MINISTRY OF HEALTH -------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
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CIRCULARS

REGULATIONS ON LABELING OF MEDICINES, MEDICINAL INGREDIENTS AND DRUG USE INSTRUCTIONS

Pursuant to Law No. 105/2016/QH13 dated April 6, 2016 on pharmacy;

Pursuant to Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government detailing a number of articles and measures to implement the Pharmacy Law ;

Pursuant to Decree No. 43/2017/ND-CP dated April 14, 2017 of the Government on goods labels;

Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government regulating the functions, tasks, powers and organizational structure of the Ministry of Health;

At the request of the Director of the Drug Administration of Vietnam,

The Minister of Health promulgates a Circular regulating the labeling of drugs, medicinal ingredients and drug use instructions.

Chapter I

GENERAL PROVISIONS

Article 1. Scope

1. This Circular regulates the content and labeling of drugs, medicinal ingredients and drug use instructions circulated on the market; Change the expiry date of the medicine listed on the medicine label in case of reasons of national defense, security, disease prevention and control, overcoming the consequences of natural disasters or catastrophes.

2. The following drugs and medicinal ingredients are not regulated by this Circular:

a) Medicines and medicinal ingredients intended for export do not have a certificate of circulation registration in Vietnam;

b) Drugs imported for non-commercial purposes specified in Clause 1, Article 75 of Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government detailing a number of articles and measures implementation of the Pharmaceutical Law (hereinafter referred to as Decree No. 54/2017/ND-CP);

c) Imported drugs used to meet urgent needs for national defense, security, disease prevention and control, and overcoming the consequences of natural disasters specified in Clause 1, Article 67 of Decree No. 54/2017/ND -CP .

Article 2. Explanation of terms

In this Circular, the following terms are understood as follows:

1. Commercial packaging of a drug is the packaging containing the drug and the drug's instruction sheet circulated along with the drug; Commercial packaging of drugs includes packaging in direct contact with the drug, outer packaging or intermediate packaging (if any).

2. Intermediate packaging is the packaging used to package one or several units of medicine with direct packaging and located in the outer packaging of the medicine.

3. Production batch number is a symbol in numbers or words, or a combination of both numbers and letters, to identify a batch of drugs or medicinal ingredients and allow the entire background of a batch of drugs or raw materials to be traced. Medicine includes all stages of the production process, quality control activities and circulation of that batch of medicine and medicinal ingredients.

4. The original label of a drug or medicinal ingredient is the label displayed for the first time by the manufacturer on the commercial packaging of the drug or medicinal ingredient.

Article 3. Location of drug labels, medicinal ingredients and drug use instructions

1. The position of drug labels and medicinal ingredients is implemented according to the provisions of Article 4 of Decree No. 43/2017/ND-CP dated April 14, 2017 of the Government on goods labels (hereinafter referred to as Decree No. Decree No. 43/2017/ND-CP).

2. The drug instruction sheet is an inseparable part of the drug label and is contained in the outer packaging of the drug. In case the medicine does not have an outer packaging, the instruction sheet must be printed or attached to the packaging in direct contact with the

medicine.Additional

Article 4. Label size, size of letters and numbers on labels, colors of letters, symbols and images on labels, presentation language of labels and drug instructions for use

1. Label size, size of letters and numbers on labels, colors of letters, symbols and images on drug labels, medicinal ingredients and drug use instructions shall comply with the provisions of Article 5 (except for the content specified in Point b, Clause 2, Article 5) and Article 6 of Decree No. 43/2017/ND-CP .

2. Mandatory contents displayed on drug labels, medicinal ingredients and drug instructions must be written in Vietnamese, except for some contents permitted to be written in other languages with Latin roots. according to the provisions of Clause 4, Article 7 of Decree No. 43/2017/ND-CP .

Article 5. Supplementing secondary labels, supplementing and replacing drug use instructions in Vietnam

1. Medicines and medicinal ingredients imported into Vietnam but the original label does not fully express the contents compared to the label approved by the Ministry of Health, the importing facility must add additional labels in Vietnamese to ensure consistent with the label approved by the Ministry of Health before the drug is released to the market and must keep the original label intact.

2. The following cases are allowed customs clearance to supplement or replace drug use instructions in Vietnamese in Vietnam:

a) Imported drugs that already have a certificate of registration for circulation in Vietnam but in the commercial packaging there are instructions for use of the drug in Vietnamese but have not updated the content of the instructions for use according to the requirements of the drug manufacturer. Ministry of Health, except in cases where the drug does not require a drug use instruction sheet specified in Points a, b, c and d, Clause 1, Article 13 of this Circular;

b) Imported drugs do not have a certificate of registration for circulation in Vietnam and the commercial packaging does not have an instruction sheet in Vietnamese, except in cases where the drug does not require an instruction leaflet as prescribed in section 4.2. Points a, b, c, d and dd Clause 1 Article 13 of this Circular.

3. Principles and locations for adding additional labels, supplementing or replacing drug use instructions in Vietnam:

After customs clearance, imported drugs and medicinal ingredients specified in Clauses 1 and 2 of this Article must be supplemented with additional labels, supplemented or replaced with drug use instructions in Vietnamese according to the following principles. :

a) Additional labels are made at the drug and drug raw material storage warehouse that meets the principles and standards of Good Storage Practices (GSP) of the facility importing drugs and medicinal materials;

b) Supplementing or replacing drug use instructions in Vietnamese is carried out at the level 2 packaging department (secondary packaging) of the facility that meets the principles and standards of Good Manufacturing Practices (GMP). in accordance with the scope of the Certificate of eligibility for pharmaceutical business;

c) The process of adding additional labels, replacing or supplementing drug use instructions in Vietnamese in Vietnam must ensure that it does not affect the quality of drugs and medicinal ingredients.

4. In the case of supplementing or replacing drug use instructions prescribed in Point b, Clause 3 of this Article, the level 2 packaging facility that has supplemented or replaced the drug use instructions must ensure Ensure full compliance with standards and principles of Good Medicine Manufacturing Practices during the implementation of the provisions at Point b, Clause 3 of this Article and must report to the Ministry of Health as a basis for management and inspection. , inspecting pharmaceutical business activities, specifically:

a) The report must be sent within one (01) month from the date of completion of supplementing or replacing drug use instructions in Vietnam;

b) Report content includes the following information: name of import facility; drug name; registration number or import license number; Production batch number; date of manufacture; due date; quantity of medicine supplemented or replaced in the medicine instruction leaflet.

5. The organization responsible for labeling drugs is responsible for supervising and coordinating with establishments to supplement secondary labels, supplement or replace drug use instructions and must be responsible for drug quality, medicinal ingredients during the process of adding additional labels, replacing or supplementing drug use instructions.

Article 6. Responsibility for labeling drugs, medicinal ingredients and drug use instructions

1. Organizations responsible for labeling drugs and medicinal ingredients, including secondary labels and drug use instructions, must ensure that the labeling is truthful, clear, accurate, and reflects the true nature of the medicine and raw materials. medicinal.

2. For domestically produced drugs and medicinal ingredients:

a) Manufacturing establishments and establishments registering drugs and medicinal ingredients must be responsible for labeling drugs, medicinal ingredients, and instruction sheets for drugs manufactured and registered for circulation by the establishment;

b) Medical examination and treatment establishments are allowed to process, prepare, weigh (load) traditional drugs according to the provisions of Clauses 1 and 2, Article 70 of the Pharmacy Law ; who produce or prepare drugs according to the provisions of Clauses 2 and 3, Article 85 of the Pharmacy Law, must be responsible for labeling drugs produced and prepared by establishments that process, prepare, weigh (load), produce, and prepare;

c) Pharmacies that prepare prescription drugs sold at pharmacies according to the provisions of Point b, Clause 1, Article 47 of the Pharmacy Law must be responsible for labeling the drugs prepared by the facility.

3. For imported drugs and medicinal ingredients:

a) Importing establishments and drug registration establishments must be responsible for labeling drugs and drug use instructions issued by importing establishments for drugs that have registration papers for drug circulation;

b) The importer and the establishment registering medicinal ingredients must be responsible for labeling the medicinal ingredients imported by the establishment;

c) The importing facility must be responsible for labeling the drug and drug use instructions because the importing facility does not have a drug circulation registration certificate.

4. For medicinal ingredients that are divided and retailed into smaller packaging units during the wholesale and retail process: the pharmaceutical business establishment that retails the medicine is responsible for sub-labeling to meet the requirements. according to the provisions of Clauses 2 and 3, Article 7 of this Circular.

chapter II

CONTENTS OF DRUG LABELS AND INSTRUCTIONS FOR USE

Section 1. COMPULSORY CONTENTS SHOWN ON THE LABEL

Article 7. Outer packaging labels of drugs and medicinal ingredients

1. The outer packaging label of the drug must show the following contents:

a) Drug name;

b) Dosage form;

c) Ingredients, content, volume or concentration of pharmaceutical ingredients and medicinal materials in the drug formula;

d) Packaging specifications;

d) Indications, usage, and contraindications of the drug;

e) Circulation registration number or import license number (if any);

g) Production batch number, date of manufacture, expiry date of the drug, quality standards, drug storage conditions;

h) Signs to note and recommendations when using the drug;

i) Name of the drug manufacturing facility, address of the drug manufacturing facility;

k) Name and address of the import facility (for imported drugs);

l) Origin of the drug.

