THE UK HOMEOPATHIC NATIONAL RULES SCHEME

BRIEF GUIDANCE FOR MANUFACTURERS AND SUPPLIERS

April 2025 (updated)

Purpose and scope of the UK Homeopathic National Rules Scheme

Background

1. The purpose of the scheme

The UK Homeopathic National Rules Scheme was introduced in 2006 to regularise the inconsistencies that existed between the homeopathic licensing schemes at that time.

Owing to the difficulty in establishing efficacy for homeopathic products by way of clinical trials, national rules were introduced for the non-clinical tests and clinical trials of certain homeopathic medicinal products, in order that those products could be authorised with marketing authorisations. Apart from special rules on safety and efficacy data, all the other rules applicable to applicants for and holders of marketing authorisations apply.

As the UK Homeopathic National Rules Scheme does not require rigorous clinical data, indications are limited to the relief or treatment of minor symptoms or minor conditions. i.e. symptoms or conditions which can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor. Indications for serious conditions are prohibited.

This guidance represents MHRA's view of the law and is not a definitive statement of the law – that can only be given by the courts. Whilst MHRA is happy to provide guidance to companies, it cannot give legal advice. If there are any doubts about professional obligations, a professional Advisor should be consulted.

2. Products with Exemptions

There are certain exemptions from the requirement to hold a marketing authorisation, including the situation where medicinal products are supplied in response to bona fide unsolicited orders, formulated in accordance with the specifications of a doctor and for use by individual patients on the doctor's direct personal responsibility, in order to fulfil the special needs of those patients.

3. Products eligible for authorisation under the UK Homeopathic National Rules Scheme

The UK Homeopathic National Rules Scheme applies to any homeopathic medicinal product which does not satisfy the requirements of the Simplified Homeopathic Registration Scheme (Regulation 102 of the 2012 Human Medicines Regulations)and which is indicated for the relief or treatment of minor symptoms or minor conditions in

humans.

The definition of a homeopathic medicinal product is given in Regulation 8 of the Human Medicines Regulations.

Homeopathic products authorised under the National Rules Scheme products are authorised on a UK wide basis and must be prepared from homeopathic stocks made following a homeopathic manufacturing procedure described in the European Pharmacopoeia, or in the absence of a description there, the British Pharmacopoeia or a pharmacopoeia used officially in an EEA State.

In line with the Windsor Framework arrangements, products are assigned Category 2 and must include "UK Only" on the label. Guidance on UK wide licensing requirements for all medicines following the agreement of the Windsor Framework can be found here UK-wide licensing for human medicines: supplementary guidance - GOV.UK

A list of products authorised under the National Rules Scheme (with the prefix NR) can be found on the following link: https://www.gov.uk/guidance/register-a-homeopathic-medicine-or-remedy

4. Who should apply for a marketing authorisation under the scheme?

If a homeopathic medicinal product is to be marketed under the UK Homeopathic National Rules Scheme a marketing authorisation must be held by the person responsible for placing it on the market, before it is placed on the market.

Applications for authorisation may be made by any person who wishes to place products on the market under the scheme.

A homeopathic marketing authorisation may only be granted to an applicant established in the UK or EEA.

Homeopathic medicinal products which are not authorised under the UK Homeopathic National Rules Scheme or registered under the Homeopathic Simplified Registration Scheme may only be sold or supplied if there is an applicable exemption.

Companies should also be aware of the need for the following licences:

- **Manufacturers**

A company which manufactures, or which proposes to manufacture, homeopathic medicinal products will need a *manufacturer's licence*. "Manufacture" includes all processes carried out in the course of making the product, including diluting, mixing and quality control. A manufacturer's licence is also needed for "assembly" (e.g. filling and labelling containers).

• **Wholesale dealers**

A company which acts as a wholesale dealer, or which proposes to do so, for homeopathic medicinal products other than those it manufactures itself, will need a wholesaler licence also known as a wholesale dealer licence or wholesale distribution authorisation.

