EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No76** Astana city

on the Adoption of the Requirements for the Labelling of Medicinal Products for Human Use and Veterinary Medicinal Products

Pursuant to Articles 30 and 56 of the Treaty on the Eurasian Economic Union of 29 May 2014, Paragraph 14 of Appendix No. 12 to the Treaty on the Eurasian Economic Union of 29 May 2014, Article 8 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraphs 57 and 97 of Appendix No. 1 to the Regulations of the Eurasian Economic Commission as approved by Decision No. 98 of the Supreme Eurasian Economic Council of 23 December 2014, and by Decision No. 108 of the Supreme Eurasian Economic Council of 23 December 2014 on the Implementation of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union, the Council of the Eurasian Economic Commission has decided:

1. To adopt the attached Requirements for the Labelling of Medicinal Products for Human Use and Veterinary Medicinal Products (hereinafter referred to as the Labelling Requirements)

2. This Decision shall enter into force on the 10th day following that of entry into force of the Protocol of 2 December 2015 on the Accession of the Republic of Armenia to the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, but not earlier than on the 10th day following that the official publication of this Decision, except for the provisions (approved by this Decision) of the Labelling Requirements related to the labelling of veterinary medicinal products.

The provisions of the Labelling Requirements related to the labelling of veterinary medicinal products shall enter into force on entry into force of the Rules for the Regulation of the Circulation of Veterinary Medicinal Products as adopter by the Council of the Eurasian Economic Commission in accordance with Paragraph 57 of Appendix No. 1 to the Regulations of the Eurasian Economic Commission as adopted by Decision No. 98 of the Supreme Eurasian Economic Council of 23 December 2014.

Members of the Board of the Eurasian Economic Commission:

From the Republic of Armenia	From the Republic of Belarus	From the Republic of Kazakhstan	From the Republic of Kyrgyzstan	From the Russian Federation
V. Gabrielyan	**V. Matyuschevsky**	**A. Mamin**	**O. Pankratov**	**I. Shuvalov**

ADOPTED
by Decision No. 76 of the Council of the Eurasian Economic Commission of 3 November 2016

REQUIREMENTS
for the Labelling of Medicinal Products for Human Use and Veterinary Medicinal Products

I. GENERAL PROVISIONS

1. These Requirements lay down the rules for the labelling on the packaging of medicinal products for human use (hereinafter referred to as medicinal products) and veterinary medicinal products (hereinafter referred to as veterinary products) released for circulation in the common market of medicinal products within the Eurasian Economic Union (hereinafter referred to as the Union).

2. The labelling of medicinal/veterinary products shall be in Russian and, if so provided by the applicable laws of the Member States of the Union (hereinafter referred to as the Member States), in the official language(s) of the Member State where the medicinal/veterinary products are distributed.

Other languages may be used provided that the information is fully identical.

The labelling of medicinal/veterinary products shall not contradict or bias the information provided in the marketing authorisation application dossier and shall not be promotional in nature.

3. The labelling of medicinal/veterinary products shall be easily legible, clearly comprehensible and should not mislead the consumers/purchasers of the medicinal product or veterinary medicinal product (hereinafter referred to as veterinary product).

4. For the purposes of these Requirements, the following terms shall bear the following meaning:

"secondary/consumer packaging" means packaging into which a medicinal product/veterinary product in the primary or intermediate packaging is placed for sale to consumers;

"labelling" means any information printed on the packaging of a medicinal product/veterinary product;

"primary/internal packaging" means packaging which is in immediate contact with the medicinal product/veterinary product;

"intermediate packaging" means packaging into which the primary packaging may be placed for the additional protection of a medicinal/veterinary product or based on the way of use the medicinal/veterinary product;

"packaging" means any material or device that ensures protection of the quality of the medicinal/veterinary product during its shelf life and protects the medicinal/veterinary product from deterioration or loss and prevents from polluting the environment;

"blister pack" means a flexible packaging containing a medicinal/veterinary product in pre-formed cavities from which the medicinal/veterinary product is taken out by extrusion.