2. The outer packaging label of medicinal ingredients (including medicinal materials, traditional medicines, semi-finished medicinal products, semi-finished medicinal products) must show the following contents:

a) Name of medicinal ingredient;

b) Weight or volume of medicinal ingredients in the smallest packaging unit;

c) Quality standards of medicinal ingredients;

d) Circulation registration number or import license number (if any);

d) Production batch number, date of manufacture, expiration date, storage conditions of medicinal ingredients;

e) Name and address of the facility manufacturing medicinal ingredients;

g) Name and address of the facility importing medicinal ingredients (for imported medicinal ingredients);

h) Origin of medicinal ingredients.

3. Labels of medicinal ingredients subject to special control (including semi-finished medicinal products):

In addition to the content specified in Clause 2 of this Article, raw materials are pharmaceutical substances, medicinal materials or semi-finished medicinal products containing pharmaceutical substances, medicinal materials on the List of narcotic, psychotropic pharmaceutical substances, drug precursors, and toxic materials. medicine, toxic medicinal ingredients, radioactive medicinal ingredients, must be written on the packaging label in addition to the following corresponding words: "Addictive ingredients", "Psychotropic ingredients", "Medicinal precursor ingredients". ", "Toxic ingredients", "Toxic medicinal ingredients", "Radioactive ingredients".

The words "Addictive ingredients", "Psychotropic ingredients", "Medicinal precursor ingredients", "Toxic ingredients", "Toxic medicinal ingredients", "Radioactive ingredients" must be printed in bold in the frame and printed on the main side of the label with the name of the ingredient.

4. In case the outer packaging label of the drug does not fully record the content specified in Clause 1 of this Article, the content specified in Point dd Clause 1 of this Article can be summarized as follows: "Indications, methods Use, contraindications and other information: see the accompanying drug instruction leaflet.

Article 8. Label of intermediate packaging of drugs

1. The label of the intermediate packaging of the drug must contain at least the following information:

a) Drug name;

b) Production batch number;

c) Expiry date.

2. In case the intermediate packaging is a transparent material that can see the information written on the packaging label in direct contact with the drug, the intermediate packaging label is not required to record the contents as prescribed in Clause 1 of this Article. 1 This.

Article 9. Packaging labels in direct contact with drugs and medicinal ingredients

1. The packaging label in direct contact with the drug must contain the following mandatory information:

a) Drug name;

b) Quantitative ingredients, content, concentration or volume of pharmaceutical ingredients and herbal ingredients in the drug formula;

c) Production batch number;

d) Expiry date;

d) Name of the drug manufacturing facility.

2. Packaging labels in direct contact with medicinal ingredients.

In cases where medicinal ingredients already have outer packaging with full contents as prescribed in Clauses 2 and 3, Article 7 of this Circular , if not opened for retail sale, labeling on the direct packaging is not required.

3. If a drug or medicinal ingredient does not have an outer packaging, the packaging in direct contact with the medicine or medicinal ingredient must have the full contents of the outer packaging label as prescribed in Article 7 of this Circular.

Article 10. Secondary labeling

1. The secondary label must have all the required content in Vietnamese as prescribed in Article 7 of this Circular while the original label does not exist or is missing.

2. In case the secondary label is small in size and cannot contain all the required content as prescribed in Clause 1 of this Article, some of the contents are recorded as follows:

a) Indications, instructions for use, contraindications and other information: see the attached drug instruction sheet;

b) Specify how to view information about production date, expiry date, and batch number printed on the original label;

c) Circulation registration number or import license number: can be left blank, but before releasing the drug for circulation on the market, information about the circulation registration number or import license number must be clearly stated (if any).

Article 11. Medicine labels in some other cases

1. Traditional drugs are processed, prepared, weighed (loaded) according to the provisions of Clause 1 and Clause 2, Article 70 of the Law on Pharmacy and drugs manufactured and prepared according to the provisions of Clause 2 and Clause 3, Article 85 of the Law Pharmaceuticals must label with the following mandatory contents, except for the cases specified in Clause 3 of this Article:

a) The outer packaging label of traditional medicine or mixed medicine must contain the following information:

- Contents specified in Points a, b, c, d, dd, g and h, Clause 1, Article 7 of this Circular;

- Name and address of the medical examination and treatment facility that produces, mixes, processes, prepares, weighs (loads) the medicine.

b) Packaging labels in direct contact with traditional medicines must contain the following mandatory contents:

- The contents specified in Points a, b, c and d, Clause 1, Article 9 of this Circular;

- Name of the medical examination and treatment facility that produces, mixes, processes, prepares, weighs (loads) the medicine.

c) In case traditional drugs or mixed drugs do not have outer packaging, the packaging in direct contact with the drug must have the contents of the outer packaging label specified in Point a, Clause 1 of this Article.

2. Drugs prepared according to prescriptions sold at pharmacies according to the provisions of Point b, Clause 1, Article 47 of the Pharmacy Law must have an outer packaging label or a packaging label in direct contact with the drug and must fully state the required contents. force the following:

a) Drug name and dosage form;

b) Active ingredients, concentration or content;

c) Preparation date, expiration date, drug storage conditions;

d) Name and address of the pharmacy that prepares the medicine;

d) Name of patient with prescription;

e) Warning signs for drugs on the list of drugs subject to special control.

3. Traditional medicines that are weighed and loaded according to prescriptions according to the provisions of Clause 1, Article 70 of the Pharmacy Law are not required to be labeled according to the provisions of this Circular but must have an outer packaging containing the medicine and the full name. patient, patient's age on the outer packaging to avoid confusion when dispensing.

4. Drugs that do not have a drug registration certificate in Vietnam are licensed for import in the following cases: bioequivalence testing, bioavailability assessment, registration samples, testing samples, scientific research, Exhibitors at exhibitions and fairs do not have to label with the mandatory contents specified in Articles 7 and 8 of this Circular , but must keep the imported drug label intact and supplement additional labeling according to regulations. as follows:

a) Drugs used for bioequivalence testing, bioavailability assessment, testing samples, and scientific research: must have the words: "Drugs used for research purposes";

b) Drugs used as registration samples: must write the words: "Drugs used as registration samples";

c) Medicines used for display at exhibitions and fairs: must have the words: "Drugs as display samples".

5. Medicinal ingredients are pharmaceutical substances that do not have a certificate of registration for circulation in Vietnam and are licensed to be imported for use as registration samples, testing samples, drug research, and participation in exhibitions and fairs according to regulations. In Clause 3, Article 60 of the Pharmacy Law , labeling is not required with the mandatory contents specified in Articles 7 and 8 of this Circular , but the original label must be kept intact.

6. Medicinal ingredients that are pharmaceutical ingredients, excipients, and semi-finished drug products that do not yet have a certificate of registration for circulation in Vietnam must be imported to produce drugs according to drug registration dossiers that already have a certificate of circulation registration in Vietnam. Additional labeling shows the contents as prescribed in Clauses 2 and 3, Article 7 of this Circular (except for the name and address of the import facility). In cases where the original label already displays these mandatory contents in other languages with Latin roots, additional labeling is not required.

7. Imported drugs as prescribed in Point b, Clause 1, Article 68 of Decree 54/2017/ND-CP are not required to be labeled in Vietnamese according to the provisions of this Circular but must keep the original label.

Section 2. CONTENTS OF DRUG USE INSTRUCTIONS

Article 12. Contents of drug use instructions

The drug instruction leaflet includes the following contents:

1. Drug name.

2. Signs to note and recommendations when using the drug.

3. Drug formula ingredients.

4. Dosage form.

5. Indications.

6. How to use, dosage.

7. Contraindications.

8. Warnings and precautions when using medicine.

9. Use medicine for pregnant and lactating women

10. Effects of drugs on the ability to drive and operate machinery.

11. Drug interactions and incompatibilities.

12. Unwanted effects of the drug.

13. Overdose and treatment.

14. Pharmacodynamic properties (not required for non-prescription drugs, herbal drugs, traditional drugs).

15. Pharmacokinetic properties (not required for non-prescription drugs, herbal drugs, traditional drugs).

16. Packaging specifications.

17. Storage conditions, expiration date, and quality standards of the drug.

18. Name and address of the drug manufacturing facility.

Article 13. General requirements of drug use instructions

1. Drugs circulating on the market, drugs produced, mixed, and processed in medical examination and treatment establishments specified in Clause 1, Article 11 of this Circular must have instructions for use in Vietnamese, except for cases where the following:

a) Drugs produced, processed, and prepared according to prescriptions and prescriptions specified in Clause 1, Article 70 and Clause 2, Article 85 of the Pharmacy Law are only for use and direct retail according to prescriptions at the medical facility itself. Healing;

b) Drugs prepared according to prescription and retailed at pharmacies specified in Point b, Clause 1, Article 47 of the Pharmacy Law ;

c) Drugs that do not have a drug registration certificate in Vietnam are licensed for import in the following cases: bioequivalence testing, bioavailability assessment, registration samples, testing samples, scientific research, Participate in exhibitions and fairs;

d) Imported drugs as prescribed in Point b, Clause 1, Article 68 of Decree 54/2017/ND-CP ;

d) Non-prescription drugs have labels that fully display the contents of the drug instructions as prescribed in Article 12 of this Circular.

2. For drugs specified in Point d, Clause 1 of this Article, the original instructions for use in a foreign language must remain intact.

3. Drugs with the same name, same active ingredient, same medicinal material, dosage form, same route of administration, same indication and same manufacturer but with different volumes, contents, concentrations or weights, specifications Different packaging and the same permission for circulation are listed in the same drug instruction sheet. In case there are differences between the contents and concentrations of the drug, each content, concentration, volume and packaging must be specifically recorded.

