Medicines Labelling

Labelling - is information on the package of a medicine.

Medicine packaging is means or a set of means ensuring the medicine circulation process by protecting it from damage and loss, as well as protecting the environment from pollution.

Medicine labelling requirements

- clearly readable fonts in Kazakh and Russian;
- instructions for medical use (package leaflet) in Kazakh and Russian languages;
- the labelling on the package is the same for each series of medicines;
- the package marking is not in conflict with or misleading information contained in the registration dossier documents and is not of an advertising nature;
- applied in clear, legible, easily visible and indelible letters, in a readable font and retained for the entire shelf life of the medicine, provided the prescribed storage conditions are complied with.

What does the labelling include?

- the trade name of the medicine;
- international nonproprietary name (if available) in Kazakh, Russian and English;
- name of the medicine manufacturer, address (address must be indicated in full or in abbreviated form (city, country);
- name of the packer, date and time of packing (if it is not the manufacturer);
- name of the marketing authorisation holder, address (city, country);
- dosage form;
- dosage and/or activity and/or concentration (if applicable) of the active pharmaceutical substance(s);
- the quantity of the medicine in the package by weight, volume or number of dosage units, depending on the dosage form and packaging type;
- information about the composition of the medicine;
- for medicinal plant preparations that are packed medicinal plant raw materials, weight of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin is indicated at a certain moisture content;
- for medicines containing in their composition substances controlled in accordance with Law of the Kazakhstan Republic dated July 10, 1998 "On narcotic medicines, psychotropic substances, their analogues and precursors and measures of counteraction to their illicit trafficking and abuse" names of such substances and their content in weight units or percentage are indicated;
- in single-component medicines, if the name of the medicine and the active pharmaceutical ingredient are authentic and the dosage, concentration, activity is indicated, the composition of the active pharmaceutical ingredient should not be specified;
- a list of excipients:
- for parenteral, ophthalmic and topical preparations, a list of all excipients shall be given;
- for infusion solutions, the qualitative and quantitative composition of all excipients shall be listed;
- for other dosage forms, a list of antimicrobial conservatives, colourings as well as sugars and ethanol;

- the list of excipients to be indicated in the labelling of medicines to be intaken is given in the annex to the Rules for labelling medicines and medical devices;
- for infusion solutions containing more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated;
- the way of use and, depending on the dosage form, the medicine route (does not apply for tablets and capsules to be intaken);
- precautions and warning notices;
- storage conditions and, if applicable, transport conditions;
- conditions for dispensing (with or without prescription);
- serial number;
- date of manufacture (if not inserted in the series number);
- expiry date: "valid until (date, month, year)" or "(date, month, year)" with expiry date determined until the last day of the month indicated;
- registration number of the medicine in the form of the notation "RK-LS-";
- barcode (if any).

Registration requirements

When carrying out an expert review, the expert organisation[1] shall check the translation validity or translation of the general description of the medicine, instructions for medical use (package leaflet), package labelling layouts, labelling stickers into the Kazakh language.

[1] RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan