

Annex 23
to the Procedure for Conducting Expert
Evaluation of Registration Materials
Pertinent to Medicinal Products Submitted
for the State Registration (Re-registration)
and for Expert Evaluation of Materials
about Introduction of Changes to
Registration Materials during the Validity
Period of Registration Certificate
(item 2 of section V)

REQUIREMENTS for package labelling for medicinal product

1. Requirements for package labelling for finished medicinal product.

1.1. Requirements to particulars specified on package.

1.1.1. The outer package of medicinal products or, if failing this, on the immediate package shall contain the following information:

- 1) Bar-code of medicinal product;
- 2) Name of the medicinal product followed by INN and, if failing this, usual common name (where the product contains only one active substance); if name of the medicinal products is available in several pharmaceutical forms and/or different strengths, the pharmaceutical form and/or strength indicating whether this medicinal product is designed for children aged under 12 months, over 12 months or adults shall be specified;
- 3) active substances expressed qualitatively and quantitatively per dosage unit or according to the method of application for a given volume or weight, using their international non-proprietary or usual common names;
- 4) Pharmaceutical form and the contents by weight, by volume or by number of doses in a package;
- 5) List of those excipients (according to annex 24 to this Procedure) known to have a certain action or effect, and their names shall be given together with a statement such as "see instructions for medical use for further information". However, all excipients must appear on the package if the medicinal product is designed for parenteral, ophthalmic and topical use (medicinal products applied externally to the skin and transdermally, inhalation medicinal products and any oral, nasal, rectal or vaginal medicinal products, i.e. those with local or transdermal action);
- 6) Method and, if necessary, the route of administration of the medicinal product;
- 7) Special warning that the medicinal product must be kept out of reach of children, and, if necessary, out of sight of children;
- 8) Special warnings for use of medicinal product, if necessary;
- 9) Expiry date (month/year);

10) If necessary, special precautions for disposal of (un)used medicinal products or waste materials derived from such medicinal products, as well as, at the applicant's request, a reference to any suitable system for waste disposal on site;

11) Name and location of manufacturer and address where his activity takes place (manufacturer responsible for batch release of the medicinal product to be specified), and name and location of applicant or applicant's representative, if appropriate;

Where medicinal product is manufactured from "in bulk" product a statement "Manufacture from "in bulk" product", and a manufacturer of "in bulk" product responsible for batch release shall be specified along with the manufacturer's name;

12) Registration certificate number;

13) Manufacturer's batch number for the medicinal product;

14) If medicinal product is intended for self-medication, information for its use;

15) Storage conditions, special storage conditions, if necessary.

If there is no enough place for giving full information on the package, the data, listed in sub-items 1 - 4, 9, 11, 13 of this sub-item must be obligatory stated provided the instructions for medical use are available.

1.1.2. The outer package may include symbols or pictograms designed to clarify certain information mentioned in sub-item 1.1.1 of sub-item 1.1 of this item, and other information, corresponding to the summary of the product characteristics and which is useful for a patient, except for any elements contributing to promotion of this product on the market.

1.1.3. Information indicated in items 1.1.1 and 1.1.2 of sub-item 1.1 of this item shall be placed on all immediate packages except for cases specified in item 1.1.4 of item 1.1 of this item.

1.1.4. At least the following particulars shall appear on immediate package, which takes the form of blister packs, stripes etc., and on small immediate packages (ampoules, tube-droppers, syringe-tubes etc.) to be placed in an outer package that complies with the requirements laid down in items 1.1.1, 1.1.2 of sub-item 1.1 of this item:

1) name of the medicinal product;

2) weight, volume, concentration or number of units of activity of the medicinal product;

3) batch number of the medicinal product;

4) expiry date;

5) name of manufacturer and/or applicant, if necessary.

If there is no place on immediate package for giving the mentioned information, the data listed in sub-items 1, 2, 3 of this sub-item must be stated.

1.2. Package labelling requirements for medicinal products containing radionuclides

1.2.1. Outer package and immediate package of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transportation of radioactive materials, and shall comply with the following requirements:

1.2.2. The shielding label shall include the particulars stated in sub-item 1.1.1 of sub-item 1.1 of this item. In addition, the shielding label shall explain in full the coding used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the vial.

