ANNEX

to Decision of the Council
of the Eurasian Economic Commission
No. _____ dated _____,
20_____

AMENDMENTS
to the Requirements for Labelling Medicinal Products for Human Use and Veterinary Medicines

1. In these Rules, wording “instructions for human use of the medicinal product and summary product characteristic” should be replaced with “patient information leaflet and summary of product characteristics.”

2. In paragraph 4:

(a) indent 7 shall read as follows:

"a blister pack (blister)" is a flexible pack with a medicinal product for human use (veterinary medicinal product) in molded pockets, from which the medicinal product for human use (veterinary medicinal product) is removed by extrusion;”;

(b) in indent 9, delete the words “samples and.”

3. In paragraph 5, subparagraph (i), replace the words "best before date" with the word "best before."

4. Paragraphs 6 and 7 shall read as follows:

"6. On the primary package in form of a blister pack (blister) (hereinafter, blister), which is placed in a secondary (commercial) package (hereinafter, secondary package), information specified in subparagraphs (c) and (e) of these Requirements may be omitted, and information specified in

paragraph 5, subparagraph (i), of these Requirements may be specified in the form of month and year with a separating position (e.g., in the format of "02.2023", "02/2023", "02_2023" or "02 23", "02.23", "02/23", "02_23"). Similarly, the expiration date may be indicated on the tubes at the sealing or soldering points.

7. On the small primary package, which cannot accommodate all the required information and is placed in the secondary package, the information specified in paragraph 5, subparagraphs (b), (c) and (g), of these Requirements may be omitted, and the information provided for in paragraph 5, subparagraph (i), of these Requirements may be indicated in the form of month and year in accordance with paragraph 6 of these Requirements.".

5. Paragraph 8, subparagraphs (i) to (k), shall read as follows:

(i) batch number (for high-technology medicinal products, if applicable, donation identification codes are indicated);

(j) date of manufacture (for immunological veterinary medicinal products, the date of batch release into the stream of commerce);

(k) expiration date ("best before…" in the format specified in paragraph 30 of these Requirements);".

6. In paragraph 11, subparagraph (g), and paragraph 16, paragraph (j), the words "best before end..." should be replaced with the words "best before..." in the format specified in paragraph 30 of these Requirements.”

7. Paragraph 17, indent 2, shall read as follows:

"For medicinal herbal preparations that represent prepackaged herbal substances or herbal preparation, the name (except for the names of combination herbal products) formed by specifying the used part of the producing plant (morphological group) in the nominative case plural (except for the words "herb" and "bark") and the name of the producing plant in the genitive case, and the type of prepackaged product (e.g. "whole", "crushed",

"powder", etc.) shall be indicated. In addition, the name of the herbal substances or herbal preparation shall be indicated in Latin.".

8. In paragraph 18:

in indent 2, the word “name” should be followed by the word “only”;

indent 5 should be followed by the following indent:

“For high-technology medicinal products containing cells or tissues, the following shall be indicated: “the medicinal product contains cells of human (animal) origin” followed by a brief description of such cells or tissues and their direct origin, including the type of animal in the case of animal cells.".

9. In paragraph 22:

indent 1 shall read as follows:

"22. The quantity of the medicinal product (veterinary medicinal product) in the package shall be indicated by weight, volume, number of dosage units or dosing units depending on the dosage form and type of package.";

in indent 2, the words "active substance of herbal origin" shall be replaced by the words "herbal preparation."

10. Paragraph 24, subparagraph (f), shall be supplemented with the following sentence: "Except for high-technology medicinal products containing genetically modified cells, for which only a description of the preservative system is given.".

11. Paragraph 28 shall read as follows:

"28. The format of applying the batch number is established by the manufacturer of the medicinal product (veterinary medicinal product). The date of manufacture is allowed to be omitted if it is contained in the batch number and can be identified when reading the batch number.

The date of manufacture on the package of the medicinal product for human use (veterinary medicinal product) shall be specified in the format

MM.YYYY or MM/YYYYY (month, calendar year). For medicinal products with an expiration date of less than 12 months, the date of manufacture is indicated in the format DD.MM.YYYY or DD/MM/YYYY (day, month, calendar year).