Other terms have the meanings as laid down in the international treaties and acts which constitute the law of the Union.

The requirements for packaging specimens and mock-ups are laid down in the Rules for granting a marketing authorisation and assessment of medicinal products for human use approved by the Eurasian Economic Commission (hereinafter referred to as the Commission).

II. GENERAL LABELLING REQUIREMENTS

5. The following particulars shall appear on the primary/immediate packaging (hereinafter referred to as primary packaging) of a medicinal/veterinary product (except for pre-packaged herbal substances):

a) the brand name of the medicinal/veterinary product;

b) the international non-proprietary name (hereinafter referred to as INN) (if one exist) or common/generic name;

c) the pharmaceutical form;

d) the strength and/or potency and/or concentration, as applicable, of the active substance(s);

e) the contents of the medicinal/veterinary product per package;

f) the route of administration;

g) the name or logo of the marketing authorisation holder or the manufacturer, if necessary, of the medicinal product or name or logo of the holder of the veterinary product marketing authorisation;

h) the batch number;

i) the expiry date (‘best before…’).

6. The information referred to in subparagraphs c and e of paragraph 5 of these Rules may be omitted on immediate packaging which take the form of blister packs and are placed in an outer packaging.

7. The information referred to in subparagraphs b, c, and g of paragraph 5 of these Rules may be omitted on small immediate packaging units (total area of text is less than 10 cm^2) which take the form of blister packs and are placed in an outer packaging.

8. The following particulars shall appear on the outer packaging of a medicinal/veterinary product or, where there is no outer packaging, on the immediate packaging:

a) the brand name of the medicinal/veterinary product;

b) the INN (if one exists) or common/generic name;

c) the name of the marketing authorisation holder and the manufacturer of the medicinal product or name of the marketing authorisation holder and the manufacturer of the veterinary product;

d) the address of the marketing authorisation holder and the manufacturer of the medicinal product or address of the marketing authorisation holder and the manufacturer of the veterinary product;

e) the pharmaceutical form;

f) the strength and/or potency and/or concentration, as applicable, of the active substance(s);

g) the contents of the medicinal/veterinary product per package;

h) a statement of the composition of the medicinal/veterinary product;

i) the batch number;

j) the date of manufacture;

k) the expiry date (‘best before…’);

l) storage conditions and, if necessary, shipping conditions;

m) the route of administration;

n) the supply category;

o) precautional statements;

p) the authorisation number for veterinary products.

9. For products manufactured either with or without a preservative, the secondary packaging of a product that contains no preservatives shall include the following information after the list of excipients: ‘Contains no preservatives.’

10. If the information on the primary packaging cannot be read without compromising the integrity of the intermediate packaging, the information on the latter shall at least bear the same information on the primary packaging.

11. The following information shall be specified on the packaging of active substances:

a) the brand name of the active substance (if one exists);

b) the INN or common/generic name:

c) the name and address of the manufacturer of the active substance;

d) the batch number;

e) the date of manufacture;

f) the content of the active substance per the package;

g) the expiry date (‘use by…’) or, if applicable, retest date;

h) storage conditions;

i) the use.

12. Secondary packaging of a kit (medicinal/veterinary product with a solvent/diluent) or a combination pack of two or more medicinal/veterinary products shall bear the following information:

a) information on the components of the kit (combination pack):

the names of the components;

the strength and/or potency and/or concentration, as applicable, of the active substance(s);

statement of the composition;

the contents;

the batch number (in accordance with paragraphs 28 and 29 of these Requirements);

b) information on ancillary medical devices (syringes, tampons, delivery devices, etc.)

13. A statement of any selected set of information regarding the general characteristics of a medicinal product described in sections Clinical data and Pharmacodynamic properties of the Summary of Product Characteristics or equivalent sections of the Medication Guide/Patient Leaflet of that medicinal product on packaging shall not be allowed.

The text of the Medication Guide/Patient Leaflet of a medicinal product and the text of the Instructions for use/Package Leaflet of a veterinary product may be provided on the packaging.

