



**The implementation status of Article 16 of  
Directive 2001/83/EC**

*(Interim Report May 2008)*

**Brussels, 8 May 2008**

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**DISCLAIMER:**

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***“ECHAMP, The implementation status of Article 16 of Directive 2001/83/EC (Interim Report May 2007), ECHAMP Office Brussels, 8 May 2008.”***

## Introduction

In the EU the rules for the authorisation of homeopathic medicinal products, which are not eligible for the special simplified registration procedure as laid down in Directive 2001/83/EC, can be found in Article 16 of the mentioned Directive:

### Article 16

1. Homeopathic medicinal products other than those referred to in Article 14(1) shall be authorized and labelled in accordance with Articles 8, 10, 10a, 10b, 10c and 11.
2. A Member State may introduce or retain in its territory specific rules for the pre-clinical tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State. In this case, the Member State concerned shall notify the Commission of the specific rules in force.
3. Title IX shall apply to homeopathic medicinal products, with the exception of those referred to in Article 14(1).

Accordingly, Member States have two options. They can either choose to apply the standard rules for authorisation of homeopathic medicinal products in conformity with Article 16(1), or they can adopt an authorisation regime under Article 16(2) which contains tailor made rules for pre-clinical tests and clinical trials “*in accordance with the principles and characteristics of homeopathy as practised in that Member State*”.

As there existed no clear information on how Member States have implemented Article 16 of Directive 2001/83/EC until date, ECHAMP intends to bring clarification with *The implementation status of Article 16 of Directive 2001/83/EC*. It contains a compilation of the national rules in the 25 Member States that implement Article 16, including an English translation of the legal provisions. It is intended to serve as a reference document for competent authorities and stakeholders active in the field of homeopathic and anthroposophic medicinal products.

Three categories have been distinguished in order to facilitate the understanding of the current legal situation: **1)** Member States with an implementation of Article 16(2), **2)** Member States with an option to implement Article 16(2) provided for by National Royal/Ministerial Decree/Regulation, without having realised this yet, **3)** Member States with an implementation of Article 16(1). Per category the Member States are placed in alphabetical order.

## 1) Article 16(2) Implemented

### Austria

<i>Implementation Status:</i>	Article 16(2) implemented
<i>Reference to legislation:</i>	§ 9b Arzneimittelgesetz (Medicinal Products Law), BGBl. Nr. 185/1983, as amended by BGBl. I Nr. 107/2005.
<i>Text Legal Provision:</i>	<p><b>§ 9b (Zulassungsunterlagen)</b></p> <p>(1) Einem Antrag auf Zulassung einer homöopathischen Arzneispezialität müssen Unterlagen gemäß § 9a Abs. 1 Z 18 bis 20 nicht beigelegt werden. Weiters sind Unterlagen gemäß § 9a Abs. 2 nicht beigelegen, jedoch</p> <ol style="list-style-type: none"><li>1. Unterlagen, die für die toxikologische Beurteilung der Arzneispezialität von Bedeutung sind, und</li><li>2. Unterlagen über die spezifische homöopathische oder zutreffendenfalls über die spezifische anthroposophische Wirksamkeit anzuschließen.</li></ol> <p>(2) Für homöopathische Arzneispezialitäten, die durch Verdünnung von nur einem Stoff hergestellt werden, ist für den Stoff und seine Verdünnungen ein einziger Antrag ausreichend.</p>
<i>English Translation:</i>	<p><b>§ 9b (Required Documents for Authorisation)</b></p> <p>(1) An application for the authorisation of a homeopathic medicinal products does not need to contain the documents required in § 9a, section 1, points 18 to 20 [<i>documentation on pharmacological and toxicological tests and clinical trials</i>]. Furthermore, the documents required in § 9a, section 2, need not to be attached; however,</p> <ol style="list-style-type: none"><li>1. Documents which are of importance for the toxicological evaluation of the medicinal product, and</li></ol>

2. Documents regarding the specific homeopathic or in case applicable the specific anthroposophic effectiveness should be attached to the application.

(2) For homeopathic medicinal products, which are manufactured by dilution of only one material, a single request is sufficient for the [*starting*] material and its dilutions.

## **Belgium**

*Implementation Status:* Article 16(2) implemented

*Reference to legislation:* **Artikel 28bis, § 6**, Koninklijk Besluit Betreffende de Registratie van Geneesmiddelen (Royal Decree on the Registration and Authorisation of Medicinal Products), B.S. 10 July 1969, as amended by K.B. 23 June 1999.

*Text Legal Provision:* **Artikel 28bis, § 6**

Voor de andere homeopathische geneesmiddelen dan deze bedoeld in § 2 van dit artikel, bepaalt de Minister die de Volksgezondheid onder zijn bevoegdheid heeft, op advies van de Commissie bedoeld in § 4, bijzondere voorschriften voor de farmacologische, toxicologische en klinische beproeving overeenkomstig de principes, de bijzonderheden en de tradities van de homeopathische geneeskunde.

*English Translation:* **Article 28bis, § 6**

For homoeopathic medicinal products other than those mentioned in § 2 of this Article [*Special simplified registration*], the minister competent for public health stipulates, on the advice of the Commission as mentioned in § 4 [*special commission for homeopathic medicinal products*], special requirements for the pharmacological, toxicological tests and clinical trials in accordance with the principles, characteristics and the traditions of homoeopathic medicine.

## **Bulgaria**

<i>Implementation Status:</i>	Article 16(2) implemented
<i>Reference to legislation:</i>	Чл. 36, ЗАКОН ЗА ЛЕКАРСТВЕНИТЕ ПРОДУКТИ В ХУМАННАТА МЕДИЦИНА (2007) (Law on Medicinal Products for Human Use)
<i>Text Legal Provision:</i>	<p><b>Чл. 36.</b></p> <p>(1) За хомеопатични лекарствени продукти, различни от посочените в чл. 35, ал. 1, се прилагат разпоредбите на чл. 27 - 32.</p> <p>(2) За хомеопатични лекарствени продукти по ал. 1 лицето по чл. 26, ал. 1 не представя резултати от предклинични и клинични изпитвания, когато може да докаже с библиографски данни от научната литература, че хомеопатичната употреба на лекарствения продукт или хомеопатичните източници, които влизат в състава му, са с установена безопасност.</p> <p>(3) В случаите по ал. 2 от библиографските данни трябва да са установени:</p> <ol style="list-style-type: none"><li>1. хомеопатичният характер на използваните суровини и тяхната традиционна употреба при заявеното показание;</li><li>2. безвредността на хомеопатичния лекарствен продукт по отношение на степента на разреждане на всяка от съставките.</li></ol>
<i>English Translation:</i>	<p><b>Article 36</b></p> <p>(1) For homeopathic pharmaceutical products, other than those mentioned in Article 35, first paragraph, the rules of Articles 27-32 apply.</p> <p>(2) For homeopathic pharmaceutical products described in the first paragraph data on preclinical tests and clinical trials do not have to be submitted in accordance with Article 26, first paragraph, if bibliographic data in the form of scholarly literature can establish that the homeopathic use of the</p>

pharmaceutical product or the homeopathic source material(s) used is/are safe.

(3) In the cases mentioned in paragraph 2 the following data must be submitted:

1. Proof of the homeopathic character of the stocks and their traditional use;
2. The innocuousness of the homeopathic pharmaceutical product on the basis of the individual characteristics of the ingredients used.

## **Finland**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

**Section 3.8.1, Föreskrift 4/2005**, Ansökan om och upprätthållande av försäljningstillstånd för läkemedelspreparat och registrering (Administrative Regulation 4/2005, Applying for and Maintaining a Marketing Authorisation and Registration for a Medicinal Product) of 7-11-2005

*Text Legal Provision:*

**3.8.1** Homeopatiska och antroposofiska preparat som kräver försäljningstillstånd (Artikel 16 i direktiv 2001/83/EG; artikel 19 i direktiv 2001/82/EG)

Ansökan om försäljningstillstånd måste göras då ett homeopatiskt eller antroposofiskt preparat inte uppfyller alla registreringskriterier enligt 22 a § i läkemedelslagen.

Till ansökan om försäljningstillstånd skall alltid den administrativa delen, sammanfattningarna eller expertrapporterna, kvalitetsdokumentationen, behövlig dokumentation för att garantera säkerheten samt en utredning om preparatets homeopatiska karaktär baserat på tillräcklig litteratur bifogas i fullständig form.

Vid ansökan om medicinsk indikation för ett homeopatiskt eller antroposofiskt läkemedel, skall ansökningsdokumentationen inlämnas i fullständig form (se kapitel 3.1).

*English Translation:*

**3.8.1 Homeopathic and anthroposophic preparations requiring marketing authorisations**  
(Article 16 of Directive 2001/83/EC; Article 19 of Directive 2001/82/EC)

An application for a marketing authorisation must be made for those homeopathic and anthroposophic preparations that do not meet the criteria for registration in section 22a of the Medicines Act.

An administrative section, summaries or expert reports, quality documentation, sufficient documentation to guarantee safety and a report on the homeopathic nature of the product based on sufficient literature must be appended to the application for a marketing authorisation.

If an application is made for a therapeutic indication for a homeopathic or anthroposophic preparation, the application documentation must be submitted in full (see Chapter 3.1).

**France**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

**Article L5121-20(16°), Article R5121-29(4°), and Article R5121-31** of the consolidated version of the Code de la Santé Publique (Public Health Code).

*Text Legal Provision:*

**Article L5121-20**

Les modalités d'application du présent chapitre sont déterminées par décret en Conseil d'Etat, et notamment:

(...)

16° Les règles particulières applicables aux essais pharmacologiques, toxicologiques et cliniques des médicaments homéopathiques faisant l'objet d'une autorisation de mise sur le marché, en prenant en compte la spécificité du médicament

homéopathique et un usage généralement lié à la tradition;

(...)

#### **Article R5121-29**

Par dérogation aux dispositions des articles R. 5121-21 et R. 5121-25 :

(...)

4° Pour un médicament homéopathique soumis à autorisation de mise sur le marché, compte tenu de la spécificité de ce médicament, le demandeur est dispensé de produire tout ou partie des résultats des essais pharmacologiques, toxicologiques et cliniques lorsqu'il peut démontrer par référence détaillée à la littérature publiée et reconnue dans la tradition de la médecine homéopathique pratiquée en France que l'usage homéopathique du médicament ou des souches homéopathiques le composant est bien établi et présente toutes garanties d'innocuité.

#### **Article R5121-31**

Pour l'application du 4° de l'article R. 5121-29, lorsqu'il est fait référence à la littérature publiée et reconnue dans la tradition de la médecine homéopathique pratiquée en France, des experts justifient, sur la base de la documentation fournie :

- 1° Le caractère homéopathique des souches utilisées et leur utilisation traditionnelle dans l'indication revendiquée ;
- 2° L'innocuité du médicament homéopathique, notamment au regard du degré de dilution de chacun de ses composants ;
- 3° La voie d'administration, pour les médicaments homéopathiques injectables.

*English Translation:*

#### **Article L5121-20**

The modalities for the application of the present chapter are determined by decree of the Conseil d'Etat [Council of State], and in particular:

(...)

Specific rules applicable to the pharmacological, toxicological and clinical essays of the homeopathic medicinal products which have to the object of a marketing authorization, taking into account the specificity of the homeopathic medicinal product and a use generally linked to tradition;

(...)

**Article R5121-29**

In derogation of the requirements laid down in articles R. 5121-21 and R. 5121-25:

(...)

