but it is not possible to provide evidence of the safety data for the preparation of raw materials in theory and in practice does not pose a security risk.

13. If the applicant fails to demonstrate the safety of information (data), recording the proceedings in place of Module 4 to submit a written statement and evidence that the claimed medicinal product meets one of the criteria of paragraph 12 of Schedule.

CLINICAL REQUIREMENTS

14. The applicant must submit clinical trial information (data) regarding the registration of homeopathic medicinal efficacy.

15. Registration file Module 2 of the clinical expert, corresponding to the requirements of paragraph 12 of the Rules, ready for clinical assessment, which must be assessed in accordance with Schedule 16 to claim the information (data), and explain how this information (data) proves acceptable homeopathic medicinal efficacy and homeopathic medicinal formulation rationality (if it contains more than one active ingredient) for each proposed Homeopathic indication. If homeopathic efficacy based on the individual active substances effectiveness evidence, it must explain how this information (data) proves the effectiveness of the finished product in the proposed indication.

16. Registration file Module 5 shall be described in the homeopathic treatment experience and the scientific and clinical research information (data) (eg., Research reports, scientific articles copies reference to the pharmacopoeia monographs of Materia Medica, homeopathic test results), which should be sufficient It proves that homeopathic medicine is effective when administered in accordance with the homeopathic indications. If homeopathic medicinal product contains more than one active substance, must be sufficient to show that the composition of the rational (to be based on active substances in combination, the dilution ratio, the pharmaceutical form and route of administration, the product structure of the story, and if it is the homeopathic tests for the entire combination). If the finished product is based on the effectiveness of the individual active substances effectiveness evidence must be provided for each of the efficacy and effectiveness of the compliance of the finished product indication showing information (data). If necessary, it may additionally be provided in forms other than scientific information (data).