Notice to applicant

Notice to Applicant for Labelling Requirements for Unauthorized Investigational Medicinal Products for Human Use

Year 2025

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Required Information for Investigational Medicinal Product (IMP) Labelling:

Section 1- General Requirements:

The following information should be included on labels, unless its absence can be justified:

(a) Name, address and telephone number of the sponsor, contract research organization and investigator except where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times.
(b) Name of the substance and its strength or potency, pharmaceutical dosage form, route of administration, quantity of dosage units:

- In case of open-label trials, the name/identifier and strength/potency
- In case of blind clinical trials, the name of the substance is to appear with the name of the comparator or placebo on the packaging of both the unauthorized investigational medicinal product and the comparator or placebo.

(c) Batch and/or code number (When necessary for blinding purposes, the batch number may be provided separately.)
(d) Clinical trial reference code.
(e) Subject identification number and the visit number.
(f) Instructions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product).
(g) "For clinical trial use only" or similar wording
(h) Storage conditions.
(i) Period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity
(j) "Keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects.

Special Cases:

1- **When the product is to be provided to the trial subject or the person administering the medication within a primary package together with secondary packaging that is intended to remain together, and the secondary packaging carries the particulars listed in "section 1 general requirements", the following information shall be included on the label of the primary package (or any sealed dosing device that contains the primary packaging):**

(a) Name of sponsor, contract research organization or investigator;
(b) Pharmaceutical dosage form, route of administration, quantity of dosage units and in case of open label trials, IMP name/identifier and strength/potency;
(c) Batch and/or code number to identify the contents and packaging operation;
(d) Trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
(e) Trial subject identification number/treatment number and where relevant, the visit number**.**

2. **If the primary packaging takes the form of blister packs or small units such as ampoules "where all the required information cannot be displayed on primary packaging" on which the particulars required in "section 1 general requirements" cannot be displayed, secondary packaging should be provided bearing a label with those particulars. The primary packaging should nevertheless contain the following:**

(a) Name of sponsor, contract research organization or investigator;
(b) Route of administration and in the case of open label trials, the name/identifier and strength/potency;
(c) Batch and/or code number to identify the contents and packaging operation;
(d) Trial reference code; allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
(e) Trial subject identification number/treatment number and where relevant, the visit number.

N.B Particulars should appear in the official language(s) of the country in which the investigational medicinal product is to be used (If Arabic language is not applicable for the label, a leaflet or other explanatory document intended for the trial subject or person administering the product should be available in Arabic.). Other* suitable *languages could be included. The information which is to appear on the outer packaging and immediate packaging shall be clearly legible. Symbols or pictograms may be included to clarify certain information

mentioned above. Additional information, warnings and/or handling instructions may be displayed.
If it becomes necessary to change the use-by date, an additional label should be affixed to the investigational product. This additional label should state the new use by date and repeat the batch number. The original batch number should remain visible. This labelling activity should be performed in accordance with GMP principles and standard operating procedures and should be checked by a second person. This additional labelling should be recorded both in the trial documentation and in the batch records.

References:

1. WHO Good Manufacturing Practices for Investigational Products, Annex 7.
2. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 13.
3. Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards labelling requirements for unauthorized investigational and unauthorized auxiliary medicinal products for human use.