4° For a homeopathic medicinal product subjected to a marketing authorization, taking into account the specificity of this medicinal product, the applicant is exempted from producing in whole or in part, the results of the pharmacological, toxicological and clinical tests when it can be shown by detailed reference to the literature published and recognized in the tradition of the homeopathic medicine practised in France that the homeopathic use of the medicinal product or the homeopathic stocks of which it is composed, is well established and gives full guarantee of harmlessness.

**Article R5121-31**

For the application of point 4° of article R. 5121-29, when reference is made to the literature published and recognized in the tradition of the homeopathic medicine practised in France, experts determine, on the basis of provided documentation:

- 1° The homeopathic character of the stocks used and their traditional use in the asserted indication;
- 2° The harmlessness of the homeopathic medicinal product, in particular with regard to the extent of dilution of each of its components;

3° The route of administration, for the injectable homeopathic medicinal products.

## **Germany**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

§ 22(3) of the Arzneimittelgesetz (Medicines Law), in conjunction with **Section 5** of the Arzneimittelprüfrichtlinien, 20-05-1995, and § 5 of the Bekanntmachung über die Zulassung, Nachzulassung und Registrierung von Arzneimitteln, 18-11-1998.

*Text Legal Provision:*

### **§ 22 Zulassungsunterlagen**

(...)

(2) Es sind ferner vorzulegen:

(...)

2. die Ergebnisse der pharmakologischen und toxikologischen Versuche,

3. die Ergebnisse der klinischen Prüfungen oder sonstigen ärztlichen, zahnärztlichen oder tierärztlichen Erprobung,

(...)

(3) An Stelle der Ergebnisse nach Absatz 2 Nr. 2 und 3 kann anderes wissenschaftliches Erkenntnismaterial vorgelegt werden, und zwar

1. bei einem Arzneimittel, dessen Wirkstoffe seit mindestens zehn Jahren in der Europäischen Union allgemein medizinisch oder tiermedizinisch verwendet wurden, deren Wirkungen und Nebenwirkungen bekannt und aus dem wissenschaftlichen Erkenntnismaterial ersichtlich sind,

2. bei einem Arzneimittel, das in seiner Zusammensetzung bereits einem Arzneimittel nach Nummer 1 vergleichbar ist,

3. bei einem Arzneimittel, das eine neue Kombination bekannter Bestandteile ist, für diese Bestandteile; es kann jedoch auch für die Kombination als solche anderes wissenschaftliches Erkenntnismaterial vorgelegt werden, wenn die Wirksamkeit und Unbedenklichkeit des Arzneimittels nach Zusammensetzung, Dosierung, Darreichungsform und Anwendungsgebieten auf Grund dieser Unterlagen bestimmbar sind.

Zu berücksichtigen sind ferner die medizinischen Erfahrungen der jeweiligen Therapierichtungen.

**Arzneimittelprüfrichtlinien nach § 26 AMG, Fünfter Abschnitt** (Bekanntmachung der Neufassung der Allgemeinen Verwaltungsvorschrift zur Anwendung der Arzneimittelprüfrichtlinien, BAnz. Nr. 96a vom 20. Mai 1995): Abweichende Anforderungen an die Unterlagen

(...)

3. Anforderungen an die Unterlagen für Arzneimittel der homöopathischen und anthroposophischen Therapierichtungen Bei Arzneimitteln der homöopathischen und anthroposophischen Therapierichtungen ist das wissenschaftliche Erkenntnismaterial entsprechend dem Selbstverständnis und der Eigenerfahrung der jeweiligen Therapierichtung zu bewerten. Dies ist in der Formulierung der Anwendungsgebiete erkennbar zu machen.

**Bekanntmachung über die Zulassung, Nachzulassung und Registrierung von Arzneimitteln**

(Empfehlungen der Kommission D des Arzneimittelgesetzes nach § 25 Abs. 6 und Abs. 7 zur Planung und Durchführung homöopathischer Arzneimittelprüfungen).

(...)

## 5. Unterschiedliche Voraussetzungen für Homöopathische Arzneimittelprüfungen

Das vorliegende wissenschaftliche Erkenntnismaterial und die Monographien der Kommission D müssen berücksichtigt sein.

a) Bei Homöopathischen Arzneimittelprüfungen mit Ausgangsstoffen, Urtinkturen und tiefen Potenzen muß eine dem jeweiligen Stand der wissenschaftlichen Erkenntnisse entsprechende pharmakologisch-toxikologische Prüfung sichergestellt sein. Bei bekannten Prüfsubstanzen kann auf anderes wissenschaftliches Erkenntnismaterial (§ 22 Abs. 3 AMG in Verbindung mit den Arzneimittelprüfrichtlinien nach § 26 AMG) Bezug genommen werden;

(...)

*English Translation:*

### **§ 22 (Required Documents for Authorisation)**

(...)

(2) furthermore are to be submitted:

(...)

2. the results of the pharmacological and toxicological tests,

3. the results of the clinical trials or other medical, dental or veterinary testing,

(...)

(3) With regard to the results in accordance with Section 2 NR. 2 and 3, other scientific proof can be submitted,

1. for a medicinal product, whose active substances were used for at least ten years in the European union generally medically or animal-medically, whose admits effects and side effects and are shown by scientific studies,

2. for a medicinal product, which is by its composition comparable to a medicinal product mentioned under number 1,

3. for a medicinal product, which is a new combination of well-known components, for these components; however such other scientific proof can be submitted also for the combination as, if the effectiveness and safety of the medicament are qualifiable on the basis of the submitted documents on composition, dosage, pharmaceutical form and areas of application.

In addition, medical experiences of the respective therapy directions are to be considered.

**Guidelines on Medicinal Products' testing on the basis of § 26 AMG, fifth section** (proclamation of the revised version of the general administrative regulation for the application of the Guidelines on Medicinal Products' testing, BAnz. No. 96a of 20 May 1995): Deviating requirements for the documents to be submitted

(...)

3. Requirements regarding the documents for medicinal products used by homoeopathic and anthroposophic therapies

For medicinal products used by homoeopathic and anthroposophic therapies the scientific literature is to be evaluated according to the self understanding and own experience of the respective therapy. This should be reflected in the formulation of the areas of application.

**Proclamation on the authorisation, 'Nachzulassung' and registration of medicinal products** (recommendations of the Commission D of the Medicines Law in conformity with § 25 Sections 6 and 7 for the planning and execution of homeopathic medicinal products testing).

(...)

## 5. Special conditions for Homeopathic medicinal products' testing

Available scientific literature and the Monographs of the Commission D must be considered.

a) For homeopathic medicinal products' testing of raw materials, mother tinctures and low potencies, it must be guaranteed that the pharmacological and toxicological testing is done accordance with the current state scientific knowledge.

For well-known test substances other scientific literature may be considered (§ 22, Section 3 Medicines Law in conjunction with the Guidelines on Medicinal Products' testing according to § 26 Medicines Law);

(...)

### **Ireland**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

**Regulation 11, S.I. No. 540 of 2007 Medicinal Products (Control of Placing on the Market) Regulations 2007**

*Text Legal Provision:*

**Regulation 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.

## Latvia

<i>Implementation Status:</i>	Article 16(2) implemented
<i>Reference to legislation:</i>	<b>§ 29.1 jo. § 4 of Noteikumi nr. 381 Zāļu reģistrēšanas noteikumi</b> (Regulation No. 381 on the Registration of Medicinal Products) <b>(Consolidated Version)</b>
<i>Text Legal Provision:</i>	<p>§ 4. Homeopātiskajām zālēm, kuras reģistrē pēc vienkāršotas reģistrācijas procedūras, nav nepieciešama terapeitiskās iedarbības pierādīšana. Vienkāršotai reģistrācijas procedūrai var pakļaut arī tās antropozofiskās zāles, kas iegūtas, pamatojoties uz homeopātisko zāļu izgatavošanas metodēm.</p> <p>§ 29. Reģistrācijas pieprasījumā (reģistrācijas dokumentācijā) iekļauj visu informāciju, kas attiecas uz konkrēto zāļu novērtēšanu, neatkarīgi no tā, vai tā ir 14 labvēlīga vai nelabvēlīga, īpaši uzsverot informāciju par nepabeigtiem un/vai pārtrauktiem farmakotoksikoloģiskiem un/vai klīniskiem testiem vai izpēti, kā arī norādot pabeigtu klīnisko izpēti par terapeitiskajām indikācijām, uz kurām neattiecas zāļu reģistrācijas pieprasījums.</p> <p>Homeopātiskajām zālēm:</p> <p>§ 29.1 kuras neattiecas uz šo noteikumu 4.punktā minētajām zālēm, toksikoloģiskās un farmakoloģiskās pārbaudes un klīniskās izpētes prasības īsteno, ņemot vērā Latvijā praktizētās homeopātijas principus un iezīmes;</p> <p>(...)</p>

### *English Translation:*

### **Regulation No. 381**

§ 4. Homeopathic medicinal products registered in accordance with a simplified registration procedure do not require proof of therapeutic effect. Such anthroposophical medicinal products as have been obtained on the basis of methods for the manufacture of homeopathic medicinal products

may also be subjected to the simplified registration procedure.

§ 29. Registration request (registration documentation) shall include all information regarding tests on the relevant medicinal product, without reference if it is advantaged or disadvantaged, especially accenting the information regarding incomplete and/or suspended pharmacological, toxicological tests and/or clinical trials, as well as indicating completed clinical trials regarding therapeutic indications that are not subject of the registration request of the medicinal product.

For homeopathic medicinal products:

§ 29.1 which are not related to medicinal products stated in Paragraph 4 of these Regulations, the requirements for toxicological and pharmacological tests and clinical trials shall be realized, taking in account principles and features of the Latvian homeopathic practice;

(...)

### **The Netherlands**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

**Artikelen 3.11 to 3.13 of Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 25 juni 2007, nr. GMT/MVG 2780607, houdende uitvoering van bepalingen van de Geneesmiddelenwet (Regeling Geneesmiddelenwet) (Regulation Medicinal Products) jo. Artikel 42(3) and (4) Wet van 8 februari 2007 tot vaststelling van een nieuwe Geneesmiddelenwet (Law on Medicinal Products 2007)**

*Text Legal Provision:*

#### **Artikel 3.11**

Een beschrijving van de preklinische en klinische proeven als bedoeld in artikel 3.7, eerste lid, onder j, tweede en derde gedachtestreepje, en onder l, hoeft

niet te worden overgelegd indien de aanvraag betrekking heeft op:

a. een homeopathisch geneesmiddel als bedoeld in artikel 42, vierde lid, van de wet, dat noch op de verpakking noch in de bijsluiter een therapeutische indicatie vermeldt;

b. een homeopathisch geneesmiddel dat op de verpakking of in de bijsluiter een therapeutische indicatie vermeldt, indien door de aanvrager van de handelsvergunning wordt voldaan aan de voorwaarden en de procedure van artikel 3.12, eerste, tweede en derde lid, en het College nog niet heeft beslist over de therapeutische werking van het desbetreffende geneesmiddel.

### **Artikel 3.12**

1. Degene die vóór de inwerkingtreding van de wet homeopathische geneesmiddelen als bedoeld in artikel 42, vierde lid, van de wet, in de handel bracht met vermelding van een therapeutische indicatie en die voornemens is deze indicatie te handhaven na de inwerkingtreding van de wet, meldt dit voornemen binnen zes maanden na de inwerkingtreding van de wet aan het College en geeft daarbij aan op welke wijze hij de therapeutische werking, bedoeld in artikel 45, eerste lid, onder b, van de wet, zal aantonen en welke preklinische en klinische gegevens hij als onderbouwing zal overleggen.

2. Indien bij de melding, bedoeld in het eerste lid, klinische gegevens worden aangekondigd die naar het oordeel van het College redelijkerwijs niet kunnen leiden tot het bewijs van de gestelde therapeutische werking, meldt het College zulks aan de betrokkene en beslist het College dat het geneesmiddel niet de gestelde werking heeft.