14. Any additional information may be provided on secondary packaging of a medicinal/veterinary product where it corresponds to the documents of the marketing authorisation application dossier.

A packaging may also contain a barcode, holographic and other protective signs, stickers, text duplicates in other languages and in Braille, symbols or pictograms that help clarify information on the medicinal/veterinary product to a consumer/purchaser.

15. If the intermediate or secondary packaging of a medicinal product contains desiccant sachets or tablets, they shall contain a respective warning labelling.

16. The following information shall be provided on shipping containers of bulk products:

a) the brand name of the medicinal/veterinary product;

b) the pharmaceutical form;

c) the INN or common/generic name, if applicable;

d) the strength and/or potency and/or concentration, as applicable, of the active substance(s);

e) the name and address of the manufacturer of the medicinal/veterinary product;

f) the content of the medicinal/veterinary product per the package and/or the number of packages in a shipping container;

g) storage conditions and, if necessary, shipping conditions;

h) the batch number;

i) the date of manufacture;

j) the expiry date (‘use by…’).

Where necessary a product manufacturer’s logo, precautionary labelling, and markings for handling may be provided on the packaging.

III. REQUIREMENTS FOR INFORMATION ON THE LABELLING

17. The trade name of the medicinal/veterinary product on the packaging shall be provided in the nominative case.

Additionally for herbal medicinal products representing pre-packaged herbal substances, the Latin name of the herbal substance or herbal preparation (except for the name of the collections) in plural (except for the words ‘grass’ and ‘bark’) and the type of a pre-packaged product (e.g., ‘whole’, ‘crushed’, ‘powder’, etc.) should be provided.

18. The INN of the active substances of a medicinal/veterinary product shall be provided in Russian in the nominative case and in English (in accordance with the English version of the INN List of the World Health Organisation).

If no INN exists, the common/generic name in Russian in the nominative case shall be provided.

The INN or the common/generic name of medicinal/veterinary products may not be provided if it is the same as the brand name.

For heterologous immunosera products, the species whose blood or plasma was used shall be provided.

If no INN exists or common/generic name for biological medicinal/veterinary products, the source of the product shall be provide.

A packaging of medicinal/veterinary radiopharmaceuticals shall bear the chemical symbol of the element together with the radionuclide index and the international symbol for radioactivity.

19. The names of the marketing authorisation holder and the manufacturer of a medicinal product or names of the marketing authorisation holder and the manufacturer of a veterinary product shall be provided in the nominative case. If several manufacturers participate in the manufacturing, the name of the manufacturer performing the release testing of the medicinal/veterinary product shall be provided.

If the names of the marketing authorisation holder and the manufacturer of the medicinal product or names of the marketing authorisation holder and the manufacturer of the veterinary product coincide, the name of the medicinal product marketing authorisation holder or the veterinary product marketing authorisation holder shall only be provided.

Where necessary the name of the filling and/or packaging site shall be provided together with the preceding wording ‘filled by’ and/or ‘packaged by’ or ‘packager’, as appropriate.

20. The addresses may be provided in concise way (country or city and country) or in full; telephone, fax, and email may be additionally provided.

If a medicinal product marketing authorisation holder or veterinary product marketing authorisation holder is the same as a manufacturer of that product, only the address of the medicinal product marketing authorisation holder or veterinary product marketing authorisation holder shall be provided.

21. The strength and/or potency and/or concentration of the active substance(s) shall be provided together with respective the units of measurement.

22. The contents of the medicinal/veterinary product in the package may be expressed in weight, volume, or number of dosage units depending on the pharmaceutical form and type of packaging.

For herbal medicinal products representing pre-packaged herbal substances, the weight of the herbal substance and/or herbal preparation shall be provided at its specified humidity.

The strength/potency of a biological medicinal product shall be expressed in accordance with the Requirements for the Medication Guide and Summary of Product Characteristics of medicinal products for human use subject to approval by the Commission.

For medicinal/veterinary radiopharmaceuticals, the amount of radioactivity per dose or container shall be indicated.

23. The active substances (components) and their amount shall be stated in the composition of medicinal/veterinary products.

