IRISH MEDICINES BOARD

GUIDE TO THE NATIONAL RULES SCHEME FOR HOMEOPATHIC MEDICINAL PRODUCTS FOR HUMAN USE

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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1. SCOPE

This guideline concerns the homeopathic medicinal products national rules scheme, under which applications may be made for the granting of a product authorisation to certain homeopathic medicinal products. It aims to provide information and guidance on the documentation and particulars required to make such an application. It does not cover homeopathic medicinal products under the simplified registration scheme or veterinary homeopathic medicinal products.

2. INTRODUCTION

The Directive on human medicines 2001/83/EC, as amended by Directive 2004/27/EC has been transposed into Irish law by the Department of Health and Children. The Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) were implemented on **23 July 2007** by the Minister for Health and Children.

EU legislation is designed to provide an appropriate legal framework for placing human medicinal products, including homeopathic medicinal products, on the market within the European Union. The above national Regulations facilitate this process in Ireland and in particular these regulations introduce a new national rules scheme for certain homeopathic medicinal products [Article 11 of S.I. No. 540 of 2007 (Annex 1)], as provided for under Article 16.2 of Directive 2001/83/EC, as amended. Specifically Article 16 (2) permits member states to introduce national rules for the pre-clinical tests and clinical trials of homeopathic medicinal products other than those provided for under the simplified registration scheme according to Article 14 (1).

The IMB as the Competent Authority for implementation of this legislation has established the homeopathic medicinal products national rules scheme (NRS). Under this scheme an applicant can apply for a product authorisation for their homeopathic medicinal product.

The purpose of this scheme is to provide a mechanism whereby homeopathic medicinal products that do not qualify for registration under the simplified registration scheme can be authorised; e.g., homeopathic medicinal products with certain indications.

As defined in Directive (2001/83/EC) a homeopathic medicinal product is:

‘Any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

A homeopathic medicinal product may also contain a number of principles.'

Article 16.2 of Directive 2001/83/EC, as amended by Article 15 (b) of Directive 2004/27/EC, states that '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 practiced in that Member State.'

Accordingly, applicants will not be required to supply pre-clinical tests and clinical trial data for products submitted under the NRS but they may do so if the data are available. However, the applicant must submit with his application particulars and documents relating to the safety and efficacy of the homeopathic medicinal product in question as outlined later in this guidance. In addition, the application must be accompanied by a full quality dossier with appropriate product labelling and product literature.

In summary, all provisions of the Directive other than those relating to the 'preclinical test and clinical trials' apply to homeopathic medicinal products licensed under the National Rules Scheme in Ireland.

As outlined in S.I. 540 of 2007, in order to obtain an authorisation under this scheme the applicant must demonstrate:

- that the product is a homeopathic product that conforms with the principles and characteristics of homeopathy as practised in the State;
- that the indication sought is appropriate;
- that any such indication is suitable for use without the intervention of a registered medical practitioner for diagnosis, or for prescription or for the monitoring of treatment;
- that the efficacy of the product is based on evidence that the particular class of product has been in use in the State as a homeopathic treatment for the indication sought and;
- that the safety of the product has been established as set down in the relevant regulations.

Applicants should ensure that they are familiar with the relevant EU legislation and guidelines published for human medicines including:

- Directive 2001/83/EC, as amended.
- EUDRALEX Volume 2 - Pharmaceutical Legislation: Notice to Applicants
- Scientific guidelines for human medicinal products published by the EMA available at www.ema.europa.eu.
- Monographs and methods of Ph.Eur.
- Eudralex Volume 9A of the Rules Governing Medicinal Products in the European Union: the Guidelines on Pharmacovigilance for Medicinal Products for Human Use

In addition, applicants should refer to guidance from the Homeopathic Medicinal Products Working Group (HMPWG) of the Heads of Medicines Agencies (HMA):

- Module 1.2 Homeopathic application form.
- Guidance on Module 3.
- Points to Consider on Stability testing of Homeopathic Medicinal Products.
- Points to Consider on non-clinical safety of homeopathic medicinal products of botanical, mineral and chemical origin.
- Points to Consider on Safety of Homeopathic Medicinal Products from Biological Origin.

Applicants should also refer to any additional guidance, which may be published on the HMA web site (www.hma.eu) from time to time.