12. In paragraph 30:

(a) indent 1 shall read as follows:

"30. When applying the expiration date of a human medicinal product (veterinary medicinal product) on the package, the month and year shall be indicated in the format specified in paragraph 5, subparagraph (i), of these Requirements. In this case, when indicating the month in the expiration date, this shall mean the last day of the specified month. The expiration date is indicated as “month, calendar year”, e.g., in the format such as MM YYYY, MM.YYYY, MM/YYYY, MM_YYYY. For medicinal products with an expiration date of less than 12 months, when indicating the expiration date, the day (if applicable), month, calendar year is specified.”;

(b) in indent 2, the words "preparation or dilution of solution (suspension)" shall be replaced by "preparation of suspension or dilution of solution."

13. In paragraph 37:

(a) indent 9 shall read as follows:

"If necessary, other warning inscriptions and symbols shall be applied to the package, if provided for in the normative document, as well as special precautions for disposal of unused pharmaceuticals or their waste."

(b) add subparagraph (c) to read as follows:

“(h) a unique patient identifier and the indication “For autologous use only” (for high-technology medicinal products for autologous use). This information is accepted to be applied on the primary package if no secondary package is available.".

14. Paragraph 38, subparagraph (d), should be specified as follows:

"(d) the expiration date in accordance with paragraphs 5, 6, 7, 8 of these Requirements;".

15. The third sentence in paragraph 49 should be supplemented with the words "without specifying the words "best before..."."

16. The Annex to these Requirements shall read as follows:

"Annex
to the Requirements for Labelling
Medicinal Products for Human
Use and Veterinary Medicinal Products"

THE LIST
of excipients indicated on the secondary package of medicinal products (veterinary medicinal products) for oral use

Excipient	Excipient code	Threshold
Azo dyes:		
(1) azorubine (carmoisine)	E122	0
(2) Brilliant Black BN (Black PN)	E151	0
(3) crimson 4R (Ponceau 4R, cochineal red A)	E124	0
(4) Sunset yellow	E110	0
(5) tartrazine	E102	0
(6) Erythrosine	E127	0 prohibited in medicinal products for pediatric use
Peanut butter		0
Aspartame	E951	0

Excipient	Excipient code	Threshold
Galactose		0
Glucose (dextrose)		0
Glycerol (glycerine)	E422	10 g/dose
Isomalt	E953	0
Potassium-containing compounds		39 mg/dose
Polyoxyl castor oils (macrogolglycerol ricinoleate, macrogolglycerol hydroxystearate)		0
Preservatives:		
(1) benzalkonium chloride		0
(2) benzyl alcohol		0
(3) benzoic acid and benzoates: potassium benzoate benzoic acid sodium benzoate	E212 E210 E211	0
Xylitol	E967	10 g
Sesame oil		0
Lactitol	E966	0
Lactose		0
Latex (natural rubber)		0
Maltitol maltitol syrup (hydrogenated glucose syrup)	E965	0
Mannitol	E421	10 g
Urea		0
Sodium-containing compounds		23 mg/dose
Parahydroxybenzoates and their esters:		0
1) methyl hydroxybenzoate	E218	0
2) sodium methyl hydroxybenzoate	E219	0

Excipient	Excipient code	Threshold
3) sodium propylhydroxybenzoate	E217	0
4) propylhydroxybenzoate	E216	0
5) ethyl hydroxybenzoate	E214	0
Propylene glycol and its ethers	E1520	500 mg/kg/day for adults
		1 mg/kg/day for children
Wheat starch		0
Invert sugar		0
Sucrose		0
Soybean oil		0
Sorbitol	E420	0
Sulfites, including metabisulfites:		0
1) potassium bisulfite	E228	0
2) potassium metabisulfite	E224	0
3) sodium bisulfite	E222	0
4) sodium metabisulfite	E223	0
5) sodium sulfite	E221	0
6) sulfur dioxide	E220	0
Phenylalanine		0
Formaldehyde		0
Fructose		0
Ethanol <*> (ethyl alcohol)		0

<*> Percentage (v/v) in liquid dosage forms."