24. A list of excipients shall be provided in the following cases:

a) on the secondary packaging of the oral medicinal/veterinary products if they are included in the List of excipients to be provided in the secondary packaging of oral medicinal/veterinary products, in accordance with the Appendix to these Requirements;

b) on the secondary packaging of medicinal/veterinary products for injections, the full qualitative composition;

c) on the secondary packaging of inhalational medicinal/veterinary products, the full qualitative composition;

d) on the secondary packaging of topical medicinal/veterinary products, the full qualitative composition;

e) on the secondary packaging of ophthalmological medicinal/veterinary products, the full qualitative composition;

f) on the secondary and primary packaging of solutions for infusion, the full qualitative and quantitative composition.

The medicinal product marketing authorisation holder or veterinary product marketing authorisation holder may provide full qualitative and quantitative composition of the excipients on packaging.

On the primary and secondary packaging of infusion solutions, the theoretical value of osmolality is indicated.

On the secondary packaging of immunological medicinal/veterinary products, the amount of preservatives, sorbents and adjuvants is specified.

25. The composition of homeopathic medicinal/veterinary products shall be provided in accordance with terminology adopted in homeopathy; Latin names of homeopathic stocks shall be provided together with scale and degree of their dilution; Russian names of the excipients shall be provided in accordance with marketing authorisation application dossier.

26. For herbal medicinal/veterinary products representing pre-packaged herbal substances, the composition shall be provided for collections only.

27. References to quality standards for active substances and/or excipients shall not be indicated.

28. The manufacturing date may be omitted if it is included in the batch number.

29. Secondary packaging of a kit (medicinal/veterinary product with a solvent/diluent) or a combination pack of two or more medicinal/veterinary products shall additionally bear the batch numbers of all medicinal/veterinary products in the kit/combination pack or the kit/combination pack batch number.

30. The expiry date provided on packaging of a medicinal/veterinary product shall consist of the month and year; the expiry date in this case shall mean the last day of the appropriate month.

Where necessary shelf-life and storage conditions of a medicinal/veterinary product after first opening or following reconstitution shall be provided in accordance with the Medication Guide and stability data taking into account the Requirements for the Medication Guide and Summary of Product Characteristics of medicinal products for human use.

Secondary packaging of a kit (medicinal/veterinary product with a solvent/diluent) or a combination pack of two or more medicinal/veterinary products shall bear the release date of the kit/combination pack and expiry dates of each element or a single expiry date for the kit/combination pack shall be provided.

Where the expiry date is provided for each element separately, the expiry date of the entire kit/combination pack shall be considered to be the earliest expiry date of the elements constituting the kit/combination pack.

31. For herbal medicinal/veterinary products representing pre-packaged herbal substances, the method of obtaining of aqueous extracts shall be provided together with shelf-life and storage conditions of the latter.

32. The route and method of administration shall be provided in accordance with the Summary of Product Characteristics and Instructions for Use of the given veterinary product. The route/method of administration shall not be provided if it is included in the name of the pharmaceutical form. Method of administration for tablets and capsules for oral use may be omitted.

The following wording may be indicated: ‘Method of administration: see the Medication Guide (Patient Leaflet)’ for a medicinal product or ‘Method of administration: see the Instructions for Use (Package Leaflet)’ for a veterinary product.

33. Small immediate packaging units (total area of text is less than 10 cm^2) not allowing to provide all necessary information may provide the following conventional abbreviations for the routes of administration of injectable medicinal/veterinary products: ‘IV’ (intravenous administration), ‘IM’ (intramuscular administration), or ‘SC’ (subcutaneous administration).

34. Where a package allows, it is preferable to provide full information on the method of administration of the medicinal product in accordance with the Summary of Product Characteristics and Instructions for Use of the given veterinary product.

35. Labelling conventions of narcotic or psychotropic medicinal/veterinary products or their precursors are provided in the applicable laws of the Member States.