WHO have also published a document on 'Safety issues in the preparation of homeopathic medicines', which should be consulted.

3. FORMAT AND CONTENT OF DOSSIER

Application under the national rules scheme (NRS) should be made in the format of a dossier based on the common technical document (CTD). The CTD is an internationally agreed structure and format for an application dossier and is the format currently used for marketing authorisation applications. General guidance on the compilation of dossiers in CTD format is given by the European Commission. There is a specific Module 1 application form for homeopathic medicinal products and, in addition, the HMPWG has also prepared guidance on submitting an application for a homeopathic medicinal product in the CTD format. These documents should be consulted:

- Notice to Applicants-Volume 2B, incorporating the Common Technical Document (CTD)
- Homeopathic Medicinal Products Module 1
- Guidance document on Module 3 of the Homeopathic Medicinal Products Dossier

Details of documents and particulars to be submitted as part of an application for an authorisation are given in Articles 8, 10, 10a, 10b, 10c and 11 of Directive 2001/83/EC, as amended.

Applications to the IMB in accordance with these articles and in CTD format will consist of:

- Module 1- Administrative data including EU Part IA (application) form
- Summary of Product Characteristics (SPC)
- Product label and package leaflet
- Module 2 - Summaries of the dossier and/or required expert reports
- Module 3 - Quality data
- Module 4 - Supporting Safety Data

- Module 5 - Efficacy/Justification of Homeopathic Use

Particular attention should be given to the revised Annex 1 (of Directive 2001/83/EC) in Directive 2003/63/EC; specifically Part III, section 3, which sets out specific provisions on the application of Modules 3 and 4 to homeopathic medicinal products.

4. APPLICATION FORM

An application form must be submitted as part of Module 1 of the application dossier.

The application form for a homeopathic medicinal product authorisation is a specific EU application form - Module 1.2 Homeopathic application form.

5. PRODUCT INFORMATION

A Summary of Product Characteristics (SPC) is required as part of the product information in Module 1 of the application. The SPC includes the name of the product, strength, pharmaceutical form, quantity of active ingredients, posology, method of administration, indications, contraindications, excipients, shelf life and any special warnings and precautions for use etc.

The following guidance should be consulted:
- Notice to Applicants Guideline on Summary of Product Characteristics - SmPC (September 2009)

The proposed product labelling and package leaflet must be submitted as part of the product information in Module 1. The proposed label information and the user package leaflet should be in English and meet the requirements of Articles 54 to 65 and articles 68 and 69 of Directive 2001/83/EC, as amended. In addition, Articles 11 and 16 of S.I. 540 of 2007 (Annex 1) also apply to products submitted under national rules.

It is necessary to submit a mock-up of the label and package leaflet for each product. Article 56a of Directive 2001/83/EC as amended, requires certain information on the packaging and package leaflet to be in Braille for the blind and partially sighted. Please see Annex 2 for details of these requirements. The following guidance should also be consulted:
- Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC, as amended by Directive 2001/27/EC)
- Volume 3B Guidelines-Medicinal Product for human use-Safety, environment and information - Excipients in the label and package leaflet of medicinal products for human use, July 2003

- Guideline on the readability of the label and package leaflet of medicinal products for human use

Overall summaries and expert reports on the quality, safety and efficacy data must be submitted in Module 2 of the application. It is in the interests of the applicant to ensure the experts compiling these reports have appropriate qualifications and experience, which should be set out in an attached brief curriculum vitae.

6. QUALITY

The quality aspect of a medicinal product is independent of the nature of the medicinal product and so the normal quality requirements applicable to all authorised medicinal products, also apply to homeopathic medicinal products for human use.

In addition to the EU quality guidance on medicinal products for human use, specific guidance on the quality requirements for certain homeopathic medicinal products is available on the Heads of Medicines Agencies website.

Applicants should be familiar with all the relevant available guidance on quality when considering the quality aspects of their product.

The quality data are submitted in Module 3 of the dossier. A pharmaceutical expert is required to provide a Quality Overall Summary in Module 2.3 of the application. Products must be manufactured by an authorised manufacturer and compliance with Good Manufacturing Practice (GMP) is required. Importation of a product from outside the European Economic Area must also be done under a manufacturer's authorisation. There is also a requirement to hold a wholesaler's authorisation where appropriate. Further information on obtaining a manufacturer's or wholesaler's authorisation is available on the IMB website at www.imb.ie under Medicines/Manufacturing & Distribution.

7. SAFETY

The applicant must submit data, together with an expert report, to demonstrate the safety of the homeopathic medicinal product in question.

The applicant is reminded that products, including their indications, submitted under the NRS must be suitable for use without the intervention of a medical practitioner for diagnosis, prescription or monitoring of treatment.

The safety of the product must be demonstrated in accordance with the Medicinal Products (Control of Placing on the Market) Regulations, (S.I. No.540 of 2007), specifically Article 11, subparagraphs 3 and 4.

'Article 11.3

(3) For the purposes 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.

Article 11.4

(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.'

An expert report on the safety data must also be provided, in which the applicant must include an evaluation of the available scientific data, including an explanation as to how the data demonstrates an acceptable level of safety and how it justifies the proposed product labelling.

If no scientific data are available the application must be accompanied by other supporting data and a report to demonstrate that the product has an acceptable level of safety. The safety of the homeopathic medicinal product will then need to be monitored for the duration of the authorisation in accordance with Regulation 17 and 18 of S.I. 540 as outlined in section 7.1 Pharmacovigilance below. A summary of the required safety data and the expert report are submitted in Module 2.4 of the application and the supporting safety data are submitted in Module 4 of the dossier.

7.1 Pharmacovigilance

It is important to note that the requirements for pharmacovigilance specified in S.I. 540 of 2007 are also applicable in the case of homeopathic medicinal products that are authorised. These requirements include the need for the person responsible for

placing a homeopathic medicinal product on the market, which is the subject of a marketing authorisation, to have permanently and continuously at his disposal an appropriately qualified person responsible for Pharmacovigilance (QPPV), as required by Title 1X of Directive 2001/83/EC, as amended. The responsibilities of the QPPV are described in both national and EU legislation and guidance, and include the requirements to establish and maintain a system for collection and collation of adverse reaction data, record and report suspected adverse reactions electronically, provide usage data, submit periodic safety update reports (PSURs) and other pharmacovigilance data, as necessary. Full details of the requirements may be found in the above S.I. and in Volume 9a of the Rules Governing Medicinal Products in the EU.

8. EFFICACY

While the evidence of efficacy of the product does not have to be based on the outcome of clinical trials, the applicant must submit data as to the efficacy of the homeopathic medicinal product by providing suitable evidence, together with an expert report, demonstrating that the particular class of homeopathic medicinal product has been in use in the State as a homeopathic treatment for the indication sought.

Information provided must consist of at least one of the following types of data:
- Study reports in relation to the product which is the subject of the application.
- Published scientific literature or the results of investigations commonly known as homeopathic provings; which consist of the administration of a substance to a human subject in order to ascertain the symptoms produced by that substance.

The applicant must also submit an expert report to include an evaluation of the data, including an explanation as to how the data establishes that the product has a recognised level of efficacy in the therapeutic indication for which authorisation is sought and is sufficient to demonstrate that a homeopathic practitioner in this State would accept the homeopathic use of the product for those indications.

A summary of the required efficacy data and the expert report are submitted in Module 2.5 of the application and the supporting efficacy data are submitted in Module 5 of the dossier.

9. LEGAL STATUS

The normal procedure for assigning legal status applies. The IMB will determine the method of sale and supply and of sales promotion on a case-by-case basis, taking into consideration that no medical prescription would be required for products authorised by this procedure (Regulation 12 of SI. 540).

ANNEX 1: STATUTORY INSTRUMENT NUMBER 540 OF 2007

(Excerpt - Articles 11 and 16)

Article 11: Authorisation of homeopathic medicinal products under national rules

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

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

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

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

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

(4) In regard to the active principles referred to in subparagraphs (3)(c) and (d), the Board may refuse to grant an authorisation where it is satisfied that the active principle concerned is toxic and as such would present concerns in regard to the

safety of the product. For the purposes of this subparagraph, the Board may publish and update from time to time a list of the substances that it considers to be in this category.

(5) A homeopathic medicinal product that is placed on the market on foot of a marketing authorisation granted in accordance with this Regulation shall, in addition to compliance with the requirements of Regulation 16 (relating to labelling and package leaflets), be presented in such a manner as to show:

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

Article 16: Labelling and package leaflets

16. (1) Without prejudice to the provisions of Regulation 17 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), a person responsible for placing a medicinal product on the market, which is the subject of a Community marketing authorisation or of a marketing authorisation, certificate of registration or certificate of traditional-use registration, shall not sell, supply or procure the sale or supply of such product unless:

(a) the labelling and any package leaflet accompanying the product are in compliance with Title V of the 2001 Directive; and
(b) except where all the information required to be included in the said package leaflet is directly conveyed on the outer packaging or immediate packaging of the product, the packaging contains a package leaflet in compliance with Title V of the 2001 Directive.

(2) A person, other than the person responsible for placing a medicinal product on the market, shall not, in the course of a business conducted by him, sell, supply, offer or keep for sale or supply or procure the sale or supply of such product unless the product meets the requirements of this Regulation.

(3) In this Regulation the reference to ‘Title V of the 2001 Directive’ shall, in the case of a traditional herbal medicinal product, include the requirements of Article 16g.2 of the 2001 Directive.

ANNEX 2: LABELLING

Article 68 of Directive 2001/83/EC as amended, specifies that homeopathic medicinal products, other than those registered in the simplified registration scheme, must be labelled in accordance with the provisions of this Directive (i.e. the same labelling and patient information leaflet requirements as for conventional medicines) and must include a statement indicating their homeopathic nature in clear and legible form. The CMD (h) Annotated QRD template provides general guidance on preparing labelling particulars and a patient information leaflet.

Articles 11 and 16 of S.I. 540 of 2007 and articles 54 to 65 and 68 and 69 of the Directive specify the labelling particulars required.

Particulars required on the immediate packaging and outer packaging (if applicable) are as follows:

- Clear mention of the words 'Homeopathic Medicinal Product'.
- A statement for the use of the product e.g. 'A homeopathic medicinal product for the symptomatic relief of (or treatment of)……based on homeopathic tradition and not on the outcome of clinical trials'.
- The name of the medicinal product.
- The scientific name(s) of the stock(s) followed by the degree of dilution.
- The pharmaceutical form and the contents by weight, volume or number of doses.
- A list of excipients, known to have a recognised action or effect. If the product is a topical or eye preparation then all excipients must be stated. (Refer to the EU guideline 'Excipients in the label and package leaflet of medicinal products for human use. July 2003').
- The method of administration and if necessary, the route. Dosage instructions are required when the product is intended for self administration. It is recommended that the duration of treatment is included in the dosage instructions. If the product is to be administered to children, an age range should be specified and administration instructions provided. According to Article 2(1) of the European Regulation on Paediatric Medicines, the paediatric population is defined as 'that part of the population aged between birth and 18 years'. The ICH guideline (CPMP/ICH/2711/99) provides age ranges for subsets within the paediatric population which may be adopted in the labelling particulars when applicable.
- A warning 'Keep out of the reach and sight of children'.
- Any special warnings, if necessary for the product. It is recommended that a warning advising the patient to consult a doctor if the symptoms worsen or persist and a time frame included within which a doctor should be consulted is included, together with a warning advising the patient to report any adverse effects not stated in the patient information leaflet to their doctor or pharmacist. If no adverse effects are known, then the statement should advise the patient to consult their doctor or pharmacist for advice if any adverse effects occur.
- The expiry date of the product in clear terms (month/year).
- Special storage precautions, if any.

- Specific precautions relating to the disposal of any unused product.
- The name and address of the holder of the national rules authorisation and where applicable, the name of the representative appointed by the holder to represent him.
- The national rules authorisation number (prefixed by HNR).
- The manufacturer's batch number.
- Any instructions for use.
- Article 56a of Directive 2001/83 EC as amended requires that the name of the medicinal product be expressed in Braille.

For guidance on the labelling of small container and blisters see page 14.

Leaflets

Article 58 of Directive 2001/83/EC, as amended, states that the supply of a leaflet is compulsory unless all of the information required is contained on the outer packaging or on the immediate packaging. Article 56a states that the authorisation holder must ensure that the patient information leaflet is made available on request from patients' organisations in a format appropriate for the blind and partially sighted. Additionally, Article 59 states the particulars required on the package leaflet, the order in which the information should appear and the requirement that package leaflets are user tested.

