

Annex 20
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 Instructions for medical use for medicinal product

1. Instructions for medical use accompanying the medicinal product shall be compiled according to the summary of products characteristics approved in the applicant's/manufacturer's country or according to the official information on use of the medicinal product approved according to regulatory requirements of the applicant's/manufacturer's country or other country the regulatory authority of which follows the high quality standards complying with the WHO recommended standards, and/or results of clinical trials.

2. Instructions for medical use shall accompany the medicinal product if the information included in the instructions is not stated on the outer or immediate packaging of the medicinal product.

3. Text of instructions for medical use shall be clearly stated in Ukrainian. At the manufacturer's/applicant's request the text of instructions may be additionally stated in regional language or minorities' language along with the Ukrainian text provided the same information is given in the texts in other languages used.

4. For certain medicinal products the requirement to indicate some data on the use of the medicinal product in instructions for medical use may be cancelled provided that medicinal product is not intended for self-medication by a patient.

5. The font size shall be as large as possible for easier readability. Minimal requirements include: font 8 Didot' type with line spacing of at least 1 mm.

6. The number and date of MoH Ukraine Order on state registration or re-registration of medicinal product according to which the medicinal product concerned is approved for medical use in Ukraine, and the number of registration certificate shall be placed at the upper right hand corner of the instructions for medical use to be inserted in the outer package of the medicinal product.

7. Instructions for medical use shall contain the following information:

7.1. Name of the medicinal product.

7.2. Full qualitative composition (of active substances and excipients) and quantitative composition (of active substances) using common names for each presentation of the medicinal product (strength and package).

7.3. Pharmaceutical form.

Main physicochemical properties.

7.4. Pharmacotherapeutic group. ATC code.

7.5. Pharmacological properties and, if such information is useful for treatment, pharmacokinetic characteristics or immunological and biological properties.

Section "Pharmacological properties" for medicinal products not subject to medical prescription shall be stated in language understandable to patient, and, at applicant's request, information may be reduced.

Section "Immunological and biological properties" is a section of instructions for medical use of some categories of medical immunobiological products (vaccines, toxoids etc.).

7.6. Clinical particulars:

Therapeutic indications.

7.7. Contraindications.

7.8. Special warnings and precautions for use to be followed by persons who handle medicinal products and administer them to patients, and all precautions to be followed by patients, if appropriate.

7.9. Interaction with other medicinal products and other forms of interaction.

7.10 Peculiarities of use:

7.10.1. Specify and provide information on all excipients, knowledge of which is essential for safe and effective use of the medicinal product (according to annex 24 to the Procedure).

7.10.2. Pregnancy and lactation.

7.10.3. Effects on ability to drive and use machines.

7.11. Posology and method of administration to adults.

7.11.1. Pediatric population.

7.12. Overdose (symptoms, urgent treatments and antidotes).

7.13. Adverse reactions (frequency and severity, if any).

7.14. Shelf life (the shelf life after the medicinal product manipulation for direct use, e.g. after dilution or reconstitution or after first opening of immediate packaging, if appropriate).

7.15. Storage conditions.

7.16. Incompatibility (main types) if the information available.

7.17. Nature and contents of immediate package (container).

7.18. Special precautions for disposal of a (un)used medicinal product or waste materials derived from such medicinal product, if applicable.

7.19. Dispensing category for medicinal product established during state registration/re-registration/introduction of changes to registration materials with due respect of requirements of MoH Ukraine Order of May 17, 2001, № 185 “On Approval of Criteria for Referring Medicinal Products to Dispensing Categories” registered with the Ministry of Justice of Ukraine on May 31, 2001 under № 464/5655.

7.20. Name and location of manufacturer and address where his activity takes place (manufacturer responsible for batch release of the medicinal product, and optionally other manufacturers involved in the manufacture, to be specified), and at applicant’s request – name and location of applicant’s and/or applicant’s representative.

7.21. Date of revision of instructions for medical use (date of the MoH Ukraine Order on registration/re-registration/introduction of changes into instructions for medical use for medicinal product during validity period of registration certificate to be specified).

7.22. For radiopharmaceutical medicinal products, full details of internal radiation dosimetry, additional detailed instructions for extemporaneous preparation and quality control of such preparations and, where appropriate, maximum storage period during which any intermediate preparation such as an eluate or the ready-to-use medicinal product will conform with its specifications.

Besides, instructions for medical use for radiopharmaceutical medicinal products shall describe all precautions, which are to be followed by medical staff and patients during preparation and use of medicinal product, and also special precautions for disposal of package or its (un)used content.

8. Instructions for medical use may include symbols or pictograms which clarify information specified in it, and other information compatible with summary of product characteristics which is useful for health education except for advertising information which contributes to the promotion of medicinal products on the market.

9. Instructions for medical use for traditional herbal medicinal product shall note that:

medicinal product is a traditional herbal medicinal product designed for use according to indications justified by a long-term use;

the user shall consult a doctor if the disease symptoms have not disappeared during the use of the medicinal product or,

adverse reactions not specified in instructions for medical use for medicinal product are observed.

10. Instructions for medical use for homeopathic medicinal products which comply with requirements stated in annex 7 to the Procedure shall contain:

Statement “homeopathic medicinal product without approved therapeutic indications for use;

Warning advising the user to consult a doctor if the symptoms persist during use of the medicinal product.

{ Annex 20 in wording of MoH Ukraine Order №460 as of 23.07.2015 }