3. De preklinische en klinische gegevens worden door de betrokkene binnen achttien maanden na de inwerkingtreding van de wet overgelegd aan het College. Het College kan deze termijn één maal verlengen met ten hoogste een jaar indien dit naar

het oordeel van het College kan leiden tot het bewijs van de gestelde therapeutische werking.

4. Het College beslist na ontvangst van de desbetreffende preklinische en klinische gegevens of het desbetreffende homeopathische geneesmiddel de opgegeven therapeutische werking bezit.

5. Indien het College op de voet van het tweede of het vierde lid beslist dat het desbetreffende homeopathische geneesmiddel niet de gestelde werking heeft, is artikel 51, eerste lid, aanhef en onder b, van de wet van toepassing tenzij het homeopathisch geneesmiddel geen therapeutische indicatie meer vermeldt op de verpakking en in de bijsluiter.

### **Artikel 3.13**

Onverminderd de artikelen 3.7 en 3.11, aanhef en onder a, worden bij de aanvraag om een handelsvergunning voor een reeks van homeopathische geneesmiddelen als bedoeld in artikel 42, derde lid, van de wet, die van dezelfde homeopathische grondstoffen zijn afgeleid, de volgende gegevens en bescheiden overgelegd:

a. de wetenschappelijke benaming of een andere in een farmacopee voorkomende benaming van de homeopathische grondstoffen, onder vermelding van de verschillende toedieningswijzen, farmaceutische vormen en verdunningsgraden;

b. een dossier waarin wordt beschreven hoe de homeopathische grondstoffen worden verkregen en gecontroleerd en waarin het homeopathische karakter door bibliografie wordt aangetoond;

c. het fabricage- en controledossier voor elke farmaceutische vorm en een beschrijving van de verdunnings- en potentiëeringsmethoden;

d. een kopie van de voor hetzelfde geneesmiddel in andere lidstaten verkregen vergunning of andere vorm van toestemming om het geneesmiddel in de handel te brengen;

e. gegevens betreffende de houdbaarheid van het geneesmiddel.

**Article 42(3) and (4)**

3. De aanvrager is niet gehouden preklinische en klinische gegevens over te leggen indien de aanvraag betrekking heeft op homeopathische geneesmiddelen die voldoen aan de volgende voorwaarden:

a. het middel is voor oraal of uitwendig gebruik bestemd;

b. noch in of op de verpakking ervan noch in de bijsluiter wordt melding gemaakt van enige therapeutische indicatie;

c. de verdunningsgraad is zodanig dat het middel gegarandeerd onschadelijk is en in elk geval niet meer bevat dan één deel per 10 000 van de oertinctuur dan wel één honderdste van de kleinste in de allopathische geneeskunde gebruikte dosis werkzame stoffen die in een UR-geneesmiddel aanwezig is.

4. Onverminderd het tweede lid, kunnen bij ministeriële regeling ten aanzien van andere homeopathische geneesmiddelen dan die bedoeld in het derde lid, bijzondere voorschriften worden gegeven met betrekking tot het overleggen van preklinische en klinische gegevens en bescheiden.

*English Translation:*

**Article 3.11**

A description of the preclinical and clinical tests as described in Article 3.7, first paragraph, under j, second and third indent, and under l, does not have to be submitted provided that the application concerns:

a. a homeopathic medicinal product as described in Article 42, fourth paragraph of the Law [*on Medicinal Products*] which does neither bear a therapeutic indication on the package nor on the leaflet.

b. a homeopathic medicinal product with a an therapeutic indication on the package or leaflet, provided that the applicant for a marketing authorization complies with the requirements and procedure in Article 3.12, first, second and third paragraphs, and the [Medicines] Agency has not yet delivered a decision on the therapeutic effect of the medicinal product in question.

### **Article 3.12**

1. Who marketed a homeopathic medicinal product as described in Article 42, fourth paragraph of the Law with a therapeutic indication before the Law [on Medicinal Products] came into force, and who plans to maintain this indication under the new Law, will notify the [Medicines] Agency within six months after the Law gained legal force and will indicate how the therapeutic effectiveness, as described in Article 45, first paragraph, under b of the Law, will be proven and which preclinical and clinical data will be used as reference material.

2. If the notification mentioned in paragraph one refers to clinical data which according to the [Medicines] Agency cannot reasonably be expected to prove the therapeutic indication used, the Agency will inform the applicant thereof and it will render a decision that the medicinal product does not have the effect claimed.

3. The applicant will submit the preclinical and clinical data to the [Medicines] Agency within 18 months after the new Law [on Medicinal Products] came into force. The Agency can extend this term once with a maximum of one year if this according to the Agency could lead to proof of the claimed therapeutic effect.

4. The [Medicines] Agency will decide after receipt of the preclinical and clinical data whether the homeopathic medicinal product in question has the claimed therapeutic effect.

5. If the [Medicines] Agency renders the decision on the basis of the second or fourth paragraph that the homeopathic medicinal product in question does

not have the effect claimed, Article 51, first paragraph, opening words and under b, of the Law [*on Medicinal Products*] applies, unless the indication on the outer packaging or package leaflet of the homeopathic medicinal product does no longer appear.

### **Article 3.13**

Notwithstanding Articles 3.7 and 3.11, opening words and under a, the following information and documentation will be required in an application for a marketing authorisation of a series of homeopathic medicinal products as described in Article 42, third paragraph of the Law [*on Medicinal Products*], which are derived from the same homeopathic substance(s):

- a. Scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;
- b. dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic use, on the basis of an adequate bibliography;
- c. manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentization,
- d. copies of any registrations or authorizations obtained for the same medicinal product in other Member States,
- e. data concerning the stability of the medicinal product.

### **Article 42(3) and (4)**

3. The applicant is not required to submit preclinical and clinical data if the application concerns homeopathic medicinal products which comply with the following requirements:

a. the product is intended for oral or external administration.

b. no specific therapeutic indication appears on the inner or outer packaging nor on the package leaflet of the medicinal product

c. there is a sufficient degree of dilution to guarantee the safety of the medicinal product and it does not contain in any case more than one part per 10 000 of the mother tincture or one hundredth of the smallest dose of active substances used in allopathic medicine in prescription only medicinal products.

4. Notwithstanding the second paragraph, for homeopathic medicinal products others than those mentioned in the third paragraph, special requirements with respect to the submission of information and documentation on preclinical and clinical data can be established by ministerial decree.

## **Poland**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

**§ 41., § 51, § 52., and § 53. Rozporządzenie Ministra Zdrowia z dnia 11 sierpnia 2005 r. w sprawie określenia grup produktów leczniczych oraz wymagań dotyczących dokumentacji wyników badań tych produktów (Dz. U. Nr 160, poz. 1358) *jo.* Art. 21.1., Prawo farmaceutyczne, (Pharmaceutical Act of 6 September 2001, Consolidated Version), Dz. U. 2001 r. Nr 126 poz. 1381, Dz. U. 2004 r. Nr 53 poz. 533.**

*Text Legal Provision:*

**§ 41.**

Do grupy produktów leczniczych homeopatycznych innych niż te, o których mowa w art. 21 ust. 1 ustawy, należą w szczególności produkty lecznicze homeopatyczne, które w oznakowaniu i w ulotce zawierają wskazania do stosowania, w tym

produkty lecznicze homeopatyczne weterynaryjne, zwane dalej "produktami leczniczymi homeopatycznymi".

#### **§ 51.**

Dokumentację toksykologiczną i farmakologiczną wyników badań surowców homeopatycznych, roztworów macierzystych oraz produktów leczniczych wykonanych z surowców, które są znane i stosowane oraz są opisane w literaturze homeopatycznej, w szczególności: *Materia Medica-Boericke*, *Clarke*, *Kent*, *Leeser*, *Mezger*, *Staufer*, *Voisin*, *Charette*, i posiadają monografię w uznanych farmakopeach homeopatycznych, przygotowuje się na podstawie literatury fachowej.

#### **§ 52.**

1. Dokumentację badań klinicznych dotyczącą surowców homeopatycznych, roztworów macierzystych oraz produktów leczniczych wykonanych z surowców, które są znane i stosowane oraz są opisane w literaturze homeopatycznej, w szczególności wymienionej w § 51, i posiadają monografię w uznanych farmakopeach homeopatycznych, przygotowuje się na podstawie literatury fachowej.

2. Dokumentacja badań klinicznych może zawierać publikowane i niepublikowane doświadczenia kliniczne, takie jak próby patogenetyczne (*Homeopatyczne Badanie Leku*), zbiór pojedynczych przypadków pozwalający na ocenę naukową lub naukowo udokumentowany eksperyment medyczny. Badanie kliniczne i doświadczenia kliniczne ocenia się przy współdziałaniu lekarza z udokumentowanym doświadczeniem homeopatycznym.

#### **§ 53.**

Dokumentacja wyników badań produktu leczniczego homeopatycznego zawiera raporty ekspertów dotyczące wyników badań jakościowych, farmakologicznych i toksykologicznych oraz klinicznych.

#### **Art. 21.**

1. Produkty homeopatyczne, które:

- 1) są podawane doustnie lub zewnętrznie,
- 2) w oznakowaniu i ulotce nie zawierają wskazań do stosowania,
- 3) charakteryzują się odpowiednim stopniem rozcieńczenia, gwarantującym bezpieczeństwo stosowania; to jest nie zawierają więcej niż 1/10 000 części roztworu macierzystego lub nie więcej niż 1/100 najmniejszej dawki substancji czynnej zawartej w produkcie leczniczym wydawanym na podstawie recepty

- podlegają uproszczonej procedurze dopuszczenia do obrotu.

(...)

*English Translation:*

**§ 41.**

The group of homeopathic medicinal products other than those mentioned in Article 21, clause 1 of the Act [*read Pharmaceutical Act*] comprises especially homeopathic products whose labelling and leaflets contain indications for use, including veterinary homeopathic medicinal products, hereinafter referred to as “homeopathic medicinal products”.

**§ 51.**

Toxicological and pharmacological documentation of results of tests of homeopathic raw materials, stock solutions and medicinal products made of raw materials that are known, used and described in homeopathic literature, especially in: *Materia Medica-Boericke*, *Clarke*, *Kent*, *Leeser*, *Mezger*, *Staufer*, *Voisin*, *Charette* and have a monograph in recognised homeopathic pharmacopoeias, is prepared on the basis of professional literature.

**§ 52.**

1. Documentation of clinical studies concerning homeopathic raw materials, stock solutions and medicinal products made of raw materials that are known, used and described in homeopathic literature, especially literature mentioned in § 51 and have a monograph in recognised homeopathic pharmacopoeias is prepared on the basis of professional literature.

2. Documentation of clinical studies may contain both published and unpublished clinical experiments such as pathogenic tests (Homeopathic Drug Testing), a collection of single cases enabling a scientific evaluation or scientifically documented medical experiment. A doctor with documented homeopathic experience takes part in a clinical study and clinical experiments.

**§ 53.**

Documentation of results of tests of homeopathic medicinal product contains reports of experts concerning results of quality, pharmacological, toxicological and clinical investigations.

**Article 21**

1. Homeopathic products:

- 1) that are administered orally or externally,
- 2) whose labelling or leaflet does not contain therapeutic indications,
- 3) that are characterised by a sufficient degree of dilution to guarantee safety of use, which means that they do not contain more than 1/10,000 part of the mother solution or more than 1/100 of the smallest dose of the active substance contained in a medicinal product dispensed on the basis of a prescription

- shall be placed under a simplified marketing procedure.

