

THE GOVERNMENT

DECREE No. 45/2005/ND-CP OF APRIL 6, 2005 PROVIDING FOR THE SANCTIONING OF ADMINISTRATIVE VIOLATIONS IN THE FIELD OF HEALTH

THE GOVERNMENT

*Pursuant to the December 25, 2001 Law on
Organization of the Government;*

*Pursuant to the June 30, 1989 Law on Protection
of People's Health;*

*Pursuant to the July 2, 2002 Ordinance on
Handling of Administrative Violations;*

*Pursuant to the May 31, 1995 Ordinance on HIV/
AIDS Prevention and Combat;*

*Pursuant to the February 25, 2003 Ordinance
on Private Medical or Pharmaceutical Practice;*

*Pursuant to the July 26, 2003 Ordinance on
Food Hygiene and Safety;*

At the proposal of the Minister of Health,

DECREES:

Chapter I

GENERAL PROVISIONS

Article 1.- The regulation scope

1. This Decree provides the sanctioning of administrative violations in the field of health.

2. Administrative violations in the field of health mean acts of intentionally or unintentionally violating provisions of legislation on state management in the field of health, which are not crimes but, according to law provisions, must be administratively sanctioned.

3. Administrative violations in the domain of state management over health provided for in this Decree include:

a) Violation of regulations on hygiene, epidemics prevention and combat;

b) Violation of regulations on food hygiene and safety;

c) Violation of regulations on vaccine- medical bio-products;

d) Violation of regulations on medical examination and treatment, including medical examination and treatment with traditional medicine;

e) Violation of regulations on preventive and curative medicines for human use, including traditional medicines and cosmetics directly affecting human health;

f) Violation of regulations on medical equipment.

Article 2.- Subjects of application

1. This Decree applies to Vietnamese organizations and individuals committing acts of administrative violation in the field of health.

2. This Decree also applies to foreign organizations and individuals operating or residing in Vietnam, that commit acts of administrative violation in the field of health. Where international treaties, which Vietnam has been a signatory to, otherwise provide for, the provisions of such

international treaties shall apply.

Article 3.- Sanctioning principles

1. The principles for sanctioning of administrative violations in the field of health shall comply with the provisions of Article 3 of the Ordinance on Handling of Administrative Violations.

2. The sanctioning of administrative violations in the field of health shall be carried out by the competent persons defined in Articles 45, 46 and 47 of this Decree.

3. The handling of violations committed by persons competent to handle administrative violations in the field of health shall comply with the provisions of Article 121 of the Ordinance on Handling of Administrative Violations.

Article 4.- Extenuating circumstances, aggravating circumstances

The extenuating circumstances and the aggravating circumstances applicable in the sanctioning of administrative violations to violation acts prescribed in Chapter II of this Decree shall comply with the provisions of Articles 8 and 9 of the Ordinance on Handling of Administrative Violations.

Article 5.- Statute of limitations for sanctioning

1. The statute of limitation for sanctioning of an administrative violation in the field of health shall be one year, counting from the date the act of administrative violation is committed.

2. For acts of administrative violation in the field of health, which are related to export, import or production of fake goods, the statute of limitation

for sanctioning shall be two years, counting from the date the acts of administrative violation are committed.

Article 6.- Time limit for being regarded as not yet being sanctioned for administrative violations

Individuals, organizations sanctioned for administrative violations in the field of health, if past one year as from the date of completely serving the sanctioning decisions or the date of expiration of the sanctioning decisions having not repeated the violations, shall be regarded as not yet being sanctioned for administrative violations in the field of health.

Article 7.- Sanctioning forms

1. The application of forms of sanctioning of administrative violations and measures to remedy consequences of the administrative violations shall be based on the specific regulations on the sanctioning measure applicable to every act of administrative violation.

2. For each act of administrative violation, the violating individuals or organizations shall be subject to only one of the following principal sanctioning forms: caution or fine.

a) The form of caution shall apply to minor administrative violations, committed for the first time, involving extenuating circumstances or to acts of administrative violation committed by minors aged between full 14 and under 16 years old.

b) Application of the form of fine:

- The fining levels shall be based on the nature and seriousness of violations, personal identity of violators, extenuating or aggravating circumstances

in the fine bracket specified for such violation acts;

- When applying the sanctioning form of fine, the specific fine level for an administrative-violation act shall be the average of the fine bracket prescribed for such act; if the violations involve extenuating circumstances, the fine levels may be reduced but must not be lower than the lowest level of the fine bracket; if the violations involve aggravating circumstances, the fine levels may be increased but must not exceed the highest level of the fine bracket.