4. Each outer packaging of the drug must include at least 01 instruction sheet in Vietnamese. In case the medicine does not have an outer packaging, each packaging in direct contact with the medicine must have at least 01 instruction for use of the medicine.

Chapter III

HOW TO LABEL AND INSTRUCTIONS FOR MEDICINE USE

Article 14. How to write drug names and medicinal ingredients

1. The name of the drug or medicinal ingredient must be in a prominent, easy-to-read position and must be the largest in size compared to other mandatory contents on the label and instruction sheet.

2. The names of drugs and medicinal ingredients are written in Latin and may include numbers written in the form of numerals, Roman numerals or some other symbols written in the Greek alphabet (for example: alpha, beta).

3. The drug name is recorded according to the trade name or international generic name. For traditional medicines on the List of traditional medicines recognized by the Ministry of Health, they can be recorded by trade name or by the name of a traditional remedy recognized by the Ministry of Health, except for traditional medicines. The trade name of the drug must ensure the following principles:

a) Not of advertising nature;

b) Do not cause misunderstandings about the ingredients and origin of the medicine. In case a drug has many active ingredients or herbal ingredients, the name of each ingredient cannot be used to name the drug;

c) Do not cause misunderstanding or be overly descriptive about the effects, effectiveness, or indications of the drug;

d) Do not violate the customs, fine customs and traditions of Vietnam;

d) Do not cause conflicts with intellectual property objects of other individuals and organizations that are being protected;

e) Not identical or similar to the name of a drug that has been granted a circulation registration certificate by another registration facility;

g) Do not give the drug the same name if the drug has different active ingredients;

h) Do not name the drug differently in case the drug has the same all of the following criteria: active ingredients, medicinal ingredients, dosage form, route of administration, concentration, content and manufacturer. This regulation does not apply to processed drugs and these processed drugs comply with the regulations of the Minister of Health on drug manufacturing processing;

i) For drugs with the same name, same manufacturer, same dosage form, same active ingredient but with many different contents and concentrations, the drug name can be written with the corresponding content and concentration next to it. Drug names to identify and differentiate.

4. Names of medicinal ingredients (except medicinal materials and semi-finished medicinal products) are recorded according to the provisions of Clause 2, Article 16 of this Circular.

5. The name of the traditional medicine is recorded according to the name of the medicinal material specified in Clause 3, Article 16 of this Circular and the phrase "traditional medicine" is added before the Vietnamese name of the medicinal material.

6. The name of the medicinal material is recorded according to the provisions of Clause 3, Article 16 of this Circular.

7. The name of the semi-finished medicinal product is recorded according to the provisions of Clauses 4 and 5, Article 16 of this Circular.

8. The name of semi-finished medicinal products (except semi-finished medicinal products) is recorded according to the provisions of Clause 6, Article 16 of this Circular.

Article 15. Signs to note and recommendations when using the drug

1. Signs to note and recommendations when using the drug must be written on the label and instruction sheet, including:

a) The words: "Keep out of reach of children", "Read instructions carefully before use";

b) For prescription drugs:

- On the outer packaging label: must write the symbol "Rx" in the upper left corner of the drug name and the words "Prescription drug";

- Drug instruction sheet: must write the symbol "Rx" in the upper left corner of the drug name; write the words "This medicine is for use only by prescription".

c) For drugs subject to special control or other drugs:

- Radioactive drugs: must write the words " **RADIOACTIVE DRUGS** ", bold, capital letters;

- Drugs on the list of toxic drugs according to regulations of the Ministry of Health: must have the warning words: " **TOXIC DRUGS** ", in bold, capital letters;

- Drugs serving the state health program: write the words: "Program drugs, not for sale";

- Aid medicine, humanitarian aid: write the words: "Aid medicine, not for sale";

- Drugs used for clinical trials: the label must have the words: "Drugs for clinical trials." Use for other purposes is prohibited";

- For similar biological products: must clearly state "name of similar biological product" as the biological product that is similar to the reference biological product "name of reference biological product".

d) Other signs of note and recommendations for each drug are as follows:

- Injectable drugs: On the label of injectable drugs or infusions, the route of administration of the injected drug must be fully specified or abbreviated as follows: intramuscular injection (tb), subcutaneous injection (tdd), intravenous injection (ttm), intravenous infusion vascular (tttm) or other specific injections;

- Eye drops, eye drops: Write the words: "Eye drops" or "Eye drops". Nose drops have the words: "Nose drops"; ear drops with the words "Ear drops";

- Medicines for external use must have the words: "Medicine for external use"; Medicines packaged in ampoules for oral administration must have the words: "Do not inject";

- For drugs that require careful shaking before use (For example: Suspension drugs, powders, multi-dose granules for oral use that require mixing into a suspension or dosage form that is easy to settle and stagnate after mixing. or separate layers) must clearly state the words: "Shake thoroughly before use".

2. How to write notes and recommendations when using medicine:

a) Note lines and signs must be clearly printed on the outer packaging label or secondary label and drug use instruction sheet. The content must ensure easy recognition under normal observation conditions;

b) For drug use instructions: Write immediately below the drug name the signs to note and recommendations when using the drug specified in Points a, b and c, Clause 1 of this Article, except for the symbol Rx;

c) In case a drug has many cautionary signs, all cautionary signs of the drug must be recorded.

Article 16. Ingredients of drug formulas and semi-finished drugs

1. General regulations:

a) Outer packaging labels of drugs and semi-finished drugs:

- Record the full name and content, volume or concentration of each pharmaceutical ingredient or medicinal material in the drug formula or semi-finished drug product for the smallest dosage unit or smallest packaging unit;

- For vaccines: Must clearly state the active ingredient corresponding to each dose unit;

- For biological products: The content of biological products is expressed in mass units, biological activity units or international units for each biological product;

- For traditional drugs, herbal drugs, semi-finished traditional drugs, semi-finished herbal drugs: The name of each medicinal ingredient is recorded according to the Vietnamese name, it is not required to write the scientific name of the ingredient. medicine;

- It is not required to record the ingredients, content, weight, volume or concentration of excipients;

- Particularly for traditional medicines on the List of State secrets and traditional medicines according to regulations of the Ministry of Health, it is allowed not to display on the commercial packaging label of the medicine some medicinal ingredients, content, and mass. amount of medicinal ingredients in the drug formula. In this case, on the outer packaging label, the corresponding words must be written: "Drug production formula is a state secret" or "Drug production formula is a family secret".

b) Packaging labels in direct contact with drugs and semi-finished drugs:

- Drugs, semi-finished drugs in the form of single pharmaceutical ingredients, medicinal materials or combined form with less than or equal to 03 (three) pharmaceutical ingredients, medicinal materials: write all active ingredients, medicinal materials in the drug formula , semi-finished drug products as prescribed in point a of this clause;

- Medicines and semi-finished medicinal products with a combination of more than 03 (three) pharmaceutical ingredients and medicinal ingredients: There is no requirement to write the pharmaceutical ingredients and medicinal ingredients in the drug formula or semi-finished medicinal products. In case the ingredients and content of pharmaceutical ingredients or medicinal materials are recorded, they must be recorded according to the provisions of Point a of this Clause;

- In case the medicine is in liquid form, the volume must be recorded on the medicine label for the smallest packaging unit.

c) Instructions for use:

- Write the full name and content, volume or concentration of each pharmaceutical ingredient or medicinal ingredient in the drug formula for the smallest dosage unit or smallest packaging unit and must have the words "Ingredients". Pharmaceutical ingredient:" or "Active ingredient:" before writing the names of pharmaceutical ingredients and medicinal herbs in the drug formula;

- Write the full name of the excipients in the drug formula and the words "Excipients:" before writing the names of the excipients in the drug formula. It is not required to record excipients that have evaporated or lost during the manufacturing process and it is not required to record the mass, volume, content or concentration of each excipient ingredient in the drug formula;

- For vaccines: Must clearly state the active ingredient corresponding to each dose unit;

- For biological products: The content of biological products is expressed in mass units, biological activity units or international units for each biological product;

- For traditional medicines and herbal medicines: the name of each medicinal ingredient is recorded in Vietnamese, accompanied by the scientific name of each medicinal ingredient. The scientific name of the medicinal ingredient is printed in italic font to in parentheses immediately after the Vietnamese name of the medicinal material;

- Particularly for traditional medicines on the List of State secrets and traditional medicines according to regulations of the Ministry of Health, it is allowed not to display some medicinal ingredients, content, and volume of medicinal ingredients in the medicine formula. In this case, the drug formula must have the corresponding words: "Drug production formula is a state secret" or "Drug production formula is a family secret".

2. How to write names of pharmaceutical ingredients and excipients:

a) The names of pharmaceutical substances and excipients are recorded according to the international generic name or scientific name of the pharmaceutical substance and excipients;

b) Names of pharmaceutical ingredients and excipients do not require translation into Vietnamese.

3. How to write names of medicinal herbs and traditional medicines:

a) Vietnamese name:

- The names of medicinal herbs and traditional medicines are recorded according to the conventional Vietnamese names prescribed in the Vietnam Pharmacopoeia or the names recorded in the lists of drugs and medicinal ingredients issued by the Minister of Health;

- In case the Vietnamese name of the medicinal material is not in the Vietnam Pharmacopoeia or is not in the lists of drugs and medicinal ingredients issued by the Ministry of Health: write the Vietnamese name of the medicinal material in the book "Plants". Vietnamese medicines and herbs" by Do Tat Loi; book "1000 Medicinal Plants and Medicinal Animals" authored by the Institute of Medicinal Materials; The name of the medicinal material in this case must be decided by the Advisory Council for issuance of Drug Circulation Registration Certificate of the Ministry of Health advising the Minister of Health.