36. The supply category of a medicinal product shall be provided in accordance with the supply category as authorised for marketing and determined in accordance with Rules of determining of supply category of medicinal products subject to prescription and not subject to prescription subject to approval by the Commission; the supply category of veterinary products shall be in accordance with their Instructions for Use.

The following information shall be provided on the packaging of the medicinal/veterinary products supplied for hospitals only: ‘For hospitals’. In this case, the phrase ‘Prescription only’ (‘Over the counter’) shall not be provided.

37. The following precautionary markings and symbols shall be provided on the secondary packaging:

a) ‘Keep out of reach of children’;

b) ‘Sterile’ (for sterile medicinal/veterinary products);

c) ‘No HIV-1/HIV-2, hepatitis C virus antibodies or hepatitis B surface antigen was detected’ (for medicinal products derived from human blood, plasma, organs, or tissues);

d) ‘Homeopathic’ (for homeopathic medicinal/veterinary products);

e) Ionizing radiation trefoil warning symbol (for medicinal/veterinary radiopharmaceuticals);

f) ‘This product has passed radiation control’ (for herbal medicinal/veterinary products representing pre-packaged herbal substances);

g) ‘For veterinary use’ (for veterinary products).

Where necessary other precautionary marks and symbols may be provided on the packaging if so prescribed by the normative document on quality.

38. The labelling of a registrable homeopathic medicinal product registered in accordance with a simplified registration procedure (as laid down in the Rules for granting a marketing authorisation and assessment of medicinal products for human use) shall contain the following information only and no other data:

a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used for this registration procedure in accordance with Rules for granting a marketing authorisation and assessment of medicinal products for human use; if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by a brand name;

b) the name and address of the registration holder and, where appropriate, of the manufacturer;

c) the method of administration and, if necessary, route;

d) the expiry date, in clear terms (month, year);

e) the pharmaceutical form;

f) the contents of the sales presentation;

g) special storage precautions, if any;

h) a special warning if necessary;

i) the manufacturer’s batch number;

j) the registration number (for veterinary products);

k) a statement: ‘homeopathic medicinal product without approved therapeutic indications’;

l) a warning advising the user to consult a doctor if the symptoms persist.

IV. REQUIREMENTS FOR THE LABELLING METHODS

39. The colour of the statements, marks, and symbols in the labelling of medicinal/veterinary products shall be chosen to ensure a good contrast between the text and the background. The printing method shall ensure preservation of labelling during the entire shelf-life of a medicinal/veterinary product, provided that the established storage conditions are met. The

batch number, manufacturing date, and expiry date may be embossed; in this case the symbols and the background should be of the same colour.

The requirements for drawing up and laying out of the Medication Guides provided in Requirements for the Medication Guide and Summary of Product Characteristics of medicinal products for human use are also applicable to the labelling of medicinal products. It is recommended that particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm. The text on small packs shall be presented in as large a type size as possible to reduce the likelihood of medication error.

40. The surface available on the primary and secondary packaging of medicinal/veterinary products should be used in the best way possible. Information important for the accurate and safe use of the medicinal/veterinary product should be indicated in as large a type size as possible on the most suitable surfaces of the packages.

The name of a product, its strength, and, if applicable, the total amount of the active substance, as well as the route of administration shall be provided in one visual field using the largest possible font size. If it is not possible to fit all critical information in one visual field of a small pack, it may be placed in different fields. To ensure readability of the information provided, reasonable space between the lines and between words with respect to the font size shall be left.

41. Company logos and pictograms may be presented, where space permits, on the outer packaging and on immediate packaging, provided they do not interfere with the legibility of the mandatory information.

42. The use of any innovative technique in packaging design to aid in the identification and selection of the medicinal/veterinary product by consumers/purchasers is allowed.

43. Highly glossy, metallic or reflective packaging should be avoided, as this affects the legibility of the information. Different colours in the name of the medicinal/veterinary product are discouraged since they may negatively impact on the correct identification of the product name.