The information in the package leaflet must be consistent with the Summary of Product Characteristics (SPC) in its entirety. Particulars required and their order are as follows:

(a) Identification of the product:
   (i) The name of the medicinal product. The scientific name(s) of the stock(s) followed by the degree of dilution.
   (ii) Clear mention of the words 'Homeopathic Medicinal Product'.

(b) A statement for use of the product 'A homeopathic medicinal product used within the homeopathic tradition for the relief of or treatment of….'.

(c) A list of information which is necessary before the product is taken:
   (i) Contra-indications.
   (ii) Appropriate precautions for use.
   (iii) Interactions with other medicines.
   (iv) Special warnings.

The following should be taken into account when considering the above:
- the user, e.g. children, pregnant or breast feeding women, the elderly, persons with specific pathological conditions;
- possible effects on the ability to drive vehicles or operate machinery;

- excipients of known effect knowledge of which is important for the safe and effective use of the medicinal product.

(d) Instructions for:

(i) The dosage. It is recommended that an age range is specified if the product is to be administered to children. According to Article 2(1) of the European Regulation on Paediatric Medicines, the paediatric population is defined as 'that part of the population aged between birth and 18 years'. The ICH guideline (CPMP/ICH/2711/99) provides age ranges for subsets within the paediatric population which may be adopted in the labelling particulars when applicable.

(ii) The method, route of administration and instructions for administering the product to children, if applicable.

(iii) The frequency of administration and, if necessary, the time at which the medicine should be administered,

And as appropriate:-

(iv) The duration of treatment. It is recommended that a statement is included advising the patient to consult a doctor if symptoms worsen or persist during the use of the product and a time frame included within which a doctor should be consulted.

(v) The action to be taken in case of an overdose.

(vi) What to do when one or more doses have not been taken.

(vii) An indication of the risk of withdrawals effects.

(viii) A specific recommendation to consult the pharmacist for any clarification on the use of the product.

(e) A description of adverse reactions that may occur under the normal use of the product and if necessary, any action to be taken in such a case. The patient should be asked to communicate any adverse reaction which is not mentioned to his doctor or pharmacist. If no adverse reactions are known, a statement should be included advising the patient to report any adverse reactions that occur to their doctor or pharmacist.

(f) A reference to the expiry date indicated on the label:

(i) A warning against using the product after that date.

(ii) Where appropriate, special storage instructions.

(iii) A warning concerning visible signs of deterioration.

(iv) A full qualitative list of homeopathic stocks and excipients. Warnings for excipients known to have a recognised effect present at levels equal or above the threshold must be included (please refer to Guideline on Excipients in the label and package leaflet of medicinal products for human use, July 2003).

(v) The pharmaceutical form and contents by weight, volume or number of doses.

(vi) The name and address of the holder of the national rules authorisation and where applicable, the name of his appointed representatives.
(vii) The name and address of the manufacturer.

(g) The date the package leaflet was last revised.

LABELLING OF SMALL CONTAINERS, STRIPS AND BLISTER PACKS

Article 55 of Directive 2001/83 EC as amended, states an exemption from full labelling for small containers (which are defined as being not more than 10ml capacity), strips and blister packs.

Article 68 of the Directive, specifies that the homeopathic nature must be clearly stated on the label.

Labelling particulars required are:
- Clear mention of the words 'Homeopathic medicinal product'.
- The name of the medicinal product.
- The scientific name(s) of the stock(s) followed by the degree of dilution.
- The expiry date of the product in clear terms.
- The name of the holder of the national rules authorisation.
- The manufacturer's batch number.

For small containers only:
- The method of administration;
- The contents of the presentation, specified by weight, volume or number of doses; on the condition that the outer packaging includes all of the labelling particulars required, including those already stated on the small container, strips or blister packs.

LABELLING FOR HOMEOPATHIC KITS

On most occasions, the individual containers will be considered to be small containers and therefore qualify for the proposed minimum labelling particulars which apply to the immediate container but in such circumstances, the outer kit packaging must contain all of the above labelling particulars.

The following guidance should also be consulted:
- Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC amended by Directive 2001/27/EC).
- Volume 3B Guidelines-Medicinal Product for human use-Safety, environment and information-Excipients in the label and package leaflet of medicinal products for human use, July 2003.
- Guideline on the readability of the label and package leaflet of medicinal products for human use.