**Portugal**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

**Artigo 3.º, Decreto-Lei n.º 94/95**, Regime jurídico da introdução no mercado, do fabrico, da comercialização, da rotulagem e da publicidade dos produtos homeopáticos para uso humano (Decree on the Authorisation and Registration of Homeopathic Medicinal Products), in combination with **Instruções aos Requerentes**, Apresentação do Pedido de Autorização de Introdução no Mercado de Medicamentos Homeopáticos (Notice to

applicants for the authorisation of homeopathic medicinal products).

*Text Legal Provision:*

**Artigo 3.º** Medicamentos homeopáticos

1 - Entende-se por medicamento homeopático qualquer produto homeopático que possua propriedades curativas ou preventivas das doenças do homem e dos seus sintomas, com vista a estabelecer um diagnóstico médico ou a restaurar, corrigir ou modificar as suas funções orgânicas.

2 - Ao processo de introdução no mercado, ao fabrico, comercialização e direcção técnica, à rotulagem, folheto informativo e à publicidade dos medicamentos homeopáticos é aplicável, com as necessárias adaptações, o regime jurídico previsto para os medicamentos de uso humano, constante do Decreto-Lei n.º 72/91, de 8 de Fevereiro, e dos Decretos-Leis n.os 100/94 e 101/94, ambos de 19 de Abril.

**Instruções aos Requerentes**

**Apresentação do Pedido de Autorização de Introdução no Mercado de Medicamentos Homeopáticos**

(...)

Para os medicamentos homeopáticos, o referido Decreto-Lei, preconiza um regime semelhante ao existente para os medicamentos, ou seja, ao processo de introdução no mercado, fabrico, comercialização, direcção técnica, rotulagem, folheto informativo e publicidade dos medicamentos homeopáticos é aplicável, com as necessárias adaptações, o regime jurídico previsto para os medicamentos de uso humano, constante do Decreto-Lei n.º 72/91, de 8 de Fevereiro, e os Decretos-Leis n.os 100/94 e 101/94, ambos de 19 de Abril.

Este documento tem como objectivo, estabelecer o plano de apresentação da documentação química, farmacêutica e biológica, da documentação toxicológica e farmacológica e da documentação

clínica, tendo em conta as particularidades dos medicamentos homeopáticos.

(...)

#### **PARTE I-C: RELATÓRIOS DE PERITO**

- 1) Sobre documentação química e farmacêutica.
- 2) Sobre documentação toxicológica e farmacológica.
- 3) Sobre documentação clínica.

Os relatórios de peritos apresentados devem justificar:

- O carácter homeopático dos stocks utilizados, e sua utilização tradicional para a indicação reivindicada;
- A inocuidade do medicamento homeopático, tendo em atenção o grau de diluição de cada um dos seus compostos. O relatório toxicológico deve ser assinado por um perito em toxicologia;
- A escolha da via de administração, para os medicamentos homeopáticos injectáveis.

(...)

#### **PARTE III: DOCUMENTAÇÃO TOXICOLÓGICA E FARMACOLÓGICA**

A avaliação toxicológica versa sobre três pontos:

- A(s) preparação(ões) homeopática(s) utilizada(s) como substância(s) activa(s);
- Os excipientes: solventes, aromas, agentes conservantes, etc.;
- O produto acabado.

##### **1. As preparações homeopáticas**

*A) Preparações homeopáticas provenientes de substâncias cuja toxicidade é conhecida e para as quais as doses sem efeitos tóxicos podem ser determinadas.*

Se os dados provêm da literatura publicada, esses dados devem ser fornecidos, com fotocópia

dos artigos citados. Os dados numéricos devem ser expressos em unidades internacionais.

*B) Preparações homeopáticas provenientes de substâncias para as quais não se dispõem de estudos específicos*

Para todas as diluições inferiores a 5CH de substâncias que não possuem uma estrutura química conhecida, ou que façam parte de uma família química de risco, uma avaliação genotóxica é necessária: um ensaio de mutagenese e um ensaio de clastogenese.

Para todas as concentrações inferiores a 2CH, é necessário ter em conta a nota explicativa ICH Q3B: Impurity in new drug products (CPMP/ICH/282/95).

(...)

#### **PARTE IV: DOCUMENTAÇÃO CLÍNICA**

Referências bibliográficas fornecidas com vista a demonstrar a utilização homeopática bem estabelecida do medicamento, ou dos stocks utilizados para a sua preparação, e demonstrar as indicações reivindicadas, devendo ser seleccionadas e classificadas de forma lógica.

Estas referências devem limitar-se às referências reconhecidas na tradição da medicina homeopática (não podem ser referências de fitoterapia, oligoterapia, etc.) devendo estar em português, inglês ou francês.

*English Translation:*

#### **Article 3 'Medicamentos homeopáticos'**

1 - Any homeopathic medicinal product which possesses curative or preventive properties for illnesses and their symptoms in humans, by means of establishing a medical diagnosis or by restoring, correcting or modifying their organic functions, is qualified as 'medicamento homeopático'.

2 - In the process of introduction in the market, the production, marketing and technical qualification, the labelling, informative brochure and the

advertising of 'medicamentos homeopáticos', the legal regime on medicines for human use as laid down in Decree n.º 72/91, 8 of February, and the Decrees n.º 100/94 and n.º 101/94, both of 19 of April, is applicable with the necessary adaptations.

**Notice to Applicants**  
**Procedure for the application for an**  
**Authorization to market 'Medicamentos**  
**Homeopáticos'**

(...)

For medicamentos homeopáticos, referred to in the Decree, a regime applies which is similar to the existing one for medicines, or either, the legal regime on medicines for human use as laid down in Decree n.º 72/91, 8 of February, and the Decrees n.º 100/94 and n.º 101/94, both of 19 of April, on marketing, production, commercialization, technical qualification, labelling, package leaflet and advertising is applicable to medicamentos homeopáticos, with the necessary adaptations.

This document has as its objective, to establish guidelines on presentation of the chemical, pharmaceutical, biological, toxicological, pharmacological, and the clinical documentation, taking into account the particularities of medicamentos homeopáticos.

(...)

**PART I-C: EXPERT REPORTS**

- 1) Chemical and pharmaceutical documentation.
- 2) Toxicological and pharmacological documentation.
- 3) Clinical documentation.

The presented expert reports must justify:

- The homeopathic character of stock(s) used, and its traditional use for the demanded indication;

- The safety of the homeopathic medicinal product, taking into account the degree of dilution of each one of its active principles. The toxicológico report must be signed by an expert in toxicology;
- The choice of the route of administration, for injectable homeopathic medicinal products.

(...)

### **PART III: TOXICOLOGICAL and PHARMACOLOGICAL DOCUMENTATION**

The toxicological evaluation is directed at three issues:

- The homeopathic preparations used as active principles;
- The excipientes: solvent, aromas, conservative agents, etc.;
- The finished product.

#### **1. The homeopathic preparations**

*A) Homeopathic preparations derived from substances whose toxicity is known and for which the doses without toxic effects can be determined.*

If the data comes from published literature, this data must be supplied accompanied by a photocopy of the cited articles. The numerical data must be submitted in conformity with international standards.

*B) Homeopathic preparations derived from substances for which no use is made of specific studies.*

For all dilutions lower than 5CH of substances that do not possess a known chemical structure, or that they are part of a chemical family that presents risks, a genotoxic evaluation is necessary: an essay on mutagenic effects and an essay clastogenic effects.

For all concentrations lower than 2CH, it is necessary to take into account Explanatory Note ICH Q3B: Impurity in new drug products (CPMP/ICH/282/95).

#### **PART IV: CLINICAL DOCUMENTATION**

Bibliographical references should be supplied in order to demonstrate the well established homeopathic use of the medicinal product, or the stock(s) used for its preparation, and to demonstrate the claimed indication, whose selection and classification must be presented in a logical form.

These references must be limited to those recognized in the tradition of homeopathic medicine (these do not include references of a phytotherapeutic, oligotherapeutic, or any other nature), having to be in Portuguese, English or French.

### **Spain**

<i>Implementation Status:</i>	Article 16(2) implemented
<i>Reference to legislation:</i>	Artículo 55, Real Decreto 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente [19249].
<i>Text Legal Provision:</i>	Artículo 55, Clases de medicamentos homeopáticos.  Los medicamentos homeopáticos podrán ser: a) Con indicación terapéutica aprobada, cuyo procedimiento de autorización y registro, seguirá el establecido en el capítulo II, teniendo en cuenta su naturaleza homeopática. b) Sin indicaciones terapéuticas aprobadas, cuyo procedimiento de autorización y registro, será el simplificado especial de medicamentos homeopáticos, creado a tal efecto por la Agencia Española de Medicamentos y Productos Sanitarios, siempre y cuando cumplan con los requisitos establecidos para ese procedimiento. En caso contrario, deberán seguir el procedimiento

establecido en el capítulo II, teniendo en cuenta su naturaleza homeopática.

*English Translation: Article 55, Categories of homeopathic medicinal products.*

Homeopathic medicinal products can be:

a) With approved therapeutic indication, the authorisation and registration procedure for which is laid down in Chapter II, taking account of its homeopathic nature.

b) Without approved therapeutic indications, the authorisation and registration procedure for which is the special simplified registration procedure, created by the Spanish Agency of Medicines and Sanitary Products, on the condition that they fulfill the requirements established for that procedure. If this is not the case, they will have to follow the procedure laid down in Chapter II, taking account of their homeopathic nature.

## **United Kingdom**

*Implementation Status:*

Article 16(2) implemented

*Reference to legislation:*

*Statutory Instrument 2006 No. 1952*

*MEDICINES*

*The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006*

*Text Legal Provision:*

**APPLICATION FOR GRANT OF  
MARKETING AUTHORIZATION FOR  
NATIONAL HOMOEOPATHIC PRODUCT**

### **PART 1**

#### **GENERAL**

**1.—(1) An application for the grant of a United Kingdom marketing authorization for a national homoeopathic product is not required to be made in accordance with, and the applicant for such an authorization is not required to comply with—**

**(a) the second and third indents of Article 8.3(i) of the 2001 Directive (the requirement to submit**

the results of pre-clinical tests and clinical trials); and

(b) the provisions of Part I of Annex I to that Directive set out in paragraph 2(1).

(2) But the applicant must submit with his application particulars and documents relating to—

(a) the safety of the medicinal product to which the application relates, in accordance with Part 2 of this Schedule; and

(b) the efficacy of that product, in accordance with Part 3 of this Schedule.

(3) The last sub-paragraph of Article 8.3 of the 2001 Directive applies to an application referred to in sub-paragraph (1) as if the reference to the results of pre-clinical tests and clinical trials referred to in point (i) of Article 8.3 were a reference to the safety and efficacy data provided pursuant to Parts 2 and 3.

2.—

(1) The provisions of Part I of Annex I to the 2001 Directive referred to in paragraph 1(1) are—

(a) sections 2.4 to 2.7 (non-clinical and clinical overview and non-clinical and clinical summaries);

(b) section 4 (Module 4: non-clinical reports); and

(c) section 5 (Module 5: clinical study reports).

(2) The applicant must submit—

(a) the particulars and documents required by Part 2 of this Schedule in place of Module 4 of the particulars and documents accompanying his application, and

(b) the particulars and documents required by Part 3 of this Schedule in place of Module 5 of the particulars and documents accompanying his application.

(3) References in Annex I to the 2001 Directive, in provisions other than those referred to in sub-paragraph (1), to—

(a) non-clinical reports, non-clinical documentation and non-clinical data, and  
(b) clinical study reports, clinical documentation and clinical data, shall apply in relation to such an application as if they were references to the particulars and documents referred to in sub-paragraphs (2)(a) and (b), respectively.