Further information on a manufacturer or wholesaler licence may be obtained from the gov.uk website at the following link

https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences

• **Importers**

Information may be obtained from the gov.uk website at the following link

https://www.gov.uk/guidance/import-a-human-medicine

How to apply for an authorisation

Information on how to apply for an authorisation may be obtained from the gov.uk website at the following link

https://www.gov.uk/guidance/register-a-homeopathic-medicine-or-remedy

The approval process

5. Assessment of the application

When your application *and* fee have been received, the assessor will check the eligibility

of the application. We will inform you if the product is not eligible for authorisation under the Scheme

The data accompanying your application will be assessed, and if this is satisfactory the Licensing Authority will issue a homeopathic marketing authorisation. If there are deficiencies in your application, the assessor will inform you and attempt to resolve these wherever possible so that the application process can be taken forward.

6. Advisory Board on the Registration of Homeopathic Products

If advice is needed on any issue relating to safety, quality or indications for use within the UK homeopathic tradition, the application will generally be referred to the Advisory Board on the Registration of Homeopathic Products ("the Board"). The Licensing Authority is required by law to consult the "appropriate committee" (which will usually be the Board in relation to marketing authorisations under the UK Homeopathic National Rules Scheme) before rejecting any application on the grounds of safety, quality or use within the UK homeopathic tradition.

The Board may advise that an authorisation should be granted. However, if the Board considers that an authorisation should not be granted or should be granted otherwise than in accordance with the application, the company will be informed and will be given the opportunity to make representations to the Board.

7. Persons Appointed

If, following representations to the Board by the company, the Licensing Authority decides not to grant a marketing authorisation, or to grant it otherwise than in accordance with the application, the company will generally have the opportunity to appeal to a persons appointed.

8. Issue of Marketing Authorisations

Following approval, the homeopathic marketing authorisation will be sent via email and/or the post. On receipt you will be able to market the product and show the NR authorisation number on the label.

9. Time scales for approval

The Licensing Authority is required to take all appropriate measures to process applications within 210 days. However, in some cases, the clock will stop running e.g. if the Licensing Authority requires the applicant to supplement the particulars accompanying his application.

10. Information on progress

For information on the progress of your application, contact the Regulatory Information Service by e-mail at
RIS.Hom@mhra.gov.uk

Accompanying data

11. Data required

As with applications for conventional medicinal products, information must be provided in order to demonstrate the pharmaceutical quality and batch-to-batch homogeneity of the products concerned, their safety and their use within the UK homeopathic tradition for the indications sought.

An application for a marketing authorisation for a product under the UK Homeopathic National Rules Scheme is the same as any other application for a marketing authorisation – except for the rules on non-clinical and clinical data. Therefore, the applicant must follow the rules set out in Schedule 10 of the Human Medicines Regulations 2012 and should follow Annex I to the 2001 Directive, except for sections 2.4 to 2.7 and modules 4 and 5. Instead of submitting Modules 4 and 5 as described in Annex I, the applicant must submit the data required by Schedule 10 of the Human Medicines Regulations 2012. In other words, the application is submitted like any other marketing authorisation application – except that Modules 4 and 5 will be the data required by Schedule 10 of the Human Medicines Regulations 2012.

Where there are references in Annex I (other than in sections 2.4 to 2.7 and modules 4 and 5) to non-clinical reports, non-clinical documentation or non-clinical data; or to clinical study reports, clinical documentation and clinical data, you should treat those references as if they were a reference to the data required by Schedule 10 of the Human Medicines Regulations 2012.

You should note that the requirement to supply new information applies equally to information which has been provided under the UK Homeopathic National Rules Scheme.