- In case the name of the imported medicinal ingredient cannot be translated into Vietnamese, write the name of the medicinal ingredient of the exporting country (or manufacturing country) along with the scientific name of the medicinal ingredient;

- In case a medicinal ingredient or traditional medicine has many different medicinal parts: must specifically write the medicinal part of the medicinal ingredient or write by name only the medicinal part of the medicinal ingredient. For example: Lotus heart, Rose flower, Honeysuckle flower.

b) Scientific name (Latin name):

- Scientific names of medicinal herbs and traditional medicines are recorded according to the scientific names of medicinal herbs in italic type as recorded in the Vietnam Pharmacopoeia or in the lists of medicinal herbs and traditional medicines issued by the Minister of Health. promulgate;

- In case the scientific name of the medicinal material or traditional medicine is not in the Vietnamese Pharmacopoeia or in the lists issued by the Minister of Health, write the scientific name of the medicinal material listed in foreign pharmacopoeias. .

4. How to write the name of medicinal herbs, type of extract and formula of medicinal herbs:

a) How to record medicinal herbs:

- Must fully write: name of the extract, type of extract and ingredients, concentration, content or volume of medicinal ingredients in the medicinal extract;

- For herbal extracts with trade names, it is allowed to write the trade name of the medicinal extract and at the same time clearly state the name of each medicinal ingredient contained in the medicinal extract according to the provisions of Clause 3 of this Article;

- In case the herbal extract does not have a trade name, write the word "coco" (for extract with only one medicinal ingredient) before the name of the medicinal ingredient or the word "mixed medicinal extract" (for extract containing many ingredients). medicinal ingredients)

before the names of medicinal ingredients.

b) How to write medicinal herbs:

- Medicinal extracts must clearly state the type of extract including 3 types: liquid extract, concentrated extract or dry extract according to the provisions of the Vietnam Pharmacopoeia;

- In case the type of medicinal extract is not clearly stated, the moisture content limit must be clearly stated along with the name of the medicinal extract or clearly state the ratio of the extract compared to the original amount of medicinal ingredients.

c) How to write the formula for medicinal herbs:

- In cases where the monograph of the Vietnamese Pharmacopoeia or a foreign Pharmacopoeia recognized by the Ministry of Health stipulates quantitative criteria for the content of a pharmaceutical substance or group of compounds, write the medicinal material with the content (%) of the drug substance or group of compounds quantified according to each medicinal material;

- In cases where the monograph of the Vietnamese Pharmacopoeia or a foreign Pharmacopoeia recognized by the Ministry of Health does not stipulate the quantification of the content of a pharmaceutical substance or group of compounds, the medicinal herb extract must be recorded with the original quantity of medicinal ingredients. Corresponding ingredients or clearly stating the high ratio compared to the original medicinal ingredients (initial medicinal ingredients are medicinal herbs that meet medicinal standards);

- When using a solvent to extract medicinal herbs to produce extract, if it is not an alcohol solvent (ethanol), water or an alcohol mixture (ethanol-water), then the medicinal extract must be accompanied by the name of the solvent used for extraction. medicine.

5. How to write the names of semi-finished medicinal products (except medicinal herbs) in the drug formula:

a) Must fully state: name of semi-finished medicinal product and ingredients, concentration, content or volume of medicinal ingredients in semi-finished product;

b) How to label semi-finished medicinal products:

- For semi-finished products with trade names, it is allowed to write the trade name of the semi-finished medicinal products, and at the same time clearly state the name of each medicinal ingredient contained in the semi-finished medicinal products according to the provisions of Clause 3 of this Article. ;

- In case the semi-finished medicinal product does not have a trade name, write the name of the medicinal ingredient specified in Clause 3 of this Article (for semi-finished medicinal products containing only one type of medicinal ingredient) or write it as "mixture of medicinal ingredients". (for semi-finished medicinal products containing many types of medicinal herbs), and clearly state the type of semi-finished medicinal product (for example: powder, granule) before the name of the medicinal ingredient or before the phrase "mixture of medicinal herbs".

c) How to write the formula for semi-finished medicinal products:

- In cases where the monograph of the Vietnamese Pharmacopoeia or a foreign Pharmacopoeia recognized by the Ministry of Health stipulates quantitative criteria for the content of a pharmaceutical substance or group of compounds, write the semi-finished pharmaceutical product along with the content (%) of the drug substance or group of compounds quantified according to each medicinal material;

- In cases where the monograph of the Vietnamese Pharmacopoeia or a foreign Pharmacopoeia recognized by the Ministry of Health does not stipulate the quantification of the content of a pharmaceutical substance or group of compounds, the semi-finished pharmaceutical product must be accompanied by the quantity of pharmaceutical substance. Corresponding starting materials or clearly stating the ratio of semi-finished medicinal materials compared to the original medicinal materials (initial medicinal materials are medicinal materials that meet medicinal standards).

6. How to write the name of semi-finished drugs (except semi-finished medicinal products) in the drug formula:

a) Must fully state: name of the semi-finished drug product and ingredients, concentration, content or volume of the pharmaceutical ingredients in the semi-finished product;

b) How to label semi-finished drug products:

- For semi-finished products with trade names, it is allowed to write the trade name of the semi-finished product and at the same time clearly state the name of each pharmaceutical ingredient in the semi-finished product according to the provisions of Clause 2 of this Article;

- In case the semi-finished drug product does not have a trade name, write the name of the pharmaceutical substance specified in Clause 2 of this Article (for semi-finished products containing only one pharmaceutical substance) or write "mixture of pharmaceutical substances" (for semi-finished drugs) finished product containing many pharmaceutical ingredients), and clearly state the type of semi-finished drug product (eg powder, granule) before the name of the pharmaceutical ingredient or before the phrase "mixture of medicinal ingredients".

c) How to write semi-finished drug formula: follow the regulations for semi-finished drug products in Clause 1 of this Article.

7. Unit of measurement expressing content, concentration, mass, volume:

Content, concentration, mass, volume are calculated in mass units, volume units, potency units or other common units, as follows:

a) Unit of mass measurement: use units of grams (abbreviated as g), milligrams (abbreviated as mg), micrograms (abbreviated as µg or mcg) or kilograms (abbreviated as kg). If the mass is less than 1 mg, write it as a decimal number (for example, 0.25 mg);

b) Volume measurement unit: use the unit milliliter (abbreviated as ml), microliter (abbreviated as µl or mcl), or liter (abbreviated as l or L). In case the volume of medicine is less than 1 ml, write it as a decimal number (for example: 0.5ml);

c) Other units of measurement:

- Potency units according to international regulations can be used for some special pharmaceutical substances;

- Measurement units are internationalized and commonly used in the medical industry such as IU and other potency units according to international conventions for some special pharmaceutical substances, which when translated into Vietnamese can cause misunderstandings. In usage, it is possible to keep the way of recording international units of measurement, without requiring translation into Vietnamese.

d) In case the pharmaceutical substance has a form used in the drug formula that is different from the form used to calculate the dose, the content, concentration, and volume must be converted to the form used to calculate the dose on the outer packaging label and instruction sheet. Usage form of the drug substance includes base form, salt form, hydrated form or other forms of the drug substance.

Article 17. Dosage form

1. The dosage form of the drug is specifically stated as: tablets, capsules, hard capsules, injection solution, powder for injection, suppositories (specify the placement location), powder, granules or other dosage forms. Other preparations according to the provisions of Vietnam Pharmacopoeia or other common International Pharmacopoeia.

2. For drug use instructions, in addition to the contents specified in Clause 1 of this Article, the following information must be added:

a) Must describe the external characteristics of the drug in terms of color, size, physical appearance, shape or external signs of the drug (if any);

b) For tablets with a groove design, it is necessary to clearly state whether the medicine can be broken in half or not;

c) Clearly state information about pH and osmol concentration (if any).

Article 18. Designation

The drug's indications must correspond to the drug's use, dosage form, and route of administration. Information on designation must be clear and specific and must state the following contents:

1. Purpose of using the drug: clearly state the purpose of using the drug, such as: treatment, treatment support, prevention (prophylaxis), symptom reduction.

2. Drug users (if any): clearly state the indications or indication limits for each certain group of users, which can be classified by age group or age or specific age group limits.

3. Additional conditions for safe and effective use of the drug (if any).

For example, during treatment, it is necessary to coordinate with other drugs or methods to increase treatment effectiveness or reduce unwanted effects of the drug.

Article 19. Dosage and usage

1. Dosage:

a) Dosage must be clearly stated according to each route of administration or/and according to each indication and method of administration.

- Clearly state the time and duration between doses of medication during the day, and how to use the medication to achieve the highest effectiveness (for example: drink with plenty of water, drink before meals);

- Clearly state the total minimum recommended dose, total maximum recommended dose, and clearly state the time limit for drug use (if any).

b) Clearly state the dosage and method of use for adults and children (if any). Dosage for children must be clearly stated for each age group or by weight;

c) Clearly state the cases where the dose must be adjusted for special users (if any) such as: children, the elderly, patients with kidney failure, patients with liver failure or other cases.