(4) An application for the grant of a United Kingdom marketing authorization for a national homoeopathic product is not required to be made in accordance with, and the applicant for such an authorization is not required to comply with, the guidance referred to in paragraph (1) of Annex I (in the section headed “Introduction and general principles”), insofar as that guidance relates to the requirement to submit the results of pre-clinical tests and clinical trials.

## **PART 2 SAFETY DATA**

3.—(1) Subject to paragraph 4, the applicant must submit data as to the safety of the medicinal product.

(2) The data submitted by the applicant—  
(a) must include data which provides information about the following aspects of the safety of the product—  
(i) pharmacology,  
(ii) pharmacokinetics, and  
(iii) toxicology, including—  
(aa) toxicity,  
(bb) genotoxicity,  
(cc) reproductive and developmental toxicity,  
and  
(dd) local tolerance, of the medicinal product;  
and  
(b) subject to sub-paragraph (4), must be scientific data.

(3) For the purposes of sub-paragraph (2)(b), “scientific data” means—  
(a) study reports in relation to the product which is the subject of the application,

**(b) published scientific literature, or a combination of both.**

**(4) In relation to any aspect of safety of the product, the applicant may submit data other than scientific data if the conditions in sub-paragraph (5) are satisfied.**

**(5) The conditions are that—**

**(a) the applicant has made reasonable attempts to obtain scientific data in relation to that aspect; and**

**(b) having made those attempts—**

**(i) he is satisfied that no scientific data is available as to that aspect of safety, or**

**(ii) he considers that such scientific data as is available may be inadequate to demonstrate an acceptable level of safety in relation to that aspect.**

**(6) The applicant must include with his data—**

**(a) a table of contents;**

**(b) an evaluation of the scientific data, including an explanation as to how the data demonstrates an acceptable level of safety; and**

**(c) where the applicant is submitting data other than scientific data—**

**(i) a statement that he has met the conditions of sub-paragraph (5); and**

**(ii) an explanation as to why an acceptable level of safety can be demonstrated, notwithstanding the lack of scientific data.**

**4.—(1) The applicant is not required to submit data as to the safety of the product if—**

**(a) sub-paragraph (2), (3) or (4) applies; and**

**(b) the application is accompanied by a written statement that the product satisfies the conditions set out in that sub-paragraph.**

**(2) This sub-paragraph applies if the product—**

**(a) is derived from a homoeopathic stock which is commonly present in food; and**

**(b) is intended to be administered orally, and for these purposes “food” has the meaning given to it by Regulation EC No. 178/2002**

of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the Food Safety Authority and laying down procedures in matters of food safety(a).

**(3) This sub-paragraph applies if—**

**(a) the national homoeopathic product is derived from a homoeopathic stock from which a medicinal product which has a marketing authorization, certificate of registration, traditional herbal registration or product licence is derived;**

**(b) that medicinal product is within a description, or falls within a class, specified in an order under section 51 of the Act; and**

**(c) the national homoeopathic product has the same route of administration and the same degree of dilution as that medicinal product.**

**(4) This sub-paragraph applies if the product is derived from a homoeopathic stock which—**

**(a) is diluted to at least 1 in 1024 of the stock, and**

**(b) is not a material of biological origin.**

### **PART 3**

#### **EFFICACY DATA**

**5. The applicant must submit data as to the efficacy of the medicinal product.**

**6. The data must consist of at least one of the following types of data—**

**(a) study reports in relation to the product which is the subject of the application,**

**(b) published scientific literature, or**

**(c) the results of investigations, commonly known as homoeopathic provings, which consist of the administration of a substance to a human subject in order to ascertain the symptoms produced by that substance.**

**7. The applicant must include with his data—**

- (a) a table of contents, and**
- (b) 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 authorization is sought.”.**

## 2) Article 16(1) implemented; option to implement Article 16(2) provided for by National Royal/Ministerial Decree/Regulation

### Cyprus

*Implementation Status:* Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

*Reference to legislation:* Άρθρο 17(2) & (3), Νόμος 70(I)/2001 (As amended by N. 75(I)/2006)

*Text Legal Provision:* (2) ομοιοπαθητικά φαρμακευτικά προϊόντα που δεν πληρούν τις προϋποθέσεις που αναφέρονται στο εδάφιο (1), δύνανται να εξασφαλίζουν άδεια κυκλοφορίας σύμφωνα με τις διατάξεις των άρθρων 10, 10Α, 10Β, 10Γ και 11.

(3) Ο Υπουργός, μετά από σύσταση του Συμβούλιο Φαρμάκων, δύναται, με Διάταγμά του που δημοσιεύεται στην Επίσημη Εφημερίδα της Δημοκρατίας, να καθορίσει ειδικές διατάξεις για τις προκλινικές και κλινικές δοκιμές για τα ομοιοπαθητικά φαρμακευτικά προϊόντα που αναφέρονται στο εδάφιο (1), τις οποίες κοινοποιεί στην Επιτροπή.

*English Translation:* (2) homeopathic pharmaceutical products that do not fulfil the conditions that are mentioned in the section (1), can apply for a marketing authorisation in accordance with the provisions of articles 10, 10A, 10B, 10C and 11.

(3) The Minister may by Decree that is published in the Official State Gazette, after the consulting the Council of Medicines, determine special provisions on the preclinical tests and clinical trials for homeopathic pharmaceutical products that are reported in the section (1), which he communicates to the Committee.

## **Denmark**

*Implementation Status:* Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

*Reference to legislation:* § 34. Lov om lægemidler (Medicines Law), nr 1180 of 12/12/2005, in conjunction with § 3. Bekendtgørelse om homøopatiske lægemidler m.v. (Decree on Medicinal Products) nr 1232 of 12/12/2005.

*Text Legal Provision:* § 34. Indenrigs- og sundhedsministeren fastsætter regler om:

(...)

2) Særlige betingelser for udstedelse af markedsføringstilladelse til

- a) naturlægemidler,
- b) vitamin- og mineralpræparater og
- c) homøopatiske lægemidler.

3) Særlige betingelser for registrering af homøopatiske lægemidler og traditionelle plantelægemidler.

(...)

§ 3. Denne bekendtgørelse gælder ikke homøopatiske lægemidler, som er godkendt ved en markedsføringstilladelse, jf. § 8 i lov om lægemidler. For disse lægemidler gælder de almindelige regler for lægemidler og indehavere af markedsføringstilladelse.

*English Translation:* § 34. The minister for interior and health will adopt rules on:

(...)

- 2) Specific requirements for the authorisation of
  - a) natural medicinal products
  - b) vitamine- and mineralsupplements
  - c) homeopathic medicinal products

3) Specific requirements for the registration of homeopathic medicinal products and traditional herbal medicinal products.

(...)

This decree does not apply to homeopathic medicinal products that need a marketing authorisation in accordance with § 8 of the law on medicinal products. For these medicinal products the same rules are applicable as those for [regular] medicinal products and the application for a marketing authorisation.

## **Estonia**

### *Implementation Status:*

Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

### *Reference to legislation:*

**§ 15. Ravimiseadus** (Medicinal Products Act), 16 December 2004 in conjunction with **§ 3. määrus nr 52**, Sotsiaalministri of 29 March 2005, Homöopaatiliste preparaatide müügiloa taotlemise tingimused ja kord (Conditions and Procedure for Application for Marketing Authorisation for Homeopathic Medicinal Products)

### *Text Legal Provision:*

**§15.** Vabariigi Valitsuse, sotsiaalministri ja põllumajandusministri ülesanded

(...)

(5) Sotsiaalminister kehtestab lisaks käesolevas seaduses nimetatud õigusaktidele määrusega:

(...)

3) homöopaatiliste preparaatide müügiloa taotlemise tingimused ja korra;

(...)

**§ 3.** Homöopaatiliste preparaatide müügiloa taotlemine

(...)

(6) Kui homöopaatilisele preparaadile taotletakse näidustust, tegemist on muude manustamisviisidega kui suukaudne ja välispidine ning põllumajandusloomadele mõeldud homöopaatilise veterinaarpreparaadi puhul laienevad homöopaatilisele preparaadile müügiloa taotlemisel ravimitele sätestatud nõuded efektiivsuse ja ohutuse osas.

*English Translation:*

**§ 15.** Duties of Government of Republic, Minister of Social Affairs and Minister of Agriculture

(...)

(5) In addition to legislation specified in this Act, the Minister of Social Affairs shall establish the following by a regulation:

(...)

3) the conditions and procedure for application for marketing authorisation in respect of homeopathic preparations;

(...)

**§ 3.** Application for marketing authorisation for homeopathic medicinal products

(...)

(6) The requirements regarding the therapeutic effect and safety of medicinal products extend to homeopathic medicinal products upon application for marketing authorisation if a therapeutic indication is also applied for, the homeopathic medicinal product is to be administered in any other manner than orally or externally, or the homeopathic medicinal product is intended to be used on farm animals.

## Greece

*Implementation Status:* Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

*Reference to legislation:* **Article 20**, Decision Nr. ΔΥΓ3(α)/83657, Εναρμόνιση της ελληνικής νομοθεσίας προς την αντίστοιχη κοινοτική στον τομέα της παραγωγής και της κυκλοφορίας φαρμάκων που προορίζονται για ανθρώπινη χρήση, (on the harmonisation of Greek legislation in the field of production and the circulation of medicines that is intended for human use).

*Text Legal Provision:* 1. Η έγκριση και η επισήμανση των ομοιοπαθητικών φαρμάκων εκτός εκείνων που αναφέρονται στο άρθρο 18 παράγραφος 1 της παρούσας Υπουργικής απόφασης, πραγματοποιείται σύμφωνα με τα άρθρα 9 και 11, 12, 13, 14 και 15.

2. Ο Ε.Ο.Φ. δύναται να εισάγει ή να διατηρεί σε ισχύ ειδικούς κανόνες για τις προκλινικές δοκιμές και κλινικές μελέτες των ομοιοπαθητικών φαρμάκων, εκτός από εκείνα που αναφέρονται στο άρθρο 18 παράγραφος 1, σύμφωνα με τις αρχές και τις ιδιαιτερότητες της ομοιοπαθητικής που ασκείται στη χώρα. Στην περίπτωση αυτή, ο Ε.Ο.Φ. κοινοποιεί στην Ευρωπαϊκή Επιτροπή τους σχετικούς ειδικούς κανόνες που εφαρμόζει.

(...)

*English Translation:*

### **Article 20**

1. The approval and the labelling of homeopathic medicines, except those that are reported in Article 18 paragraph 1 [*Special Simplified Registration Procedure (SSRP)*] of the present Ministerial decision, are realised according to articles 9 and 11, 12, 13, 14 and 15 [*Regular Authorisation Procedure*].

2. The National Organisation of Medicines may put in force or maintain special rules for preclinical tests and clinical studies of homeopathic medicines,

apart from those that are mentioned in article 18 paragraph 1 [SSRP], according to the principles and the particularities of homeopathy that are practised in the country. In this case, the National Organisation of Medicines communicates the special rules that apply to the European Commission.

## **Hungary**

### *Implementation Status:*

Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

### *Reference to legislation:*

**§ 5 jo. § 32(5) jo. § 33(b) and (c) of 2005. évi XCV. törvény az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról (Medicines Act 2005) jo. 1. számú melléklet of 52/2005. (XI. 18.) EüM rendelethez (Annex 1 of Decree 52/2005 On the registration and authorization to place medicinal products for human use on the market).**

### *Text Legal Provision:*

#### **5. §**

(...)

(2) Az OGYI a gyógyszer forgalomba hozatali engedélyét akkor adja ki, ha annak

a) minősége, mennyiségi összetétele - ideértve a gyártás körülményeit is - ismert és meghatározott, továbbá

b) terápiás hatásossága - az egyszerűsített eljárással törzskönyvezhető homeopátiás gyógyszerek kivételével - klinikailag is bizonyított, valamint

c) előny/kockázat aránya kedvező.

