NATIONAL REQUIREMENTS for the OVERLABELLING of FOREIGN (non-English language) IMPORTED MEDICINES UNLICENSED in the UK

EDITION 1

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National requirements for the overlabelling of foreign (non-English language) imported medicines unlicensed in the UK

Background

Medicines licensed in the country of origin and imported into the UK as unlicensed products, have an important role to play in the treatment of patients for whom no suitable UK-licensed product is available. However, misuse of imports that were not labelled in English and/or included no supporting information in English have resulted in several fatalities in NHS hospitals. The use of imported products of this type is therefore a high risk activity requiring suitable quality assurance support.

This guidance has been produced by the NHS Pharmaceutical Quality Assurance Committee to protect patients from inappropriate use of imported foreign language-labelled medicines unlicensed in the UK. It consists of two sections:

- Mandatory B.P. requirements for the labelling of unlicensed medicines, with explanatory comments.
- Additional requirements of the NHS Pharmaceutical Quality Assurance Committee. Although these are not mandatory requirements there are strong reasons for compliance on patient safety grounds.

IMPORTANT:
The MHRA have officially stated that it is not appropriate to label unlicensed imported products “Prescription only” as this legal category can only be used for licensed medicines.

In order to clarify the legal status of an imported unlicensed medicine for all users, this guidance recommends that such products are labelled with the phrase “This medicine is not licensed in the UK”.

Scope

This document applies to anyone importing medicines unlicensed in the UK that are labelled in a foreign (non-English) language.

It is outwith the scope of this document to advise on the MHRA licences required for this activity.
SECTION 1: Mandatory Requirements

Based on the 2011 B.P. with additional detail where necessary:

All medicinal products in the UK should bear the following information:

1. The common name of the product.

   The generic name of the product should be given prominence but the brand name may also be stated for continuity purposes.

2. A statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or for a given volume or weight.

   This should be expressed as for MHRA best practice for licensed medicines e.g. for injections, the strength should be expressed both as total quantity per total volume and as amount per unit dose (e.g. milligrams per ml) where appropriate. Base and salt strengths should be clearly defined where appropriate.

   For oral liquids the dose should be expressed per 5ml if this is the normal dose volume. Leading and trailing zeros should not be used. Fractions of milligrams should be stated as “Micrograms” which should be spelt out in full rather than abbreviated.

3. Route of administration.

   The route of administration should be stated in all cases, even for the oral route.

4. Instructions for use, including any special warnings.

   This should include any information that is needed to allow the product to be administered e.g. a specific volume of diluent for reconstitution, shake the bottle for suspensions, cytotoxic etc.

5. The pharmaceutical form.

   As defined in the B.P.

6. The contents of the container by weight, volume or by number of doses.

   As total dose in total volume if applicable – see above.

7. Excipients of known effect. For injectable, topical (including inhalation products) and ophthalmic medicines, all excipients.

   ‘Excipients of known effect’ are published as a list which should be adhered to.

   Any excipient that may have an allergic reaction in a patient, e.g. peanut oil, should be clearly labelled.

8. 'Keep out of reach and sight of children'.

   This is a statutory requirement.
9. The expiry date expressed in unambiguous terms (dd/mm/yy).

The use of expiry dd/mm/yy is a B.P. requirement. If this is clear on the original packaging then it is not necessary to use space on the label to restate the expiry.

However, where the product is prefixed in a foreign language before a date e.g. verwendbar bis, the meaning of the phrase should be established by the importer.

(Phrases such as this may mean “use before” rather than expiry. “Use before” means the end of the preceding month whilst “expiry” means the end of the month stated.) An accurate expiry should be determined and this should be clearly stated in terms a nurse or patient can understand.

For products requiring reconstitution, e.g. dry powders for syrups, the expiry after reconstitution should be clearly expressed. An area on the label for “Date of Reconstitution” is advisable if space allows.

10. Any special storage precautions.

Storage requirements do not need to be specifically stated if they are ambient temperature but must be stated as 2-8°C if refrigeration is required for example.

11. The manufacturer's ML number, where appropriate.

Or MS number, where appropriate. The name of the hospital is not a requirement as this should be on any dispensing label.

12. The manufacturer's name and address.

The name and address of the importer/overlabeller should also be present. This should not be in the form of a ‘logo’ and should not be given prominence.

13. The batch number.

If the batch number is clear on the original packaging then this does not need to be restated on the label, however an audit trail is required to an individual overlabelling operation. This can be achieved either by including a “Date of Overlabelling” on the label, or by the importer allocating their own specific batch number. In the latter case a robust audit trail should be maintained for recall purposes.

14. Statutory warnings required by SI 1994/3144 for particular actives, e.g. aspirin, paracetamol, etc.
SECTION 2: Additional Requirements

In addition to the B.P. requirements outlined above, non-English language medicinal products imported into the UK should be labelled as follows:

15. ‘This medicine is not licensed in the UK’

The significance of this statement should be explained to the patient verbally or in any accompanying information leaflet. (Examples of suitable generic patient leaflets are to be found in the NHS QA Committee’s guidance document on unlicensed medicines.)

16. Professional assessment is needed on what information is supplied to patients.

However sufficient information should be provided in English to allow patients to use the product safely.

Any translated information must be accurate with appropriate liability arrangements.

17. For eye drops and other small containers there are reduced B.P. labelling requirements, but “flag” labelling may be required to ensure that a sans-serif font with point size of no less than 8 point is used.

18. Oral liquids should be labelled as either sugar containing or sugar free.

19. Where the primary container is in secondary packaging, such as a bottle of syrup in a box or tube of ointment in a carton, ideally both should be labelled. If the importer wishes to label only one of the containers preference should be given to labelling the inner (primary) packaging. In this instance a sticker should be placed on the outer (secondary) pack alerting the patient/nurse to the fact that the inner container is overlabelled.

The label should be positioned so as not to obscure any key text e.g. expiry, batch number, and placed in the dispensing label space if there is one.

REFERENCES

1. British Pharmacopoeia 2011 Part II General Requirements: Labelling

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