2. How to use:

a) Instructions for using the medicine must clearly state the route of administration, time of use and method of administration to achieve the highest effectiveness:

- For injectable drugs, it must clearly state how to prepare or reconstitute for injection, clearly state the injection route and injection method: intramuscular injection, intravenous injection, intravenous infusion, subcutaneous injection, deep subcutaneous injection or deep intramuscular injection and other injection cases; clearly state information about injection or infusion rate (if required);

- Must clearly state how to use the medicine for some cases requiring attention or recommendations specified in Point d, Clause 1, Article 15 of this Circular;

- For medicinal herbs: must clearly state how to use the medicine, how to drink it (water used for decoction, decoction tools, decoction method, method of soaking in alcohol, temperature and time of decoction or soaking), information on taboos and other rules. Be careful when using medicine.

b) For prescription drugs:

In addition to the provisions in Point a, Clause 2 of this Article, information must be added on how to use the drug for children, special subjects and other necessary recommendations (if any), specifically as follows:

- Dosage must be specifically recorded for each age group. The dose is calculated according to weight or body surface area (mg/kg or mg/m^2) or the dose is divided into corresponding dosing intervals. Medicines are used for children with the same indications as adults; dosage and method of administration for children must be specifically stated;

- In case the drug is not available in a dosage form for children, information must be provided on the dosage form for children from what age to use after preparing according to the manufacturer's recommendations;

- In case the drug is not indicated for one or all age groups of children, the dosage and method of use must be clearly stated in one of the following presentations:

+ The safety and effectiveness of the drug for children of a certain age (by month or year), or other appropriate patient groups (for example by gender, weight) have not been proven;

+ The drug is not recommended for children within certain age ranges (in months or years), or other relevant patient groups (e.g. gender, weight) due to safety concerns. and drug effectiveness;

+ The drug should not be used on children of a certain age (in months or years), (or other appropriate groups of patients, for example by gender, weight) with certain indications. drug prescription.

- Necessary recommendations on dosage and method of use (if any):

+ When stopping taking the drug, forgetting to take a dose, using the drug with food and water, reusing the drug after a course of treatment;

+ Adjust the dose when using other drugs concurrently, adjust the dose to suit the patient's condition (depending on clinical signs and symptoms and, or test results assessing kidney function, the patient's liver function corresponds to the adjusted dose level);

+ Measures to prevent some specific adverse reactions (for example, taking antiemetics before using cancer treatment drugs), adverse reactions that are not serious but common with the initial dose;

+ Special recommendations on manipulation or how to give drugs to medical staff or patients when using drugs (if any), information on other ways to give drugs, especially drugs given via gastric inhalation ((in case information is available), for drugs administered parenterally, information on the rate of injection or drug infusion should be clearly stated.

3. Some special notes on drug handling before and after using the drug:

Additional notes on how to use the drug in some cases of drug use that require drug treatment before and after using the drug, specifically as follows:

a) Handling medicine before use (if any):

- Clearly state how to prepare the medicine before use (reconstitute or dilute);

- Describe measures to protect drug dispensers;

- Clearly state the external characteristics of the drug before reconstitution or dilution, and the characteristics of the drug after reconstitution for drug forms that require reconstitution before use.

b) Handling medicine after use (if any):

- Clearly state the precautions for disposing of drugs after use for some specific cases such as: cytotoxic drugs, preparations containing living organisms and other cases with separate regulations;

- In case there are no instructions for use or special handling, please notify medical staff and clearly state "There are no special requirements for handling the drug after use".

Article 20. Contraindications

1. If a medicine has contraindications, it must specifically state the cases in which the medicine cannot be used.

2. Drugs with contraindications in children must clearly state children of a specific age (in months or years) or other appropriate patient groups (for example by gender, weight) for each contraindication of the drug. medicine.

Article 21. Warnings and precautions when using medicine

1. Must clearly state how to prevent and be cautious when using the drug, conditions that require caution when using the drug, and special recommendations when using the drug for children and people with chronic diseases (if any information is available).

2. Conditions requiring caution when using the drug:

a) Tests or patient's condition that need to be evaluated before using the drug, necessary measures to minimize the risk of harmful reactions to the patient during drug use;

b) Serious adverse reactions that require alerting medical staff;

c) Preventive measures and early detection of symptoms of serious adverse reactions;

d) Risks related to initiating or stopping treatment;

d) Special subjects at high risk of adverse reactions related to the drug group (these reactions are often serious or common);

e) Clinical or laboratory signs and symptoms that need to be monitored during treatment. Tests are affected by medication use;

g) Warnings and precautions in children related to the safety of the drug when used long-term (for example, effects on child development, neuropsychological development, genitals and other fields). other cases);

h) Warnings regarding excipients or residues with known adverse effects or effects. Warnings regarding this excipient ingredient must be clearly stated in this section or in the section on warnings and precautions when using the drug;

i) Warning about the ethanol ingredient in the drug formula;

k) Risks related to errors that may occur during drug use.

3. For similar biological products (Biosimilars):

Warnings must be clearly stated about the risks related to substitution or conversion between reference biological products and similar biological products during treatment.

Article 22. Use of drugs for pregnant and lactating women

1. Using medicine for pregnant women:

a) Provide information about the risks of drugs on pregnant women. In case there is not enough information about the effects of the drug on pregnant women, it must clearly state "There is no data on the use of the drug in pregnant women, the drug should only be used if the benefits outweigh the risks." ";

b) Recommendations for use of drugs for pregnant women must include the following: use of drugs in women who are capable of becoming pregnant or are using contraceptive methods, and use of drugs in different stages of pregnancy. pregnancy;

c) Additional information about the drug's effects on the fetus, including key information about the drug's possible effects on the fetus. If there is no information on fetal toxicity, it must be clearly stated in this case;

d) Provide recommendations on monitoring fetuses and newborns whose mothers used drugs during pregnancy (if information is available).

2. Using medicine for breastfeeding women:

Record specifically for each case such as: stop or continue breastfeeding, stop or continue treatment (if complete information is available).

Article 23. Effects of drugs on the ability to drive and operate machinery

1. Clearly state the following level of influence of the drug on the ability to drive and operate machinery: no influence or negligible influence, mild influence, moderate influence, severe influence.

In case there is no evidence of the drug's influence on the ability to drive or operate machinery, it must clearly state "There is no evidence of the drug's influence on the ability to drive or operate machinery".

2. Provide other important information (if any) such as the time period for these effects to subside and the ability to tolerate the drug with continued use.

Article 24. Drug interactions and incompatibilities

1. Drug interactions:

a) Fully record the interactions of the drug with other drugs and other types of interactions (for example: alcohol, food, food) that can affect the effects and treatment effectiveness of the drug, specifically as follows: after:

- Specify drug interactions in case of clinically significant interactions based on the pharmacodynamic properties and pharmacokinetic studies of the drug;

- Clearly state the consequences of drug interactions: clinical manifestations (if any), effects of drug interactions on drug concentrations in blood, pharmacokinetic parameters of active ingredients or active metabolites, Effects of drug interactions on test results. Clearly state how to minimize the consequences of the interaction;

- Specify the mechanism of the interaction if the mechanism is clear. If there are no studies on drug interactions, it should be clearly stated in this section;

- Other serious drug interactions such as: drug absorption into packaging and infusion sets.

b) For medicinal herbs and traditional medicines, taboos when using the medicine must be clearly stated (if any). For example, if you take heat-warming medicine, you should abstain from cold raw foods; If you take cold medicine, you need to abstain from spicy and stimulating foods.

2. Drug incompatibility:

a) Record information about the chemical and physical incompatibility of the drug with other drugs when mixed or used at the same time, especially with drugs that are reconstituted or diluted before use by intravenous infusion. ;

b) In case there is not enough information about drug incompatibility, add the sentence: "Due to the lack of research on drug incompatibility, do not mix this drug with other drugs."

Article 25. Unwanted effects of the drug

1. Clearly state the cases in which the drug should be stopped, the cases in which the doctor or pharmacist must be notified of any adverse reactions that may be encountered when using the drug, or report any adverse reactions to the drug. Center for Drug Information and Adverse Drug Reaction Monitoring.

2. In addition to the contents specified in Clause 1 of this Article, the following summary table of adverse reactions according to regulations (if any) must be recorded:

a) Summary table of adverse reactions: grouped by frequency: very common (ADR $\geq$ 1/10), common (1/100 $\leq$ ADR < 1/10), uncommon (1/1000 $\leq$ ADR < 1/100), rare (1/1000 $\leq$ ADR < 1/10000) and very rare (ADR < 1/10000);

For herbal medicines and traditional medicines: only adverse reactions are required to be listed, no grouping of adverse reactions is required by frequency.

b) For pediatric patients, it is necessary to describe: age characteristics and severity of adverse reactions in pediatric patients (if any); Clinically meaningful differences between adults and children (or specific age groups) in drug safety (if any). In cases where this information is already mentioned in another section of the instructions for use, a reference to the section containing the information must be included;

c) Any clinically significant differences (in terms of reaction frequency, severity, reversibility and need for monitoring) in special populations (e.g. the elderly , patients with liver failure, kidney failure, patients with other comorbidities) must be clearly stated.

3. In case no adverse drug reactions have been recorded or there is no evidence, add the words: "No reports of adverse drug reactions have been recorded" and the sentence "Notify your doctor immediately." pharmacist or pharmacist about adverse reactions encountered

when using the drug".