3. Depending on the nature and seriousness of violations, individuals or organizations committing administrative violations in the domain of state management over health shall also be subject to the application of the following additional sanctioning forms:

a) Deprivation of the right to use permits, practice certificates, certificates of eligibility for professional practice for 6 to 12 months or for indefinite duration;

b) Confiscation of material evidences, means used for commission of administrative violations.

4. Apart from the above sanctioning forms, individuals and organizations committing administrative violations may also be subject to the application of one or many of the following remedial measures:

a) Forced restoration of the initial state altered due to the administrative violations;

b) Forced application of measures to redress the environmental pollution, epidemic spread caused by administrative violations;

c) Forced taking out of Vietnamese territory or forced re-export of goods, articles, means;

d) Recycling or forced destruction of articles that cause harms to human health;

e) Other remedial measures specified in this Decree.

5. Administratively-sanctioning forms may be applied independently or together with additional sanctioning forms or remedial measures. The remedial measures cannot be applied independently but together with principal sanctioning forms, except for the cases provided in Article 69 of the Ordinance on Handling of Administrative Violations.

6. Sanctioned state organizations must abide by sanctioning decisions. After abiding by the sanctioning decisions, the sanctioned organizations shall identify the individuals who are blamed for causing the administrative violations while performing their public duty in order to discipline them and request the reimbursement of damages already paid by the organizations under provisions of law.

Chapter II

ACTS OF ADMINISTRATIVE VIOLATION IN THE FIELD OF HEALTH, SANCTIONING FORMS AND LEVELS

Section 1. ACTS OF ADMINISTRATIVE VIOLATION RELATED TO HYGIENE, EPIDEMIC AND HIV/AIDS CONTROL, SANCTIONING FORMS AND LEVELS

Article 8.- Violation of regulations on water- and air-related hygiene

1. Caution or a fine of between VND 50,000 and

200,000 for acts of discharging garbage, daily-life waste, human and animal wastes into water sources used for drinking and daily-life activities.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Failing to comply with regulations on tests for monitoring water quality by organizations or individuals that supply water for drinking or daily-life activities;

b) Supplying drinking, daily-life water, which fails to ensure the prescribed water source hygiene and protection.

3. A fine of between VND 10,000,000 and 15,000,000 for one of the following acts:

a) Letting waste matters, waste water pollute sources of water used by people for drinking, daily-life activities;

b) Discharging toxic gases, causing harms to the health of people in vicinities.

4. Remedial measures:

a) Forced application of remedial measures provided for at Point b, Clause 4, Article 7 of this Decree, for violation acts defined in Clause 1, Point b of Clause 2 and Clause 3 of this Article;

b) Forced compliance with the prescribed technical processes, for violation acts defined at Point a, Clause 2 of this Article.

Article 9.- Violation of regulations on preventing and fighting epidemic-causing contagious diseases

1. Caution or a fine of between VND 50,000 and 200,000 for acts of failing to give vaccinations or giving inadequate vaccinations under programs on enlarged vaccinations for people, required by health

bodies.

2. A fine of between VND 200,000 and 500,000 for one of the following acts:

a) Failing to make declarations according to regulations when persons themselves or members of their families, agencies, organizations or units are infected with epidemics-causing contagious diseases;

b) Making untruthful declarations or declining to make declarations according to regulations when persons themselves or members of their families, agencies, organizations or units are infected with epidemics-causing contagious diseases or covering their state of being infected with epidemics-causing contagious diseases;

c) Failing to apply or applying inadequately measures to prevent and fight vectors causing contagious diseases at requests of health bodies.

3. A fine of between VND 500,000 and 1,000,000 for one of the following acts:

a) Urinating or throwing not at right places substances or objects which may spread epidemic-causing contagious diseases;

b) Failing to apply reserve therapeutic measures (chemical therapy) according to regulations;

c) Failing to apply measures of cleansing, disinfecting wastes, clothes, devices, surrounding environment, means of carrying patients according to regulations;

d) Failing to comply with regulations on isolation upon the infection with epidemic-causing contagious diseases;

e) Permitting or creating conditions for patients,

persons carrying pathogens and/or persons infected with epidemic-causing contagious diseases to do jobs which may easily cause spread of contagious diseases;

f) Spreading diseases to other persons;

g) Refusing or failing to abide by orders on mobilization for epidemic control according to regulations;

h) Failing to handle corpses infected with extremely dangerous contagious diseases according to regulations.

i) Failing to comply or inadequately complying with regulations on combating the spread of epidemic-causing contagious diseases to other persons when persons themselves or their family members are infected with such diseases.