(...)

#### **32. §**

(...)

(5) Felhatalmazást kap az egészségügyi miniszter, hogy

a) a gyógyszerek forgalomba-hozatali engedély kiadásával kapcsolatos eljárás részletes szabályait, az engedélyezés feltételeit, továbbá a forgalomból való kivonás rendjét,

(...)

### 33. §

Ez a törvény a törvény végrehajtására a 32. § (5) bekezdésében adott felhatalmazás alapján megalkotott miniszteri rendeletekkel együtt a következő uniós jogi aktusoknak való megfelelést szolgálja:

b) az Európai Parlament és a Tanács 2001/83/EK irányelve (2001. november 6.) az emberi felhasználásra szánt gyógyszerek közösségi kódexéről;

c) az Európai Parlament és a Tanács 2004/27/EK irányelve (2004. március 31.) az emberi felhasználásra szánt gyógyszerek közösségi kódexéről szóló 2001/83/EK irányelv módosításáról;

#### **1. számú melléklet az 52/2005. (XI. 18.) EüM rendelethez**

*A forgalomba hozatali engedély iránti kérelem formai és tartalmi követelményei: analitikai, farmako-toxicológiai és klinikai követelmények és eljárások a gyógyszerek vizsgálatára*

#### **BEVEZETÉS ÉS ÁLTALÁNOS ALAPELVEK**

(11) A előny/kockázat arány kiértékelésének ellenőrzésére minden új információt, melyet az eredeti kérelem nem tartalmazott, valamint minden gyógyszer-mellékhatásra vonatkozó információt az OGYI-hoz be kell nyújtani. Miután a készítmény engedélyezésre került, a dosszié adataiban bekövetkező minden erre vonatkozó változást be kell az OGYI-hoz jelenteni.

Ez a melléklet négy különböző részre tagolódik:

(...)

- A 3. rész a biológiai gyógyszerekre (plazma-alapadatok: Plazma Master File, vakcina-antigén-alapadatok: Vakcina Antigen Master File), radioaktív gyógyszerekre, **homeopátiás gyógyszerekre**, növényi eredetű gyógyszerekre és a ritka betegségek gyógyszereire **vonatkozó kérelemmel kapcsolatos különleges követelményekkel foglalkozik.**

(...)

### **3. HOMEOPÁTIÁS GYÓGYSZEREK**

Ez a pont felsorolja azokat a különleges rendelkezéseket a 3. és 4. fejezet alkalmazásával kapcsolatban, melyeket a homeopátiás gyógyszereknél kell alkalmazni.

#### **3. fejezet**

A 3. fejezet rendelkezései alkalmazandók a 9. § (1) bekezdés szerint benyújtott dokumentumokra, a homeopátiás gyógyszerek egyszerűsített eljárására, valamint a 9. § (2) bekezdés által szabályozott egyéb homeopátiás gyógyszerek engedélyezésével kapcsolatos dokumentumokra, a következő módosításokkal.

##### **a) Terminológia**

A forgalomba hozatali engedély iránti kérelem dossziéjában leírt hasonszenvi törzsoldat latin nevének összhangban kell lennie az Európai Gyógyszerkönyv latin címeivel, vagy ennek hiányában egy tagállam hivatalos gyógyszerkönyvével. Ahol fontos, az egyes tagállamokban használt hagyományos neve(ke)t is fel kell tüntetni.

##### **b) A kiindulási anyagok ellenőrzése**

A kiindulási anyagokra - azaz minden felhasznált anyagra a nyersanyagoktól kezdve, a köztitermékeken át a végső hígításig, mely belekerül a késztermékbe - vonatkozó adatokat és dokumentumokat, melyeket a kérelemhez csatoltak,

ki kell egészíteni a hasonszenvi törzsoldatra vonatkozó adatokkal.

Az általános minőségi követelményeket kell alkalmazni minden kiindulási és nyersanyagra csakúgy, mint a gyártási folyamat köztes lépéseire, egészen a végső hígításig, mely belekerül a késztermékbe. Ha lehetséges, tartalmi meghatározást kell végezni, ha toxikus összetevő van jelen a készítményben és a nagyfokú hígítás miatt a végső hígítás minőségének ellenőrzése nem lehetséges. A gyártási folyamat minden lépését a kiindulási anyagoktól a késztermékbe kerülő végső hígításig részletesen le kell írni.

Abban az esetben, ha hígításokat is alkalmaztak, a hígítási lépéseket az Európai Gyógyszerkönyvben, vagy ennek hiányában egy tagállam hivatalos nemzeti gyógyszerkönyvében található, megfelelő cikkelyei szerint kell elvégezni.

c) A készterméken végzett ellenőrző vizsgálatok  
Az általános minőségi követelmények vonatkoznak a homeopátiás késztermékekre is, bármilyen kivételt a kérelmezőnek megfelelően igazolnia kell.

Minden toxikológiai fontos alkotórész azonosítását és vizsgálatát el kell végezni. Ha igazolható, hogy minden toxikológiai fontos alkotórész azonosítása és vizsgálata nem végezhető el pl. a késztermékben előforduló nagy hígítás miatt, akkor a minőséget a gyártási és hígítási eljárás teljes validálásával kell igazolni.

d) Stabilitási vizsgálatok

Igazolni kell a késztermék stabilitását. A hasonszenvi törzsoldatok stabilitási adatai általában átvihetőek a belőlük készült dilúciókra/triturációkra. Ha a hatóanyagra vonatkozóan sem azonosítás, sem vizsgálat nem végezhető el a hígítási fok miatt, akkor a gyógyszerforma stabilitási adatait kell figyelembe venni.

#### **4. fejezet**

A 4. fejezet előírásait kell alkalmazni a homeopátiás gyógyszerek egyszerűsített eljárása során a 9. § (1) bekezdés értelmében, a következő feltételekkel:  
Minden hiányzó információt indokolni kell, például indokolni kell, hogy néhány vizsgálat hiánya

ellenére miért állapítható meg mégis a megfelelő biztonsági szint.

*English Translation:*

**§ 5**

(...)

(2) NIP shall issue the marketing authorization for the medicine if

- a) its quality, quantitative composition – including the circumstances of manufacture – is known and defined, and
- b) its therapeutic effect – with the exception of homeopathic medicines subject to simplified registration – has been clinically proven, and
- c) its risk-benefit ratio is positive.

(...)

**§ 32**

(...)

(5) Health minister shall be authorized to regulate

- a) the detailed rules of the procedure to issue a marketing authorization, the conditions thereof and the order of market recall,

(...)

**§ 33**

This law together with the implementing ministerial decrees created on the basis of the authority granted in Section (5) of Article 32 of this law intends to ensure compliance with the following European Union acts:

(...)

- b) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001

on the Community code relating to medicinal products for human use;

c) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use;

(...)

#### **Annex 1 of Decree 52/2005**

Annex No 1 to Decree No 52/2005 (18 December) of the Minister of Health

Formal and content related requirements of application for market authorisation: analytical, pharmaco-toxicological and clinical requirements and procedures for examination of drugs

(...)

(11) For checking the evaluation of benefit/risk ratio, all new information, not included in the original application, and all information pertaining to side effects of the drug shall be submitted to OGYI. After the pharmaceutical product was granted marketing authorisation, all changes pertaining to the data submitted in the dossier shall be reported to OGYI.

This Annex consists of four parts:

(...)

- Part 3 deals with special requirements pertaining to applications related to biological drugs (plasma base data: Plasma Master File, vaccine antigen base data: Vaccine Antigen Master File), radioactive drugs, homeopathic drugs, drugs of herbal origin and drugs for rare diseases.

(...)

### **3. HOMEOPATHIC DRUGS**

This point lists the special provisions with respect to the application of Chapters 3 and 4 that have to be applied for homeopathic drugs.

#### **Chapter 3**

Provisions of Chapter 3 shall be applied with the following modifications for documents submitted according to subsection (1) of Section 9, the simplified procedure for homeopathic drugs and documents related to marketing authorisation of other homeopathic drugs regulated by subsection (2) of Section 9.

##### **a) Terminology**

The Latin name of homeopathic strain described in the dossier of application for marketing authorisation shall be in harmony with the Latin titles of the European Pharmacopoeia or, in lack of such, with the official Pharmacopoeia of a Member State. Where it is important, traditional name (names) used in individual member states shall also be indicated.

##### **b) Control of precursor substances**

Data and documents pertaining to precursor substances, that is all substances used from raw materials through intermediate substances to the final dilution that is included in the finished product, enclosed with the application shall be supplemented with data pertaining to the homeopathic strain.

General quality requirements shall be applied for all precursor substances and raw materials similarly as for intermediate stages of the manufacturing process up to the final dilution that is included in the final product. If possible, content analysis shall be made if there is a toxic component in the medicinal product and quality control of the final dilution is not possible because of the high dilution. Every step of the manufacturing process from precursor substances to the final dilution included in the final product shall be described in detail.

In the event dilutions are used, dilution steps shall be carried out in line with pertaining articles of the European Pharmacopoeia or, in lack of such, the

pertaining article of the official national Pharmacopoeia of a Member State.

c) Quality control tests carried out with the finished product

General quality requirements shall pertain also to homeopathic finished products and any exception shall be appropriately justified by the applicant.

Identification and test of every toxicologically important component shall be carried out. If it is justifiable that identification and test of every toxicologically important component cannot be carried out, e.g. due to high dilution of the finished product, quality shall be certified by full validation of the manufacturing and dilution procedures.

d) Stability tests

Stability of the finished product shall be verified. Stability data of homeopathic strain solutions are usually transferable to dilutions/triturations made from such strains. If neither identification nor examination can be made with respect to the active substance due to the level of dilution, then stability data of the pharmaceutical form shall be taken into consideration.

#### **Chapter 4**

Provisions of Chapter 4 shall be applied in the course of simplified procedures of homeopathic drugs, in line with subsection (1) of Section 9, with the conditions specified below:

All missing information shall be justified, e.g.: it shall be justified why the appropriate level of safety could be established in spite of the lack of some tests.

## **Italy**

### *Implementation Status:*

Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

### *Reference to legislation:*

**Articolo 18, decreto Legislativo n. 219 del 24 aprile 2006** codifica la materia prevedendo specifiche norme in ordine all'immissione in commercio dei medicinali per uso umano, ai medicinali omeopatici e di origine vegetale, al regime autorizzatorio, all'importazione, nonché le linee guida di buona fabbricazione, etichettatura e fogli illustrativi, ingrosso, pubblicità, farmacovigilanza e sanzioni previste in caso di violazione di tali norme (Legislative Decree on Medicinal Products).

### *Text Legal Provision:*

Art. 18. Medicinali omeopatici a cui non si applica la procedura semplificata di registrazione

1. I medicinali omeopatici diversi da quelli a cui si riferisce l'articolo 16, comma 1, devono essere autorizzati ed etichettati conformemente agli articoli 8, 10, 11, 12, 13 e 14.

(...)

Per tali prodotti possono essere previste, con decreto del Ministro della salute, su proposta dell'AIFA, norme specifiche relative alle prove precliniche e alle sperimentazioni cliniche, in coerenza con i principi e le caratteristiche della medicina omeopatica praticata in Italia.

(...)

### *English Translation:*

Article 18. Homeopathic medicinal products to which the special simplified registration procedure does not apply.

1. Homeopathic medicinal products other than those referred to in Article 16, paragraph 1, have to be authorised and labelled in conformity with Articles 8, 10, 11, 12, 13 and 14.

(...)