1.2.3. The label on the vial should contain the following information:

name or code of the medicinal product, including the name or chemical symbol of the radionuclide;

batch number and expiry date;

international symbol for radioactivity;

manufacturer name;

amount of radioactivity as specified in sub-item 1.2.2 of sub-item 1.2 of this item.

1.3. Requirements to package labelling for homeopathic medicinal products:

For homeopathic medicinal products which meet the requirements of annex 7 to this Procedure the following information shall be placed on the package labelling:

bar-code of the medicinal product;

scientific name of stock or stocks followed by the degree of dilution, making use of symbols of SPhU or other pharmacopoeia (European Pharmacopoeia, German Homoeopathic Pharmacopoeia (GHP), Homeopathic Pharmacopoeia of the United States (HPUS), British Homoeopathic Pharmacopoeia (BHP), Dr. Willmar Schwabe's Homeopathic Pharmacopoeia);

name and location of manufacturer and name and location of applicant or applicant's representative, if necessary;

method of use and route of administration, if necessary;

expiry date (month/year) (the last month when the drug fits for use)

pharmaceutical form;

contents of the sale presentation;

special storage conditions, if necessary;

special warnings for the medicinal product, if necessary;

manufacturer's batch number for the medicinal product;

registration certificate number;

statement «homeopathic medicinal product without approved therapeutic indications for use»;

warnings advising the user about the need to consult a doctor if the disease symptoms persist during the use of the medicinal product.

1.4. Requirements to package labelling for traditional medicinal products:

The labelling for traditional medicinal products shall contain detailed particulars indicated in sub-items 1.1.1 and 1.1.2 of sub-item 1.1 of this item. In addition, the following information shall be specified:

medicinal product is a traditional medicinal product with indications, confirmed by long lasting use;

user shall consult a doctor if the symptoms persist during the use of the medicinal product, or the adverse reactions which are not listed in the instructions for medical use are observed.

1.5. Requirements to package labelling for medicinal products containing one or more narcotic products and/or psychotropic substances:

Detailed particulars indicated in sub-items 1.1.1 and 1.1.2 of sub-item 1.1 of this item shall appear on the package of medicinal products containing one or more narcotic products and/or psychotropic substances. In addition, an immediate package shall be marked with a double red stripe.

1.6. Requirements to labelling texts on package for medicinal product:

1.6.1. Data on the package shall be not less than of 7 Didot' type.

1.6.2. Text of labelling shall be in Ukrainian. At the manufacturer's/applicant's request text of the labelling may be stated in regional language or minorities' language alongside with the Ukrainian text provided the same information is given in the above languages.

1.6.3. In certain cases, information on the package may be placed using a sticker to be approved by the Center provided this is justified properly and agreed upon with MoH.

Information placed on stickers shall comply with requirements of items 1 and 2 of this annex.

1.6.4. On the outer package for medicinal product (except for API and "in bulk" product) the name of medicinal product, strength of active substance and pharmaceutical form shall also be specified in Braille format according to the Procedure of labelling medicinal products using Braille format approved by MoH Ukraine Order of August 25, 2010 № 722, registered at the Ministry of Justice of Ukraine on November 05, 2010 № 1044/18339.

1.7. Requirements to excipients to be placed on the package.

1.7.1. Names of excipients on the package shall be given as follows:

Excipients shall be referred to by their INNs according to the European Pharmacopeia, or failing this, their usual common name.

Name of an excipient must be accompanied by the E number, if any. The E number alone may be used on the package, provided the full name (INN, if failing this, usual common name) and the E number are stated in the instructions for medical use, in the section "Composition";

Proprietary flavors or fragrances shall be specified in general terms (e.g. 'orange flavor', 'citrus fragrance/perfume'); any known major components or those with a recognised action or effect should be specified;

Chemically modified excipients shall be declared in such a way as to avoid confusion with the unmodified excipient (e.g. pre-gelatinised starch);

All components of compound excipients or mixtures shall be specified, included in the description of composition with indication of main components (e.g. printing ink containing x, y, z). A general descriptive term of compound excipient or mixture may be used on the package provided more information is given in the instructions for medical use. Any component with a recognized action or effect shall be specified on the package.

These requirements shall not be applied to labelling of API or “in bulk” product.

1.7.2. List of excipients to be obligatory specified on the package and information on the effect of these substances depending on the route of administration and content of excipient to be indicated in the instructions for medical use indicated in annex 24 to this Procedure.

{Annex 23 in wording of MoH Ukraine Order №460 as of 23.07.2015}