4. A fine of between VND 1,000,000 and 2,000,000 for one of the following acts:

a) Obstructing the application of or failing to apply urgent epidemic-preventing and fighting measures of competent state agencies;

b) Informing epidemic-causing contagious diseases *ultra vires*.

5. Additional sanctioning measures: Individuals or organizations committing violation acts defined in Clauses 3 and 4 of this Article may also be subject to the application of one of the additional sanctioning forms provided for in Clause 3, Article 7 of this Decree.

6. Remedial measures: Individuals or organizations committing violation acts defined in Clause 3 of this Article shall also be subject to the application of remedial measures provided for at Point b, Clause 4, Article 7 of this Decree.

Article 10.- Violation of regulations on border medical quarantine

1. A fine of between VND 1,000,000 and 2,000,000 for one of the following acts:

a) Failing to make declarations according to medical quarantine regulations with medical quarantine bodies before exits, entries, export, import by transport means owners, goods owners or their representatives;

b) Using deratization or deratization exemption certificates against regulations;

c) Using foods, trading in foods in service of customers at border-gates, which are not up to food hygiene and safety standards.

2. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts:

a) Refusing to take medical quarantine or failing to respond to requests of medical quarantine officials with regard to objects liable to medical quarantine;

b) Failing to signal the application for medical quarantine according to regulations, with regard to owners of waterway transport means on entry;

c) Failing to apply measures against rats on sea shipping means when they anchor or moor at ports.

3. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Modifying or forging medical quarantine certificates;

b) Transporting corpses, remains, remain ashes, such special products as biological products, bacteria, human tissues and/or organs, blood and blood components through border-gates without being inspected and granted medical quarantine

certificates by medical quarantine bodies;

c) Exporting, importing waste matters, used objects and/or means without declaring them with medical quarantine bodies, without quarantine certificates issued by medical quarantine bodies;

d) Dumping waste matters not at right places by entering or exiting transport means;

e) Covering up or obliterating the current state subject to medical quarantine.

4. A fine of between VND 10,000,000 and 15,000,000 for acts of discharging balance water in contravention of law provisions, abandoning waste matters carrying pathogens and toxic elements before the medical quarantine bodies take medically handling measures.

5. Remedial measures: Forced application of remedial measures provided for at Point d, Clause 4, Article 7 of this Decree for violation acts defined at Point e, Clause 3 of this Article.

Article 11.- Violation of regulations on labor hygiene

1. A fine of between VND 500,000 and 1,500,000 for one of the following acts:

a) Failing to organize health checks for laborers before recruitment or organizing health checks but without dossiers thereof;

b) Failing to observe regulations on healthcare for female laborers;

c) Failing to compile dossiers on enterprise sanitation; dossiers on periodical health checks; dossiers on occupational disease declaration and annual registration for annual or periodical labor hygiene inspections;

d) Failing to arrange medical workers, technical means, emergency equipment and facilities, to work out emergency and rescue schemes for hazardous, dangerous and labor accident-prone jobs according to regulations;

e) Failing to organize training on labor hygiene, occupational disease prevention and on-spot emergency for laborers;

f) Failing to pay medical expenses from the time of first aids to the time of complete treatment of labor accident victims or occupational disease sufferers.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Failing to comply with regulations on labor hygiene regarding radiation and electromagnetic field;

b) Failing to take measures and to have equipment for handling toxins, toxic gases, smoke and dusts, contaminated waste water, industrial waste and other poisonous elements; failing to comply with regulations on labor hygiene, temperatures, humidity, light, noise, vibration, dust, poisonous gases and other toxic elements;

c) Failing to organize periodical health checks in order to detect occupational diseases for laborers; failing to complete dossiers and procedures for occupational disease sufferers to have occupational disease examination; failing to organize medical treatment and recuperation for laborers suffering from occupational diseases and to arrange other jobs suitable to their health conditions.

3. Remedial measures:

a) Forced application of remedial measures

provided for at Point b, Clause 4, Article 7 of this Decree for violation acts defined at Points a and b of Clause 2 of this Article;

b) Forced organization of training on labor hygiene, occupational disease prevention and on-spot first-aid for laborers, for violation acts prescribed at Point e, Clause 1 of this Article.