Article 26. Overdose and treatment

1. Overdose:

a) Specify the symptoms and signs of drug overdose: Specify the symptoms and signs of acute poisoning and the possibility of causing deformities (if any);

b) In case there is no information about drug overdose: specifically write the sentence "There is no data on drug overdose, do not exceed the prescribed dose of the drug".

2. How to handle drug overdose:

a) Specify the measures or treatment of overdose, including monitoring measures, use of agonists, antagonists, detoxifiers, and methods to enhance drug elimination from the body. In case there is no information or incomplete information, write the words "Actively monitoring to take timely measures";

b) Provide specialized information for special subjects such as: the elderly, pregnant and lactating women, children, people with liver failure, kidney failure, and patients with comorbid chronic diseases (if any).

Article 27. Pharmacological and clinical information

1. Pharmacodynamic properties: Includes the following contents:

a) Pharmacological group and ATC code of the drug (if any);

b) Describe the mechanism of action of the drug corresponding to the approved indications;

2. Pharmacokinetic properties: includes the following contents:

a) Pharmacokinetic properties of the drug (absorption, distribution, metabolism, excretion, and other properties) corresponding to the recommended dose, concentration, and dosage form of the drug;

b) Describe the differences between factors (such as age, gender, weight, smoking status, patients with liver or kidney failure) that affect pharmacokinetic parameters. If these effects are clinically significant, clearly state them with quantifiable parameters;

c) The relationship between dose, concentration, pharmacokinetic parameters (both main evaluation criteria, secondary criteria, unwanted effects) and characteristics of the patient population studied;

d) For pediatric patients: summarize results from pharmacokinetic studies on different age groups of children and compare with adults (if any). Specify the dosage forms used for pharmacokinetic studies in children, highlighting any uncertainties due to limited use in pediatric patients.

3. Data from clinical and non-clinical trials (if any):

a) Summary of main results recorded from major clinical trials supporting the approved indication of the drug (if any), including at least the following information:

- Describe the main characteristics of the research sample;

- Main evaluation criteria;

- Secondary evaluation criteria (if any);

- Results of the study related to the main criteria.

b) Provide key information related to non-clinical studies (if any).

Article 28. Smallest packaging unit, packaging specifications

1. The smallest packaging unit is usually specified as follows:

a) For tablet dosage form, the smallest packaging unit is the tablet. In case of small tablets, the smallest packaging unit is a package, bottle, jar or bag;

b) For liquid dosage form, the smallest packaging unit is a tube, bottle, vial, bag, syringe, prefilled syringe;

c) For dosage form that is powder for injection, the smallest packaging unit is a tube, bottle, vial, bag, syringe, pre-filled syringe;

d) For dosage forms such as powder, granules for drinking, the smallest packaging unit is a package, bottle, jar, bag;

d) For dosage forms such as cream, ointment, gel for external use, the smallest packaging unit is a tube, jar, bag;

e) For dosage forms such as patches, the smallest packaging unit is the patch;

g) For dosage form that is a spray or aerosol, the smallest packaging unit is a spray bottle, spray bottle, spray bottle, spray dose or medicine bottle used for nebulizers;

h) For dosage forms that are combination kits, the smallest packaging unit is the kit;

i) For pharmaceutical dosage forms, the smallest packaging unit is a bag, package or box;

k) For medicinal ingredients, the smallest packaging unit is a bag, bag, package, barrel, box, bottle, jar.

2. How to write packaging specifications:

a) Packaging specifications are recorded according to the natural count of quantity, weight, and volume of the drug contained in the commercial packaging;

b) In case there are many packaging units in a commercial packaging of a drug, the quantity of each packaging unit and the total packaging unit must be clearly recorded;

c) Clearly state other ingredients accompanying the drug, such as: needles, syringes, measuring spoons, measuring cups, aerosol devices and other supporting equipment in the commercial packaging of the drug (if any). .

3. For drugs on the list of drugs subject to special control, especially narcotic drugs, psychotropic drugs, drugs containing drug precursors, the outer packaging of the drug must not contain more than 100 smallest packaging units.

Article 29. Production batch number, production date, expiry date

1. Production lot number:

The production lot number is written in full as "Production lot number" or abbreviated with one of the following phrases: "Manufacturing lot number", "Manufacturing lot number", "LSX" or "SLSX" with information about the signature. production batch number. The information and structure of the production batch number symbol are specified by the manufacturer.

2. Date of manufacture, expiry date (or expiry date):

a) Production date, expiry date (or expiry date) are written in full as “Manufacturing date”, “Expiry date” or “Expiry date” or abbreviated in capital letters as “NSX”, “HD ” or “HSD”, followed by information about the drug's manufacturing date and expiration date;

b) Production date and expiry date are written in the order of day, month and year of the calendar year. Each number indicating the day, month, and year is written in two digits, but the year indicator is also allowed to be written in four digits.

The numbers indicating the day, month, and year of a time point must be written on the same line and separated between day, month, and year using "/" (day/month/year), "." (day.month.year), “-” (day-month-year), space (day-month-year) or write consecutive numbers indicating day, month, year;

c) In case the outer packaging of the medicine contains tubes, bottles of solvent for injection or other ingredients accompanying the medicine, the outer packaging label must show as follows:

- In case the production date and expiry date of all components of the product are the same, write the same production date and expiry date on the outer packaging label of the product;

- In case the production date and expiry date of each ingredient in the product are different, the outer packaging label of the product set must be written according to the expiry date of the ingredient with the shortest expiry date or specify the expiry date of each ingredient. ingredients in the product set.

3. How to record production date, expiry date (or expiry date), and production batch number:

a) In case the original label shows the date of manufacture, expiry date, and batch number in a foreign language :

- On the label, the date of manufacture, expiry date, and batch number are written in a foreign language. The secondary label must be written as follows: date of manufacture (NSX), expiry date (HD/HSD), batch number (LSX/ SLSX) view information stating the production date, expiry date, and batch number in a foreign language printed on the original product label.

For example: NSX, HD, SLSX see “Mfg Date”, “Exp Date”, “Lot.No.” printed on the packaging.

- On the label in direct contact with the drug, the expiry date is written in the form "month/year", the outer packaging label is written with the full expiry date in the form "day/month/year", then the drug's shelf life is calculated according to the recorded expiry date. on the outer packaging label;

- The expiry date in the form "month/year" is written on the label in direct contact with the medicine and the outer packaging label, but the production date is recorded on the label as follows:

+ In case the original label shows the full production date in the form "day/month/year", the expiration date on the secondary label is calculated and recorded according to the production date recorded on the original label;

+ In case the original label has the date of manufacture written in the form "month/year", the expiration date is calculated as the last day of the expiration month, the secondary label must write the words: "expiry date is the last day of the expiration month ".

b) In case the direct packaging label is small in size and does not have enough space to record the production batch number, expiry date or the corresponding symbols of "Manufacturing batch number" and "HD" as prescribed in Clause 1, Clause 2 of this Article, series of numbers representing the production batch number and expiration date can be written on the direct packaging label, but on the outer packaging label, this information must be fully recorded according to regulations;

c) How to write the drug's expiration date in the instruction sheet:

- Specify the time period from the date of manufacture;

- Expiry date after first opening the direct packaging for undivided dosage forms such as eye drops or nose drops, ear drops, ointments, gels for multiple use and multi-dose liquid medications for oral administration. or in pill form in bottles or jars with large packaging (if any);

- Expiry date after preparation for use in powder and granular forms of medicine that require mixing into a solution or suspension before use such as: powder medicine, granular medicine mixed with suspension, solution for injection or drink.

Article 30. Changing the expiry date of a drug stated on the drug label in case of reasons of national defense, security, disease prevention and control, or overcoming the consequences of natural disasters or catastrophes

In cases where, for reasons of national defense, security, disease prevention and control, and overcoming the consequences of natural disasters, the Minister of Health shall decide to change the expiry date of the drug listed on the drug label and regulate How to write the expiration date for each specific case based on the quality of the drug, the actual situation between benefits and risks or the serious shortage of domestic drug supply.

Article 31. How to record storage conditions for drugs, medicinal ingredients, and quality standards

1. Drug labels, medicinal ingredients, and instructions for use:

Clearly state the necessary storage conditions in terms of temperature (recorded in Celcius units, abbreviated as °C and must be written in specific numbers). Notes on humidity, light or other special storage requirements at the storage place or during transportation so as not to affect the quality of the drug during storage and circulation (if any).

2. Clearly state the requirements for drug storage conditions in the drug instructions for the cases specified in items 2 and 3, point c, clause 3, Article 29 of this Circular.

3. How to write quality standards:

On the outer packaging label and instructions for use of the drug, the quality standards of the drug and medicinal ingredients must be written, specifically as follows:

a) For drugs and medicinal ingredients that apply according to the standards of Vietnamese pharmacopoeia or foreign pharmacopoeia recognized by the Ministry of Health: quality standards are recorded according to the full Vietnamese name of the pharmacopoeia or recorded according to Abbreviated name in Vietnamese for Vietnam Pharmacopoeia or abbreviated name in English for foreign pharmacopoeia. It is not required to state the pharmacopoeia version or the year of publication of the pharmacopoeia;

b) Drugs and medicinal ingredients are applied according to facility standards, written in full as "Facility Standards" or written in the abbreviation: "TCCS".