Similarity in packaging of medicinal/veterinary products which contributes to medication error can be reduced by the judicious use of colour on the pack and other methods. The number of colours used on packs will need careful consideration as too many colours could confuse consumers/purchasers. Where colour is used on the outer pack of a medicinal/veterinary product, it is recommended that it is carried onto primary packaging to aid identification of the medicine by consumers/purchasers.

44. The labelling of medicinal/veterinary products released for circulation in the Member States shall follow single patterns. Where differences exist (supply category etc.), these shall be provided on an additional label/sticker in a special place on the secondary packaging. Where a place for special information of the Member State is provided on the secondary packaging, such information (e.g., a different supply category or special information: ‘Hospital packs’, ‘For governmental programmes’, etc.) may be provided therein without using a label/sticker.

The size of the place for stickers may not be larger than 1/6 of the total surface of the secondary packaging, and this place shall not cover the initial secondary packaging labelling.

45. For orphan products and certain medicinal products, an additional label/sticker may be used if so approved by the competent authority of the Member State that authorised the medicinal product for marketing.

46. Use of different colours to visually distinguish different strengths/concentrations of a medicinal products having the same pharmaceutical form.

Different strengths of the same medicinal product should be expressed in the same manner: for example 250 mg, 500 mg, 750 mg, 1000 mg and NOT 1 g. Trailing zeros should not appear (2.5 mg and NOT 2.50 mg). The use of decimal points (or comma) should be avoided where these can be removed (i.e. 250 mg is acceptable whereas 0.25 g is not). For safety reasons it is important that

micrograms is spelt out in full and not abbreviated. However, in certain instances where this poses a practical problem which cannot be solved by using a smaller type size then abbreviated forms may be used, if justified and if there are no safety concerns.

47. The route of administration should be as registered in the summary of product characteristics only according to the standard terms. Negative statements should not be used: for example “Not for intravenous use”. In principle only standard abbreviations may be acceptable (i.v., i.m., s.c.,). Other nonstandard routes of administration should be spelled out in full. Some routes of administration will be unfamiliar to patients and may need to be explained within the package leaflet. This is particularly important when medicinal products are made available for self-medication.

48. Where a multi-lingual outer and/or immediate packaging is proposed there should be a clear demarcation between different languages.

49. For blister pack presentations, it is important that the particulars remain available to the user up to the point at which the last dose is removed. Often it will not be possible to apply all the information over each blister pocket, consequently where a random display of the information is proposed it should frequently appear across the pack. In all cases it will be acceptable to apply the batch number and expiry date to the end of the blister strip. If technically possible, applying this information to both ends of each strip should be considered. Where a unit-dose blister presentation is proposed all the information required for blister packs must appear on each unit dose presentation.

APPENDIX
to the Requirements for the Labelling of Medicinal Products for Human Use and Veterinary Medicinal Products

LIST
of excipients to be stated on the secondary packaging of medicinal/veterinary products for oral use

	Code of excipient	Threshold
Azo colouring agents:		
Sunset Yellow	E110	0
Azorubine (Carmoisine)	E122	0
Crimson (Ponceau 4R red, Cochineal Red A)	E124	0
Brilliant Black BN (Black PN)	E151	0
Peanut butter		0
Aspartame	E951	0
Galactose		0
Glucose (dextrose)		0
Glycerol (glycerine)		10 g/dose
Isomaltitol (isomaltite)	E953	0
Potassium-containing compounds		39 mg/dose
Castor oil polyoxyl and castor oil polyoxyl hydrogenated		0
Preservatives		0
Xylitol (xylite)		10 g
Sesame oil		0
Lactitol (lactite)	E966	0
Lactose		0
Latex (natural rubber)		0
Maltitol (maltite)	E965	0
Mannitol (mannite)	E421	10 g
Urea		0
Sodium-containing compounds		23 mg/dose
Propylene glycol and ethers		400 mg/kg for adults 200 mg/kg for children
Wheat starch		0
Inverted sugar		0
Sucrose		0
Soya oil		0
Sorbitol (sorbite)	E420	0
Phenylalanine		0
Formaldehyde		0
Fructose		0
Ethanol* (ethyl alcohol)		0

* V/V in liquid pharmaceutical forms.