

**MEDICINES & HEALTHCARE PRODUCTS
REGULATORY AGENCY**

**UK HOMEOPATHIC REGISTRATION AND NATIONAL RULES SCHEME
GUIDANCE NOTES**

**NOTE ON LABELLING REQUIREMENTS FOR
HOMEOPATHIC PRODUCTS**

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The Simplified Registration Scheme

Article 69 of Directive 2001/83 EC as amended specifies the information that is required on the labels and leaflets of homeopathic registered products. It clearly states that no other information is permitted.

Labelling

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

- The scientific name of the stock (s) followed by the degree of dilution. If the product contains 2 or more homeopathic stocks, then the scientific names of the stocks may be supplemented by an invented name. Following the introduction of the scheme, it was agreed that the scientific name of one of the stocks may be followed by the word 'complex' or another word to indicate that the product contains a number of stocks, followed by the name of the company. In this way, the patient may distinguish the product from a similar one marketed by another company.
- The name and address of the holder of the certificate of registration and where different, of the manufacturer.
- Method of administration and if necessary the route. Please see Notes 1 & 2 for further recommendations.
- The expiry date of the product in clear terms. (month/year)
- The pharmaceutical form.
- The contents of the presentation, specified by weight, volume or number of doses.
- Special storage precautions if any.
- Any special warnings if necessary for the product. (Please see Notes 4 & 5 for further recommendations)
- The manufacturer's batch number.
- The homeopathic registration number.
- The words 'Homeopathic medicinal product without approved therapeutic indications'.
- A warning advising the user to consult a doctor if the symptoms persist during the safe use of the product. Please see Note 3 for further recommendations
- In addition the clear mention of the words 'homeopathic medicinal product'.

Note

It is recommended that the following information appears on the labelling particulars:

1. A detailed dosage regimen, on the condition that efficacy of the product is not implied.
- 2 The age range should be 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. Consideration should be given to the route of administration when specifying the age range to which the product is administered and if applicable, administration instructions provided.
3. A suitable time frame should be included in the statement advising the patient to consult a doctor if symptoms persist e.g. 'If symptoms worsen or persist for more than 7 days, please consult your doctor.'
4. A list of excipients of known recognised action or effect in line with the EU guideline 'Excipients in the label and package leaflet of medicinal products for human use. July 2003' ensuring consistency with medicines granted full marketing authorisations and homeopathic products granted national rules authorisations. If the product is a topical or eye preparation, then all excipients must be stated. This information maybe stated under the labelling particular – any special warnings for the use of the product. If a leaflet is not included with the product, it is advised to state the warning for the excipient(s) of known effect on the label as per the EU guidelines.
5. The warning 'Keep all medicines out of the reach and sight of children' ensuring consistency with medicines granted full marketing authorisations and homeopathic products granted National Rules authorisations. This warning maybe stated under the labelling particular – any special warnings for the use of the product.

Leaflets

The supply of a leaflet with a registered product is optional.

For guidance on the labelling of small containers and blisters see page 9.

The National Rules Scheme

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.

Labelling

Articles 54 and 68 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 'A homeopathic medicinal product used within the homeopathic tradition for the relief of or treatment of....',
- 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, injectable 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 maybe 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 NR)
- The manufacturers 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 10.

Leaflets

Article 58 of Directive 83/2001 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 (SmPC) 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 take into account when considering the above:

- i. the user e.g. Children, pregnant or breast feeding women, the elderly, persons with specific pathological conditions
 - ii. possible effects on the ability to drive vehicles or operate machinery
 - iii. 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 maybe 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 Guidelines – 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 & BLISTER PACKS

Simplified Registration Scheme

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. However Article 69 of Directive 2001/83 EC as amended, which provides the labelling requirements for products registered under the Simplified Registration Scheme, does not include an equivalent exemption from full labelling for small containers, strips and blister packs. Since it would be impractical for all of the required labelling particulars to be shown on small containers, strips and blister packs, a parallel may be taken from the labelling of small containers, strips and blister packs of conventional medicines. Therefore, taking into account the requirements of Article 55 of Directive 2001/83 EC as amended, and the special nature of homeopathic products, it is considered that the minimum labelling requirements for small containers, strips and blister packs of registered homeopathic products should be as follows:

- The statement 'Homeopathic medicinal product without approved therapeutic conditions'.
- 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 registration certificate,
- The manufacturer's batch number

For small containers only

In addition to the above, the following should be stated:

- The method of administration.
- The contents of the presentation, specified by weight, volume or number of doses

on the condition the outer packaging includes all of the labelling particulars required, including those already stated on the small container, strips or

blister packs.

The National Rules Scheme

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

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 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 containers will be considered to be small containers and therefore the proposed minimum labelling particulars will apply to the immediate container but in such circumstances, the outer packaging must contain all of the labelling particulars.