Guidance on the data which should be provided is set out below. However, you should refer to the legislation for the full requirements:

(i) Quality

The data relating to quality is provided in the Module 3 dossier. Detailed rules are set out in Annex I to the 2001 Directive and the Notice to Applicants. Part III of Annex I to the 2001 Directive, section 3 ("homeopathic medicinal products") sets out modifications for homeopathic products, including homeopathic products which are the subject of an application for a marketing authorization under the UK Homeopathic National Rules Scheme.

(ii) Safety

The safety data which must be submitted by the applicant is set out in Schedule 10 of the Human Medicines Regulations 2012In some cases, the applicant does not need to supply any data on safety – see below.

When an applicant is required to submit data on safety, the rules in Schedule 10 of the Human Medicines Regulations 2012 must be followed.

When is safety data not required?

The applicant is not required to provide any data on the safety of the product if one of the following applies:

a. the product is intended to be administered orally and is derived from a stock which is commonly present in food;
b. the product is derived from a stock present in a licensed medicinal product (i.e. a product which has a marketing authorisation, certificate of registration, traditional herbal registration or product licence), and that medicinal product is available by way of general sale, provided that the product which is the subject of the application has the same degree of dilution and the same route of administration as the licensed product;
c. the product is derived from a stock diluted to at least 10^{24} and is not a material of biological origin.

However, if the applicant wants to rely on one of these exemptions, he must provide a written statement that the product meets the conditions of either (a), (b) or (c).

Where safety data is required

If the product does not fall within (a), (b) or (c) above, the applicant must provide safety data.

This should address all relevant aspects of safety, including the following:

pharmacology, pharmacokinetics and toxicology (including toxicity, genotoxicity, reproductive and developmental toxicity and local tolerance).

The safety data should be “scientific data” i.e. study reports in relation to the product which is the subject of the application and/or published scientific literature. However, where the applicant has made reasonable attempts to obtain scientific data in relation to an aspect of safety and is satisfied that there is none, or considers that the available scientific data is inadequate, he may submit data other than scientific data. For example, summary of any reported adverse events together with a discussion of these events in relation to product usage.

The applicant should provide with the data:

- A table of contents;
- An evaluation of the scientific data, including an explanation as to how the data demonstrates that the product has an acceptable level of safety;
- If data other than scientific data has been provided, the applicant should confirm in writing that he meets the conditions set out above, and explain why an acceptable level of safety can be demonstrated even without the scientific data.

An expert report on the safety data should also be provided in accordance with Schedule 10 of the Human Medicines Regulations 2012.

The safety of the product will then need to be monitored for the duration of the authorisation. Companies should also be aware of pharmacovigilance requirements for electronic report of adverse reactions. .Guidance may be found on the MHRA website.

(iii) Efficacy (use within the UK homeopathic tradition)

The applicant must submit data on the efficacy (use within the UK homeopathic tradition) of the product which is the subject of the application see Schedule 10 of the Human Medicines Regulations 2012.

It should be noted that results of clinical trials are not required to support applications for marketing authorisations under the UK Homeopathic National Rules Scheme. However, the applicant must provide one or more of the following to demonstrate that UK homeopathic practitioners would accept the use of the product within the UK homeopathic tradition for the indications sought:

- UK homeopathic practitioner statements
- Study reports in relation to the product which is the subject of the application

- Published scientific literature
- Homeopathic provings

Whatever data is provided, it should be sufficient to demonstrate that UK homeopathic practitioners would accept the use of the product within the UK homeopathic tradition for the indications sought.

This evidence should be presented in Module 5 of the dossier. The applicant must provide a table of contents, and an evaluation of the data, including an explanation as to how the data establishes that the product has a recommended level of UK homeopathic use in the indications sought.

12. Minor symptoms and minor conditions

As set out in the Schedule 10 of the Human Medicines Regulations 2012 , only products which are indicated for the relief of minor symptoms and minor conditions in humans are eligible for a marketing authorisation under the UK Homeopathic National Rules Scheme. For these purposes, minor symptoms are those which can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.