For these products specific norms can be foreseen with regard to preclinical tests and clinical trials, in accordance with the the principles and characteristics of homeopathy practiced in Italy, by a decree of the Minister of Health, on the proposal of the AIFA [*Medicines Agency*].

(...)

## **Lithuania**

### *Implementation Status:*

Article 16(1) implemented; option to implement Article 16(2) provided for in the National Legislation

### *Reference to legislation:*

**§ 6, Lietuvos Respublikos sveikatos apsaugos ministro 2002 m. birželio 27 d. įsakymo Nr. 309 (Ministerial Order Nr. 309) Papildomi Homeopatinių Preparatų Registravimo Reikalavimai jo. 3 straipsnis.**, Įstatymas skelbtas: Žin., 1996, Nr. 116-2701; Straipsnio pakeitimai: Nr. IX-2166, 2004-04-22, Žin., 2004, Nr. 68-2373 (Consolidated Version Medicines Act 1997).

### *Text Legal Provision:*

#### **§ 6**

Homeopatiniai preparatai registruojami pagal Bendrąsias vaistinių preparatų registravimo taisykles ar šiame skyriuje nustatytą supaprastintą registravimo procedūrą.

#### **3 straipsnis. Valstybinis vaistų registravimas**

(...)

4. Vaistus (išskyrus veterinarinius), radioaktyvius vaistus, homeopatinius preparatus, tradicinės medicinos preparatus, medicininius bioproduktus (toksinus, serumus, diagnostinius alergenų, diagnostinius antigenus, diagnostinius serumus, vakcinas), biotechnologinius produktus, kraujo preparatus, gydomosios kosmetikos priemones bei specialios paskirties maisto produktus registruoja Valstybinė vaistų kontrolės tarnyba. Vaistų

registravimo taisyklės tvirtina Sveikatos apsaugos ministerija.

(...)

*English Translation:*

**§ 6**

(...)

**Article 3**

(...)

4. Registration of medicines (except veterinary medicines), radioactive medicines, homeopathic preparations, preparations of traditional medicine, medicinal bioproducts (toxins, serums, diagnostic allergens, diagnostic antigens, diagnostic serums and vaccines), biotechnological products, blood preparations, medicated cosmetics and special purpose food products shall be effected and the Medicines Registration Regulations shall be approved by the State Medicines Control Agency.

(...)

### **Slovak Republic**

*Implementation Status:*

Article 16(1) implemented; it remains unclear whether an option to implement Article 16(2) is available, or if such implementation has taken place.

*Reference to legislation:*

**§ 60** Pôsobnosť ministerstva zdravotníctva, **Zákon č. 140-1998**, Formuláre a pokyny - Sekcia registrácie (SUKL): **POŽIADAVKY NA REGISTRÁCIU HOMEOPATICKÝCH LIEKOV, D. OSTATNÉ HOMEOPATICKÉ LIEKY** (Application forms and instructions - Department of Registration of the Medicines Agency: Requirements for the registration of homeopathic medicinal products)

*Text Legal Provision:*

**§ 60 Pôsobnosť Ministerstva zdravotníctva**

Ministerstvo zdravotníctva v rámci svojej pôsobnosti

(...)

**b)** vydáva rozhodnutie o registrácii liekov,

(...)

**D. OSTATNÉ HOMEOPATICKÉ LIEKY**

Homeopatický liek podlieha požiadavkám na registráciu ako nový liek v plnom rozsahu a je posudzovaný podľa zákona (zákon č. 140/1998 Z.z. o liekoch a zdravotníckych pomôckach v znení zákona č. 488/2001 Z.z.) vrátane posúdenia predklinických a klinických údajov ak:

a) obsahuje základnú tinktúru v koncentrácii vyššej ako 1/10 000

b) obsahuje liečivo v dávke vyššej ako 1/100 najmenšej dávky používané v alopatickej medicíne

c) uvádza terapeutickú indikáciu

*English Translation:*

**§ 60 Competences of the Minister of Health**

The Minister of Health within the framework of his competences

(...)

Shall adopt rules on the registration of medicinal products,

(...)

**D. OTHER HOMEOPATHIC MEDICAMENTS**

Homeopathic medicinal products are subject to the requirements of an authorisation to the full extent and will be assessed in accordance with the rules of

the law (law NR. 140/1998 Slg. on Medicinal Products and Medical Devices, as amended by law NR. 488/2001 Slg.) including the evaluation of pre-clinical and clinical data if:

- a) it contains mother tincture in concentration higher than 1/10 000
- b) contains an active principle in a dose which is higher than 1/100 of the smallest dose, which is used in allopathic medicine
- c) a therapeutic indication is given

## **Slovenia**

### *Implementation Status:*

Article 16(1) implemented; it remains unclear whether an option to implement Article 16(2) is available, or if such implementation has taken place.

### *Reference to legislation:*

**§ 14 Zakon o Zdravilih** (Uradni list RS št. 31-06) (Medicinal Products Act) *jo. 9. člen Pravilnik o homeopatskih izdelkih* (Uradni list RS, št. 101/99, 70/00, 7/02, 13/02-ZKrm, 67/02 in 47/04-ZdZPZ)

### *Text Legal Provision:*

#### **14. člen** (homeopatska zdravila)

(1) Za homeopatska zdravila je treba pridobiti dovoljenje za promet v skladu s 23. členom tega zakona.

(2) Ne glede na določbo prejšnjega odstavka se za homeopatska zdravila, ki so namenjena za zunanjo ali peroralno uporabo, uporablja poenostavljeni postopek pridobitve dovoljenja za promet (postopek registracije), če izpolnjujejo naslednje zahteve:

1. na ovojnicah in v navodilih za uporabo nimajo navedenih zdravilnih učinkov oziroma terapevtskih indikacij ali informacij, ki se na te nanašajo;

2. imajo zadostno stopnjo razredčitve, da zagotavljajo varnost, kakor to določajo predpisi.

(3) Vse določbe tega zakona veljajo tudi za homeopatska zdravila, če ta zakon ne določa drugače.

(4) Natančnejšo opredelitev, označevanje, oglaševanje in pogoje izdaje dovoljenja za promet in poenostavljenega postopka registracije za homeopatska zdravila predpiše pristojni minister.

## **V. DOVOLJENJE ZA PROMET**

### **7. člen**

Homeopatski izdelki se lahko dajo v promet le na podlagi dovoljenja Agencije.

Ne glede na prejšnji odstavek dovoljenje za promet s homeopatskim izdelkom ni potrebno:

- za magistralne homeopatske pripravke;
- za galenske homeopatske izdelke.

Lekarne morajo o vrsti in sestavi galenskih homeopatskih izdelkov, ki jih nameravajo izdelovati, obvestiti Agencijo. Agencija določi način izdajanja galenskih homeopatskih izdelkov.

### **8. člen**

Določbe zakona in na njegovi podlagi izdanih predpisov se nanašajo tudi na dovoljenje za promet s homeopatskimi izdelki, kolikor ta pravilnik ne določa drugače.

## **VI. DOVOLJENJE ZA PROMET PO POENOSTAVLJENEM POSTOPKU**

### **Pridobitev dovoljenja za promet**

#### **9. člen**

Ne glede na prejšnji člen se po poenostavljenem postopku lahko pridobi dovoljenje za promet za homeopatske izdelke, ki izpolnjujejo naslednje pogoje:

- so le za peroralno ali zunanjo uporabo;
- na ovojnini in v navodilih za uporabo ne smejo imeti navedenih zdravilnih učinkov oziroma terapevtskih indikacij ali informacij, ki se na te nanašajo;
- imajo zadostno stopnjo razredčitve, da zagotavljajo varnost: ne smejo vsebovati več kot 1 del matične tinkture na 10 000 delov topila ali nosilca ali več kot 1/100 najmanjšega odmerka, ki se uporablja v alopattiji za zdravila, ki se izdajajo le na recept.

V postopku pridobitve dovoljenja za promet Agencija odobri tudi način izdajanja homeopatskega izdelka.

Vloga za poenostavljen postopek pridobitve dovoljenja za promet se lahko nanaša na več različnih stopenj razredčitev in farmacevtskih oblik, ki so pripravljene iz istih homeopatskih surovin.

*English Translation:*

#### **Article 14** (homeopathic medicine)

(1) It is necessary to obtain marketing authorization for homeopathic medicines in line with Article 23 of this Act.

(2) Notwithstanding the provision of the previous paragraph, homeopathic medicines intended for external or peroral use may use the simplified procedure to obtain marketing authorization (registration procedure) if they fulfill the following requirements:

1. They do not have any statements of medicinal effects or therapeutic indications, or any information related to these, on the packaging and instructions for use;
2. They have an appropriate level of dilution to ensure safety, as defined by regulations.

(3) All provisions in this Act also apply to homeopathic medicines, where the Act does not specify otherwise.

(...)

### **V. MARKETING AUTHORIZATION**

#### **Article 7**

Homeopathic products may only be sold on the basis of a permit issued by the Agency.

Notwithstanding the previous paragraph, a permit to sell homeopathic products is not required for:

- Compounded homeopathic preparations;
- Compounding laboratory homeopathic products.

Pharmacies must notify the Agency of the types and ingredients of compounding laboratory homeopathic products they intend to produce. The

Agency approves the production method for compounding laboratory homeopathic products.

#### **Article 8**

The provisions of the Act and regulations based on it are also valid for the sale of homeopathic products, where these Rules do not specify otherwise.

### **VI. MARKETING AUTHORIZATION USING THE SIMPLIFIED PROCEDURE**

#### **Obtaining Marketing Authorization**

#### **Article 9**

Notwithstanding the previous Article, marketing authorization for homeopathic products may be obtained through a simplified procedure if the following terms are met:

- They are only for peroral or external use;
- On the packaging and in the instructions for use they may not make statements of medicinal effects or therapeutic indications, or state any information related to these;
- They must have a degree of dilution that guarantees safety: they may not contain more than one part of mother tincture to 10,000 parts of solution or carrier, or more than 1/100 of the smallest dose that is used in allopathic medicines that are issued only by prescription.

In the procedure of obtaining marketing authorization, the Agency must also approve the production method.

Application for the simplified procedure to obtain marketing authorization may relate to many different degrees of dilution and pharmaceutical forms that are prepared with the same homeopathic raw materials.

(...)

### 3) Article 16(1) Implemented; Article 16(2) not Implemented

#### Czech Republic

*Implementation Status:* Article 16(1) implemented

*Reference to legislation:* § 24a, o léčivech a o změnách a doplnění některých souvisejících zákonů (consolidated version of the Act on Pharmaceuticals), Zákon c. 79/1997.

*Text Legal Provision:* § 24a **Humánní homeopatické přípravky**

(1) Zjednodušenému postupu registrace, v rámci kterého se nevyžaduje důkaz léčebné účinnosti, podléhají pouze humánní homeopatické přípravky splňující všechny následující podmínky

a) jsou podávány ústy nebo zevně,

b) v označení na obalu humánního homeopatického přípravku ani v jakékoli informaci, která se ho týká, není uvedena žádná specifická léčebná indikace,

c) ředěním lze za podmínek stanovených vyhláškou zaručit bezpečnost humánního homeopatického přípravku.

(2) Žádost o zjednodušený postup registrace se může vztahovat i na více humánních homeopatických přípravků odvozených ředěním od téže základní homeopatické látky nebo směsi látek a lišících se pouze stupněm ředění. Žádost se předkládá pro každou lékovou formu jednotlivě.

(3) Žádost musí obsahovat náležitosti a dokumentaci stanovené vyhláškou, dokládající zejména farmaceutickou jakost a homogenitu mezi jednotlivými šaržemi humánního homeopatického přípravku. V žádosti a dokumentaci se uplatní ustanovení § 24 odst. 5 přiměřeně povaze humánního homeopatického přípravku. S žádostí se nepředkládá návrh souhrnu údajů o přípravku a výsledky klinických hodnocení.