Article 12.- Violation of regulations on management of chemicals, insecticides, disinfectants for domestic or medical use

1. A fine of between VND 1,000,000 and 3,000,000 for one of, the following acts:

a) Failing to comply with the regulations on conditions for production of, and/or trading in, chemicals, insecticides, disinfectants for domestic or medical use;

b) Failing to comply with the regulations on packing, wrapping, preservation and transportation of chemicals, insecticides, disinfectants for domestic or medical use.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Producing, trading in chemicals, insecticides, disinfectants for domestic or medical use with the expired certificates of registration for circulation of such products;

b) Producing, trading in chemicals, insecticides, disinfectants for domestic or medical use not up to the announced standards;

c) Producing, trading in chemicals, insecticides, disinfectants for domestic or medical use without certificates of registration for circulation thereof in Vietnam;

d) Advertising for chemicals, insecticides,

disinfectants for domestic or medical use without written receipts of dossiers of registration for advertisement, issued by competent health bodies or making advertisements untrue to the registered contents or failing to amend the advertisement contents at requests of competent health bodies.

3. A fine of between VND 8,000,000 and 12,000,000 for acts of trading in expired chemicals, insecticides, disinfectants for domestic or medical use.

4. A fine of between VND 10,000,000 and 15,000,000 for acts of producing, trading in chemicals, insecticides and/or domestic- or medical-use disinfectants banned from use in Vietnam.

5. Additional sanctioning forms: Deprivation of the right to use certificates of registration for circulation of chemicals, insecticides, domestic- or medical-use disinfectants for 6 to 12 months, for violation acts prescribed in Clauses 2 and 3 of this Article.

6. Remedial measures:

a) Forced application of remedial measures prescribed at Point d, Clause 4, Article 7 of this Decree, for violation acts defined at Point b of Clause 1, Point b of Clause 2, Clause 3 and Clause 4 of this Article;

b) Payment of expenses for application of remedial measures prescribed in Clause 6 of this Article by violating establishments.

Article 13.- Violation of other regulations on hygiene

1. A fine of between VND 200,000 and 800,000 on organizations, individuals violating regulations

on hygiene to prevent and combat epidemics.

2. A fine of between VND 500,000 and 1,000,000 for one of the following acts:

a) Violating regulations on environmental hygiene in offices, hospitals, schools, creches and other public places;

b) Having classroom tables and benches with sizes unsuitable to pupils' stature; having not enough natural or artificial light in classrooms; failing to ensure per-pupil space norm; having inadequate drinking, cleaning water, hygienic toilets for pupils according to regulations.

3. A fine of between VND 2,000,000 and 5,000,000 for acts of producing, trading in teaching aids, learning means, toys for children, which cause harms to the health of children, pupils.

4. Forced application of remedial measures prescribed at Point d, Clause 4, Article 7 of this Decree for violation acts prescribed at Clause 3 of this Article.

Article 14.- Violation of regulations on HIV/AIDS prevention and combat

1. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts:

a) Disclosing testing secrets, notifying HIV test results to tested persons or other persons without permission;

b) Violating regulations on keeping secret the names, ages, addresses, images of HIV-infected persons;

c) Publishing on mass media names, ages, addresses, images of HIV-infected persons without the consents of such persons or their relatives in cases where such persons have died or lost their

civil act capacity;

d) Refusing to give medical treatment to HIV-infected persons.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts;

a) Violating regulations on blood transfusion, on sterilization, disinfection and other regulations on professional handling of HIV infection;

b) Notifying positive HIV test results not to the prescribed subjects;

c) Relying on HIV test results to recruit labor or enrol trainees, except for special cases prescribed by law;

d) Failing to supply information on HIV infection and spread prevention to laborers by production, business establishments;

e) Notifying HIV test results to tested persons by establishments not yet recognized by the Ministry of Health as having laboratories fully qualified for confirming positive HIV cases;

f) Sacking laborers or expelling pupils or students for reasons of HIV infection.

3. Remedial measures: Compelling employers to take back HIV-infected laborers for arrangement to other appropriate jobs according to regulations or compelling schools to take back HIV-infected pupils or students for continued study, for violation cases prescribed at Point f, Clause 2 of this Article.