Article 32. Circulation registration number and import license number

1. Number of registration certificate for circulation in Vietnam.

Write in full as "Circulation registration number:" or abbreviate as "Regulation:" and leave the content blank when submitting the circulation registration application. Before releasing drugs for circulation on the market, the registration number issued by the Ministry of Health must be added for drugs and medicinal ingredients that have been granted drug circulation registration certificates.

2. Import license number:

Fully write "Import license number:" or write the abbreviation on the label as "GPNK:" and leave this content blank when submitting the application for drug import. Before releasing drugs for circulation on the market, it is necessary to additionally record the import license number issued by the Ministry of Health for drugs and medicinal ingredients that do not have a circulation registration certificate.

Article 33. Name and address of manufacturing, mixing, processing, importing establishments and other establishments related to drugs (if any)

1. General regulations on how to write the name and address of the manufacturer and importer on labels and instructions for use of drugs:

a) Outer packaging labels of drugs and medicinal ingredients:

- For domestically produced drugs: write the full role, name and address of the drug manufacturing facility;

- For medicinal ingredients produced domestically or imported: write the full name and address of the facility manufacturing the medicinal ingredients;

- For imported drugs: write the full role, name and address of the drug manufacturing facility; name and address of the import facility.

b) Packaging labels in direct contact with the drug: The name of the manufacturing facility is written according to the full name or transaction name but must ensure the identification of the manufacturing facility's name.

In case a drug has multiple establishments participating in its production, it can be recorded in one of the following two ways:

- Fully record the facilities participating in the production of finished drugs;

- Write the name of the facility responsible for releasing the batch of medicine.

c) For traditional drugs specified in Clause 1 and Clause 2, Article 70 of the Pharmacy Law and drug labels manufactured and prepared in medical examination and treatment establishments specified in Clause 2 and Clause 3, Article 85 of the Pharmacy Law :

- Outer packaging label: write the full name and address of the medical examination and treatment facility that processes, prepares, mixes, and produces the medicine;

- Direct packaging label: write the full name or transaction name of the medical examination and treatment facility.

d) Drug labels prepared according to prescriptions sold at pharmacies specified in Point b, Clause 1, Article 47 of the Pharmacy Law : write the full name and address of the pharmacy that prepares the drug;

d) Drug use instructions: must fully state the role, name, and address of the drug manufacturing facility. For imported drugs, the name of the manufacturing country must be translated into Vietnamese, except in cases where the Vietnamese translation is meaningless or cannot be translated;

e) In addition to the manufacturing facility and import facility, the role, name, and address of other facilities related to the drug can be written on the label and instruction sheet (such as: drug registration facility). , drug distribution company, trademark owner, product owner and other cases).

2. How to write the role of the facility related to drugs before the facility name, specifically:

a) For production facilities:

- In case there is only one production facility participating in the production process: write the role as "Production facility:".

- In case there are many production facilities participating in the production process: clearly state the role of each production facility, such as: "Semi-finished product production facility"; “Level 1 packaging facility”; “Establishment responsible for batch release”;

- The name of the facility manufacturing drugs and medicinal ingredients is the name recorded in the certificate of eligibility for pharmaceutical business in accordance with pharmaceutical business activities issued by a competent authority.

b) For import establishments: write the role as "Import enterprise";

c) For other establishments: write the role as "Distribution facility", "Product owner", "Brand owner" and other cases related to drugs (if any).).

3. How to write the name and address of the manufacturing facility:

a) For drugs that involve the production of different manufacturing facilities, write the names of all facilities participating in drug production along with the addresses of drug manufacturing locations according to regulations on how to write names and locations. refers to the respective production facility. The names of establishments involved in drug production must be written in the same font size and on the same side of the label (same plane);

b) For processed drugs, write: "Manufactured at: (name and address of the processing party) under contract with: (name and address of the ordering party)". The name and address of the processing facility must have the same font size and be written on the same side of the label (same plane) as the processing facility;

c) For drugs manufactured in the form of technology transfer, write: "Manufactured at: (name and address of the party receiving technology transfer) transferred technology from: (name and address of the transferor) technology)". The name and address of the technology transfer facility must have the same font size and be written on the same side of the label (same plane) as the facility receiving the technology transfer.

4. How to write the name and address of the import facility: write in one of the following ways:

a) Write in full "Importing enterprise: name and address of facility importing drugs and medicinal ingredients" on the label;

b) Write in short as "DNNK: full name and address of the import facility".

Write “Importing enterprise:” or “DNNK:” and leave the name of the importing facility blank, but before putting the drug on the market, you must add the full name and address of the importing facility in this section.

5. Other regulations on how to write name and address:

a) How to write establishment name:

- Name of domestic establishment: write according to the establishment's name recorded in the certificate of eligibility for pharmaceutical business, business registration certificate or investment certificate issued by a competent authority;

As for the name of the medical examination and treatment facility: write the name according to the medical examination and treatment operation license according to the provisions of the Law on Medical Examination and Treatment .

- Name of the foreign facility: write according to the name written on the pharmaceutical product certificate or certificate of Good Medicine Manufacturing Practice issued by the competent authority in the host country or the name written on other relevant certificates. relate to.

As for the name of the manufacturing facility, it must be recorded according to the name written in the pharmaceutical product certificate or the Good Medicine Manufacturing Practice certificate issued by the competent authority in the host country.

b) How to write the address of the facility:

- Address of the domestic manufacturing facility: the address of the domestic manufacturing facility is recorded according to the address of the pharmaceutical business location recorded in the certificate of eligibility for pharmaceutical business in accordance with the business facility. pharmaceutical business, in addition, you can add the address of the business's headquarters;

- Address of the production facility: Record according to house number, street (village, hamlet), commune (ward, town), district (district, town, provincial city), province (central city). nursing);

As for the address of the medical examination and treatment facility: Write down the correct drug production location of the medical examination and treatment facility according to the medical examination and treatment operating license according to the provisions of the Law on Medical Examination and Treatment .

- For imported drugs:

Record the address of the manufacturing facility as the drug manufacturing location listed in the pharmaceutical product certificate or certificate of Good Manufacturing Practices issued by the competent authority in the host country.

c) The names, addresses, symbols (logos, if any) of organizations and individuals related to the drugs specified in this Clause written on the label or instruction sheet must be no larger than name, address or logo of the manufacturing facility unless this organization can prove that it is the owner of the product;

d) In case the label has the name, address, and logo of the drug distribution company, the name, address, and logo of the distribution company must not be larger than the name and address. designation, symbol (logo) of the manufacturing facility;

d) If the drug manufacturing facility is a member or dependent unit in an organization such as a company, corporation, corporation, association and other organizations, it has the right to write the name or name and address, label trademarks, trademarks and other content of that organization on the label when permitted by these organizations, but the address where the drug is manufactured must still be written.

For example, if a medicine is produced at the company branch at address A of company B, the label has the right to say "Company B, Company branch, manufactured at address A".

Article 34. Origin of drugs and medicinal ingredients

1. How to determine the origin of drugs and medicinal ingredients:

a) The origin of drugs and medicinal ingredients is determined according to the provisions of the Commercial Law, documents guiding the Commercial Law on origin of goods and relevant legal documents;

b) Organizations and individuals responsible for drug labeling specified in Article 6 of this Circular determine and record the origin of their drugs and medicinal ingredients but must ensure honesty, accuracy, and compliance. provisions of law on origin of goods or agreements that Vietnam has signed.

2. How to record the origin of imported drugs and medicinal ingredients:

Origin of drugs and medicinal ingredients is recorded on the outer packaging of drugs and medicinal ingredients as follows:

a) Write the phrase "origin:" , "manufactured in:" or "manufactured by:" accompanied by the name of the country or territory producing the drug or medicinal ingredient;

The name of the country or territory producing the drug or medicinal ingredient must not be abbreviated.

b) In case the drug or medicinal ingredient has the same origin as the country or territory where the drug or medicinal ingredient is produced, the name of the manufacturing country is only required in Vietnamese or English in case of translation. Vietnamese has no meaning or cannot be translated;

c) In case the drug or medicinal ingredient has an origin other than the country or territory where the drug or medicinal ingredient is produced, full information about the origin of the medicine must be recorded as prescribed in Point a, Clause 2 of this Article. .

3. For drugs and medicinal ingredients produced in Vietnam for domestic circulation that have the address of the place of manufacture of the drug or medicinal ingredient recorded, the origin of the medicine or medicinal ingredient is not required. medicine on the label.

Article 35. Other contents shown on drug labels

1. In addition to the mandatory contents prescribed in this Circular, the sample label and instructions for use of the drug are expected to be included in the drug registration dossier, drug import dossier without circulation registration certificate or drug label belonging to In the cases specified in Clauses 1 and 2, Article 11 of this Circular, other contents may be recorded but must meet the provisions in Clause 3 of this Article.

2. In addition to the mandatory contents prescribed in this Circular, before releasing the drug for circulation on the market, organizations and individuals responsible for the drug are allowed to write additional contents on the label and leaflet. Instructions for drug use compared to the content approved by the competent management agency when meeting the provisions of Clause 3 of this Article do not need to be notified and do not require approval from the competent authority, but the competent authority The facility responsible for labeling must be responsible for the accuracy of additional information, including:

a) Add or modify anti-counterfeit stamps and security and anti-counterfeit content related to the product on the medicine label to prevent counterfeiting or easily identify the product;

b) Change the form and color of the instruction sheet; change the size of the outer packaging label or direct packaging of the drug or medicinal ingredient;

c) Add or modify phone numbers, phone area codes, website addresses, and email addresses of drug-related establishments; trademark ownership facility;

d) Adding or modifying the ® symbol after the drug name, after the company name or logo; changing company logos related to drugs;

d) Change the position of the circulation registration number or import license number, the position of the secondary label, the position of the production batch number, expiry date, and production date on the label;

e) Content written in another language is translated from Vietnamese content approved by the Ministry of Health according to the drug registration dossier or drug import dossier without circulation registration certificate.