(4) V případě humánních homeopatických přípravků registrovaných zjednodušeným postupem podle odstavce 1 musí být kromě údajů stanovených

vyhláškou uvedena na obalu informace „U přípravku nebyl požadován důkaz účinnosti“; stejná informace musí být uvedena v příbalové informaci.

(5) V případě humánních homeopatických přípravků registrovaných zjednodušeným postupem podle odstavce 1 se ustanovení § 52 až 52c nepoužijí.

*English Translation:*

#### **Section 24a Homeopathic products for human use**

(1) Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a simplified marketing authorisation procedure which does not require a proof of therapeutic efficacy:

- a) They are administered orally or externally;
- b) No specific therapeutic indication appears on the labelling of the homeopathic product for human use or in any information relating thereto;
- c) Under the conditions laid down by a decree, the safety of the homeopathic product for human use can be guaranteed by means of dilution.

(2) An application for a simplified marketing authorisation procedure may cover a series of homeopathic products for human use derived by dilution from the same homeopathic stock or combination of stocks varying only in the degree of dilution. For each pharmaceutical form a separate application shall be submitted.

(3) The application must contain particulars and documentation laid down by a decree, to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic product for human use. The provisions of Section 24, paragraph 5 shall apply to the application and documentation adequately to the nature of the homeopathic product for human use. The application shall not be accompanied by the summary of product characteristics and by the results of clinical trials.

(4) Where human homeopathic products authorised by simplified marketing authorisation procedure as per paragraph 1 are concerned, the labelling must, apart from data provided for by a decree, show the information “A proof of efficacy has not been required for the product”; the same information must be contained in the package leaflet.

(5) Where homeopathic products for human use authorised by simplified marketing authorisation procedure as per paragraph 1 are concerned, provisions of Sections 52 to 52c shall not apply.

*Special remark:*

Although a specific reference is not made in the Czech legislation to the authorisation of homeopathic medicinal products, it can *a contrario* be derived that homeopathic medicinal products which do not comply with the requirements for a special simplified registration, must be authorised according to the general rules for conventional medicinal products, as laid down in Article 16(1).

**Luxembourg**

*Implementation Status:*

Article 16(1) implemented

*Reference to legislation:*

Articles 46 and 50 *jo.* Article 48, Code de la Santé 2003, Volume 1, Médicaments - B. Règlements d'exécution (Health Code 2003, Volume 1, Medicines – B. executive orders).

*Text Legal Provision:*

**Art. 46**

Sauf les dérogations et spécifications énoncées au présent chapitre, les dispositions des chapitres 1, 2, 3, 4 et 7 du présent règlement s'appliquent aux médicaments homéopathiques.

(...)

**Art. 48**

1. Par dérogation aux dispositions du chapitre 1er du présent règlement les médicaments homéopathiques qui satisfont à toutes les conditions énumérées ci-après peuvent faire l'objet d'une

procédure d'autorisation de mise sur le marché simplifiée spéciale:

- voie d'administration orale ou externe;
- absence d'indication thérapeutique particulière sur l'étiquette ou dans toute information relative au médicament;
- degré de dilution garantissant l'innocuité du médicament; en particulier, le médicament ne peut contenir ni plus d'une partie par 10.000 de la teinture-mère, ni plus d'1/100ème de la plus petite dose utilisée éventuellement en allopathie pour les principes actifs dont la présence dans un médicament allopathique entraîne l'obligation de présenter une prescription médicale.

(...)

3. Les critères et règles de procédure du chapitre 1er du présent règlement sont applicables par analogie à la procédure d'autorisation de mise sur le marché simplifiée spéciale des médicaments homéopathiques, à l'exception de la preuve de l'effet thérapeutique.

#### **Art. 50**

Les médicaments homéopathiques autres que ceux visés à l'article 48 ci-dessus sont autorisés et étiquetés conformément aux chapitres 1 et 2 du présent règlement, y compris les dispositions relatives à la preuve de l'effet thérapeutique.

*English Translation:*

#### **Article 46**

With the exception of the stated exemptions and specifications in the present chapter, the provisions of chapters 1, 2, 3, 4 and 7 of the present order shall apply to homeopathic medicinal products.

(...)

#### **Article 48**

1. In derogation of the provisions in the 1st chapter of this order the homeopathic medicinal products which satisfy all the conditions enumerated hereafter may be subjected to a simplified special marketing authorization procedure:

- the route of administration is oral or external;
- a particular therapeutic indication on the label or in any information relating to the medicinal product is absent;
- a degree of dilution guaranteeing the harmlessness of the drug; in particular, the drug may neither contain more than one part per 10.000 of the mother tincture, nor more than 1/100 of the smallest dose possibly used in allopathy for which the presence of the active principles in an allopathic drug entails the obligation to present a medical prescription.

(...)

3. The criteria and rules of procedure in the 1st chapter of this order are mutatis mutandis applicable to the special simplified marketing authorization procedure for homeopathic medicinal products, with the exception of the proof of therapeutic effect.

**Art. 50**

Homeopathic medicinal products other than those mentioned in article 48 above are authorized and labelled in accordance with chapters 1 and 2 of this order, including the provisions relating to the proof of therapeutic effect.

*Special remark:*

In practice, Luxembourg accepts applications for homeopathic medicinal products which can prove a current marketing authorisation in other Member States.

**Malta**

*Implementation Status:*

Article 16(1) implemented.

*Reference to legislation:*

**Article 11**, Medicines Act 2003 (Chapter 458), Medicines (Marketing Authorisation) Regulations 2007 (L.N. 324)

*Text Legal Provision:*

**Article 11**

Homeopathic medicinal products, other than those referred to in regulation 10 (3), shall be authorised

and labelled in accordance with regulations 5, 7 and 8.

*Special remark:*

The Article refers to the general authorisation procedures laid down in regulations 5,7 and 8.

## **Romania**

*Implementation Status:*

Article 16(1) implemented

*Reference to legislation:*

**Article 713 jo. Articles 711(1) and 702, Legea nr. 95/2006 privind reforma în domeniul sanatații, publicata în Monitorul Oficial al Romaniei, Partea I nr. 372 din 28/04/2006**

*Text Legal Provision:*

**Article 713(1)**, Medicamentele homeopate, altele decât cele prevăzute la Article 711 alin. (1), sunt autorizate și etichetate conform prevederilor Article 702 și 704 - 708.

**Article 711(1)**, Pot face obiectul unei proceduri speciale de autorizare simplificată numai medicamentele homeopate care satisfac toate condițiile următoare:

- cale de administrare orală sau externă;
- absența unor indicații terapeutice specifice pe eticheta produsului sau în orice informație legată de produsul respectiv;
- existența unui grad suficient de diluție pentru a garanta siguranța medicamentului; în particular, medicamentul nu poate conține nici mai mult de o parte la 10.000 din tinctura-mamă, nici mai mult de 1% din cea mai mică doză folosită în alopatic pentru substanțele active a căror prezență într-un medicament alopatic necesită prezentarea unei prescripții medicale.

La momentul autorizării, Agenția Națională a Medicamentului stabilește clasificarea privind modul de eliberare a medicamentului.

**Article 702,**

(1) În vederea obținerii unei autorizații de punere pe piață pentru un medicament, trebuie depusă o cerere la Agenția Națională a Medicamentului.

(2) Sunt exceptate de la prevederile alin. (1) medicamentele care trebuie să fie autorizate de Agenția Europeană a Medicamentelor prin procedura centralizată.

(3) O autorizație de punere pe piață nu poate fi eliberată decât unui solicitant stabilit în România sau într-un stat membru al Uniunii Europene.

(4) Cererea de autorizare de punere pe piață trebuie să fie însoțită de următoarele informații și documente, care trebuie să fie transmise în conformitate cu Normele și protocoalele analitice, farmacotoxicologice și clinice referitoare la testarea medicamentelor, aprobate prin ordin al ministrului sănătății publice:

(...)

*English Translation:*

**Article 713(1),** Homeopathic medicinal products other than those referred to in Article 711, paragraph (1), shall be authorized and labelled in accordance with Article 702 and Articles 704 to 708.

**Article 711(1),** Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a special, simplified authorization procedure:

1. they are administered orally or externally;
2. no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto;
3. there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

At the time of authorization, the National Medicines Agency shall determine the classification for the dispensing of the medicinal product.

**Article 702,**

(1) In order to obtain an authorization to place a medicinal product on the market an application shall be made to the National Medicines Agency.

(2) Provisions of paragraph (1) shall not apply to medicinal products to be authorized through centralised procedure by the European Medicines Agency.

(3) A marketing authorization may only be granted to an applicant established in Romania or a Member State.

(4) The marketing authorisation application shall be accompanied by the following particulars and documents, submitted in accordance with analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products approved by order of the minister of public health:

(...)

**Sweden**

*Implementation Status:*

Article 16(1) implemented

*Reference to legislation:*

**§ 2b, Läkemedelslag (1992:859); Lag (2006:253)** (Medicinal Products Act) *jo. Allmänna råd till 1 kap., Föreskrifter om ändring I Läkemedelsverkets föreskrifter och allmänna råd (LVFS 1997:9) om registrering av vissa homeopatika (LVFS 2003:2)* (Instructions regarding amendments to the Medical Products Agency's provisions and guidelines (LVFS 1997:9) on the registration of certain homeopathic products)

*Text Legal Provision:*

**§ 2b** Ett läkemedel som beretts enligt en erkänd homeopatisk metod och som inte påstås ha viss terapeutisk effekt och som är avsett att intas genom munnen eller avsett för yttre bruk skall på ansökan registreras enligt bestämmelserna i denna lag, om graden av utspädning garanterar att läkemedlet är oskadligt. Det skall särskilt beaktas att läkemedlet

inte får innehålla mer än en tiotusendel av modertinkturen eller, i fråga om humanläkemedel, mer än en hundraedel av den lägsta använda dos av en sådan aktiv substans som i läkemedel medför receptbeläggning. Homeopatiskt läkemedel avsett för djur får registreras oberoende av det sätt på vilket det ges om detta beskrivs i Europeiska farmakopén eller i annan inom Europeiska ekonomiska samarbetsområdet officiellt använd farmakopé.

(...)

**Allmänna råd till 1 kap.:**

2 § läkemedelslagen (1992:859) [*now § 2b (Consolidated Version May 2006)*] anges de grundläggande kriterier som skall vara uppfyllda för att ett homeopatikum skall kunna registreras:

(...)

Samtliga dessa kriterier måste vara uppfyllda för att en produkt skall kunna registreras. Homeopatika avsedda för livsmedelsproducerande djur kan dock ej registreras.

(...)

*English Translation:*

**§ 2b**

A product prepared according to a recognised homeopathic method, with no claim to a specific therapeutic effect, intended for oral or external administration and with sufficient dilution to guarantee its safety. However, it must not contain more than one part per ten thousand of the mother tincture or a maximum of one hundredth of any active principle which in medicines would be classed as prescription only.

(...)

**Guidelines relating to Part 1:**

The fundamental criteria which must be fulfilled for registration of a homeopathic product are stated in § 2 of the Medicinal Products Act (1992:859):

(...)

All these criteria must be fulfilled for a product to be registered.

(...)

*Special remark:*

Although a specific reference is not made in the Swedish legislation to the authorisation of homeopathic medicinal products, it can *a contrario* be derived that homeopathic medicinal products which do not comply with the requirements for a special simplified registration, must be authorised according to the general rules for conventional medicinal products, as laid down in Article 16(1).



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