It is not possible to provide an exhaustive list of indications that would not be acceptable. Nevertheless, the following are **examples** of indications that **we do not consider would be permitted** under the UK Homeopathic National Rules Scheme:

- Bone diseases
- Cardiovascular diseases
- Chronic insomnia
- Diabetes and other metabolic diseases
- Diseases of the liver biliary system and pancreas
- Endocrine diseases
- Genetic disorders
- Joint, rheumatic and collagen diseases
- Malignant diseases
- Psychiatric conditions
- Serious disorders of the eye and ear
- Serious gastrointestinal diseases
- Serious infectious diseases including HIV related diseases and tuberculosis
- Serious neurological and muscular diseases including epilepsy
- Serious renal diseases
- Serious respiratory diseases
- Serious skin disorders

- Sexually transmitted diseases
- Treatment and prevention of malaria

Again, it is not possible to provide an exhaustive list of conditions not requiring medical supervision. However, typical **examples** of conditions that **could be covered** include:

- Indigestion, heart burn, hyperacidity, dyspepsia halitosis (bad breath) or flatulence Colicky pain, stomach ache or nausea, occasional or non-persistent diarrhoea or constipation
- Travel sickness or related symptoms
- Minor skin infections, relief of pruritus or exanthematous rashes of childhood infection and boils, athlete's foot
- Common colds, coughs, conditions commonly referred to as influenza and similar upper respiratory tract infections
- Minor acute inflammatory conditions of the buccal cavity and pharynx including sore throats
- Muscular pain and stiffness including backache, sciatica, lumbago, fibrositis, rheumatic pain and cramp.
- Hay fever, rhinitis and catarrh.
- Blocked-up sinuses.
- Headache including migraine headache
- Neuralgia
- Difficulties falling asleep
- Agitation, anxiety, irritability, nervous tension, stresses, strains, tenseness

Applicants wishing to claim indications for anything other than minor symptoms or minor conditions would need to apply for a full marketing authorisation which is supported by evidence of efficacy from controlled clinical trials.

13. Legal Status

The normal procedure of assigning a legal status applies.

14. Labelling and Product literature

The usual requirements for product labelling, the Patient Information Leaflet and Summary of Product Characteristics (SPC) apply including the need for warnings and contraindications as appropriate. Companies should also be aware of the requirements for consultations with patient groups, or "user testing", on patient information leaflets and for Braille labelling.

The labelling should refer, in clear and legible form, to the homeopathic nature of the product

The authorisation number will be distinguished from full marketing authorisations (MAs) and Simplified Homeopathic Registration certificates (HRs), by using the specific prefix, NR (UK homeopathic National Rules authorisations).

15. Presentation of data

One set of data i.e. one application should cover a series of dilutions relating to one pharmaceutical form. For example, one set of data is required for Arnica tablets at dilutions of 6x, 6c, 30c and a second set of data for Arnica drops at 6x, 6c, 30c.

16. Format of presentation

Data should be presented in the eCTD format.

Other Requirements

Regulations covering matters such as labelling, advertising and pharmacovigilance, and further guidance is available on the MHRA website at the following links:

Falsified Medicines Requirements

https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

Packaging, labelling and patient information leaflets

https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets

Advertising

https://www.gov.uk/guidance/advertise-your-medicines

Pharmacovigilance

https://www.gov.uk/topic/medicines-medical-devices-blood/vigilance-safety-alerts

Persons applying for, or holding, a marketing authorisation under the UK Homeopathic

National Rules Scheme need to comply with all the relevant regulations in the Human Medicines Regulations 2012 and amendments to these regulations.. In addition, sometimes, the Human Medicines Regulations 2012 and amendments set out specific requirements applicable to homeopathic medicinal products, and you must also comply with those requirements unless they are stated to apply only to “products referred to in Part 6 of the Human Medicines Regulations 2012(these are the Simplified Homeopathic Registration Scheme products).

Failure to comply with the requirements may be an offence under Part 43 of the Human Medicines Regulations 2012.