3. Regulations for other contents shown on the label:

a) Must not violate the law, must not advertise drugs and must ensure honesty, accuracy, reflect the true nature and uses of the drug, not obscure or falsify mandatory content written on the drug label and must ensure that the required contents are consistent with the label approved by the functional units of the Ministry of Health;

b) Must not have the following information or images:

- Information and images prohibited from use in advertising activities specified in Article 8 of the Advertising Law ;

- The contents specified in Clauses 2, 3, 4, 5, 6, 10, 11, 12, 13, 14, 15 and 16 Article 126 of Decree No. 54/2017/ND-CP ;

- Contents and images specified in Clause 2, Article 18 of Decree 43/2017/ND-CP .

- Information and images about whether the similar biological product is biologically equivalent (bioequivalence) or clinically equivalent (clinical equivalence) compared to the reference biological product.

c) Content in other languages specified in Point e, Clause 2 of this Article must be corresponding and complete according to the Vietnamese content. The size of letters and numbers written in another language must not be obscured or larger than the size of letters and numbers of the content written in Vietnamese;

d) Drugs and medicinal ingredients for export are allowed to have labels and instructions for use in other languages according to the sales contract of the importing country, but the content of the labels and instructions for use must not be falsified. information and nature of drugs and medicinal ingredients.

Chapter IV

TERMS ENFORCEMENT

Article 36. Effectiveness of implementation

1. This Circular takes effect from June 1, 2018.

2. Circular No. 06/2016/TT-BYT dated March 8, 2016 of the Minister of Health regulating drug labeling expires from the effective date of this Circular, except for the specified contents. Labeling of in vitro diagnostic biological products continues to be effective until there is another legal document providing replacement guidance.

Article 37. Transitional provisions

1. Drugs and medicinal ingredients that have been granted circulation registration or import licenses before the effective date of this Circular shall be implemented as follows:

a) May continue to circulate and use label samples and instructions for use approved by the Ministry of Health until the expiration date of the batch of drugs or medicinal ingredients produced or imported during the effective period. of the circulation registration certificate or import license issued before the effective date of this Circular, except for the case specified in Point b, Clause 1 of this Article.

b) For drugs and medicinal ingredients on the List of toxic drugs and toxic medicinal ingredients according to the provisions of Circular No. 06/2017/TT-BYT dated May 3, 2017 of the Minister of Health promulgating the List section on poisonous drugs and poisonous medicinal ingredients; drugs on the List of non-prescription drugs according to the provisions of Circular No. 23/2014/TT-BYT dated June 30, 2014 of the Minister of Health promulgating the list of non-prescription drugs but not on the List of non-prescription drugs. prescription issued together with Circular No. 07/2017/TT-BYT dated May 3, 2017 of the Minister of Health on promulgation of the List of non-prescription drugs (hereinafter referred to as Circular No. 07/2017) /TT-BYT), registration establishments, establishments importing drugs and medicinal ingredients must classify, update and supplement information related to the classification of drugs and medicinal ingredients, as follows: :

- Drugs and medicinal ingredients produced before the effective date of this Circular: comply with the provisions of Point a, Clause 1 of this Article;

- Drugs and medicinal ingredients produced from the effective date of this Circular: establishments must update information related to the classification of drugs and medicinal ingredients on labels and instructions for use themselves. drugs as prescribed in this Circular before placing drugs or medicinal ingredients on the market within 12 months from the effective date of this Circular, without needing to notify the Ministry of Health, except In case the establishment carries out registration procedures to change or supplement the drug circulation registration certificate related to the instructions for use of the drug that has been granted a circulation registration certificate as prescribed in the Circular regulating drug registration, medicinal ingredients from the Ministry of Health.

2. Drug circulation registration dossiers or drug import dossiers without circulation registration certificates submitted to functional units under the Ministry of Health before the effective date of this Circular but have not yet been granted registration certificates. circulation or import license, except for drugs and medicinal ingredients specified in Clause 3 of this Article, are considered as follows:

a) Establishments registering drugs and importing drugs are allowed to submit additional documents to the Ministry of Health requesting to update and change information on labels and drug use instructions according to the provisions of this Circular for review. Appraisal and issuance of circulation registration certificate or license to import drugs without circulation registration certificate;

b) In case the facility does not supplement the dossier as prescribed in Point a of this Clause, the Ministry of Health will consider and appraise the content of the label and instructions for use according to the provisions of Circular No. 06/2016/TT- Ministry of Health dated March 8, 2016 of the Minister of Health regulations on drug labeling, except for the cases specified in Point b, Clause 1 of this Article;

Within 06 (six) months from the date of issuance of the registration certificate for circulation of drugs and medicinal ingredients, the facility responsible for labeling the drug is responsible for updating the label content and instructions for use according to regulations. of this Circular in the form of registering changes and supplements to the drug circulation registration certificate specified in the Circular regulating the registration of drugs and medicinal ingredients of the Ministry of Health, except for the cases specified in Point b, Clause 3 Article 6 of Circular No. 07/2017/TT-BYT .

3. Before the effective date of this Circular, dossiers for registration of drugs and medicinal ingredients in the form of changes or additions to the certificate of registration for circulation of drugs and medicinal ingredients related to the content of changes in label samples , drug use instructions have been submitted to functional units under the Ministry of Health but the changes and additions have

not been approved, the drug registration and drug importer must supplement the label sample, drug use instruction sheet as prescribed in this Circular.

Article 38. Publication of drug use instructions

1. The Drug Administration of Vietnam is responsible for reviewing, updating and publishing instructions for use for drugs that have been granted circulation registration on the List of original brand name drugs and reference biological products issued by the Minister of Health published on the website of the Drug Administration of Vietnam for reference by drug manufacturing and registration establishments in the process of preparing drug registration dossiers for similar generic drugs and similar biological products.

2. Instructions for use of drugs on the List of original brand-name drugs and reference biological products with content changed or supplemented during circulation must be announced and posted on the website of the Department of Management. Pharmacy within 45 days from the date of signing the official dispatch approving the additions and changes to the drug use instructions.

3. Drug registration and drug manufacturing establishments are responsible for updating and supplementing the contents of the drug instructions for generic drugs and similar biological products in accordance with the instructions for use. of drugs on the List of original brand-name drugs and corresponding reference biological products are posted on the website of the Drug Administration of Vietnam according to the following regulations:

a) Instructions for use of generic drugs and similar biological products must be consistent with the instructions for use of drugs on the List of original brand-name drugs and reference biological products corresponding to the concentration, content, and activity. substance, dosage form, route of administration of the drug, except for unavoidable differences in information (such as: expiration date, excipient ingredients, quality standards, bioavailability parameters, pharmacokinetic data, adverse effects, clinical research results). Information on unwanted effects in the instructions for use of generic drugs or similar biological products must not be less than that of the original brand name drug or corresponding reference biological product, except for unwanted effects of brand-name drugs. original, reference biological products related to excipient ingredients that are not included in the ingredients of generic drugs or similar biological products;

b) Within 12 months from the date the Drug Administration of Vietnam announces and posts the instructions for use of original brand-name drugs and reference biological products on the website of the Drug Administration of Vietnam as prescribed in Clause 1. , Clause 2 of this Article, drug registration establishments and manufacturers of generic drugs and similar biological products are responsible for updating the label content and instructions for use in accordance with the instructions for use of the original brand-name drug. , reference biological products for the information specified in Clause 2 of this Article, without notification to the Ministry of Health, unless otherwise requested by the Ministry of Health.

Article 39. Terms of reference

In case legal documents and regulations cited in this Circular are changed, supplemented or replaced, the new legal documents shall apply.

Article 40. Responsibility for implementation

Drug Administration, Traditional Medicine Administration and units under the Ministry of Health, Departments of Health of provinces and centrally run cities, Vietnam Pharmaceutical Corporation - Joint Stock Company, production facilities exporting and registering drugs domestically and internationally, establishments importing and exporting drugs and medicinal ingredients, medical examination and treatment establishments and establishments preparing drugs according to prescriptions are responsible for implementing this Circular.

During the implementation process, if there are any problems, organizations and individuals are requested to promptly report them to the Ministry of Health (Department of Drug Administration, Department of Traditional Medicine and Pharmacy) for consideration and resolution./ .

KT. MINISTER
DEPUTY MINISTER

Truong Quoc Cuong

Recipient:
- Government Office (Official Gazette, CP Electronic Information Portal);
- Health Minister;
- Deputy Ministers of Health;
- Ministries: Justice (Department of Legal Document Inspection), Science and Technology (Legal Department); Industry and Trade; Finance (General Department of Customs); Police (Department of Health), National Defense (Military Medical Department); Transportation (Department of Health);
- Department of Health of provinces and centrally run cities;
- Departments, Bureaus, General Departments, Ministry Offices, Ministry Inspectorates - Ministry of Health;
- Pharmaceutical business associations Vietnam; Vietnam Pharmaceutical Corporation - Joint Stock Company;
- Drug manufacturing and registration facilities in Vietnam;
- Electronic information portal of the Ministry of Health;
- Save: VT, PC, QLD (12b).