Section 2. ACTS OF ADMINISTRATIVE VIOLATION RELATED TO FOOD HYGIENE AND SAFETY, SANCTIONING FORMS AND LEVELS

Article 15.- Violation of regulations on food hygiene and safety

1. Caution or a fine of between VND 100,000 and 300,000 for one of the following acts:

a) Not wearing special-use clothing when directly engaging in food production, processing, trading or without certificates of being trained in food hygiene and safety;

b) Having no glass cupboards, no hygienic containers or wrappings at places where pre-processed instant foods are displayed for sale;

c) Failing to use separate tools to pick up, scoop, contain assorted instant foods;

d) Trading in instant foods without adequate clean water sources for cleaning tools or hand-washing by sellers;

e) Tools used for food containing, picking up, scooping or processing are unhygienic;

f) Failing to clean or cleaning food-selling equipment, tools and/or places where foods are put up for sale in contravention of regulations of the Ministry of Health;

g) Failing to ensure hygiene criteria on safe vegetables as prescribed for safe vegetable-producing establishments.

2. A fine of between VND 300,000 and 600,000 for one of the following acts:

a) Producing, trading in foods, food raw materials, additives at unhygienic places;

b) Failing to keep food samples according to regulations or keeping food samples in contravention of regulations;

c) Failing to observe the regime of supervising the implementation of regulations on food hygiene and safety by collective kitchens organized at establishments.

3. A fine of between VND 500,000 and 2,000,000 for one of the following acts:

a) Failing to ensure food hygiene and safety standards prescribed by the Ministry of Health for raw materials and water used for food production or processing;

b) Reusing packages already used for containing oil, fat or milk to contain industrially processed food;

c) Producing food-catering utensils, assorted food packages from raw materials, additives not on the list of permitted ones, publicized by the Ministry of Health;

d) Using equipment, containing devices, packages, means of transport or preservation with surfaces in direct contact with foods being made of raw materials, which do not ensure food hygiene and safety.

4. A fine of between VND 2,000,000 and 6,000,000 for one of the following acts:

a) Producing or trading in foods originating from animals not yet quarantined or failing to meet the requirements upon inspection thereof;

b) Producing or trading in farm produce with plant protection drug residues exceeding the permitted levels;

c) Failing to announce the food hygiene and safety standards applicable to foods before circulation thereof or food products being circulated on market but failing to reach the announced food hygiene and safety standards;

d) Failing to announce the food hygiene and safety standards applicable to foods requiring the announcement of food hygiene and safety standards according to law provisions, or having

already made the written announcements which, however, have expired;

e) Building food-producing or –processing establishments at places which fail to ensure food hygiene and safety;

f) Producing, using food-catering ice not up to the food hygiene and safety standards prescribed by the Ministry of Health;

g) Failing to comply with regulations on hygiene and safety in food preservation and transportation;

h) Persons directly involved in food production or processing are being infected with contagious diseases, skin diseases or other ailments prescribed by the Ministry of Health.

5. A fine of between VND 10,000,000 and 15,000,000 for one of the following acts:

a) Producing, trading in foods which have deteriorated, been contaminated with dirt or strange impurities or with toxins, which threaten to affect human health;

b) Producing, trading in foods carrying pathogenic parasites, micro-organisms not permitted to exist in food or to exceed the permitted limits;

c) Producing, trading in foods or products processed from poultry, cattle, aquatic animals, vegetables and/or fruits, which are diseased, poisoned, dead without clear causes or pickled, dipped in chemicals not permitted for use;

d) Having no certificates of full satisfaction of food hygiene and safety conditions, granted by competent bodies to high-risk food production and/or business establishments;

e) Producing, trading in food additives, food processing-supporting substances, micronutrients,

functional foods, high-risk foods, foods preserved by radiation methods, foods with genetic alteration but not yet permitted by competent state management agencies;

f) Producing, trading in foods with the use of food additives, micronutrients, processing-supporting substances, which are not allowed for use or used not according to the prescribed doses or limits or have unclear origins;

g) Producing, trading in foods which are expired or not up to hygiene standards;

h) Producing, trading in foods preserved by radiation methods but the labels are not inscribed with contents in Vietnamese language or international signs that the foods are preserved by radiation method;

i) Producing, trading in radiated foods outside the list of foods permitted to be radiated or foods on the list of radiated ones, but the radiation exceeds the law-prescribed doses;

j) Producing, trading in foods involving the use of genetic technology or raw materials involving the use of genetic technology, but the labels are not inscribed in Vietnamese with the content that “Thuc pham co su dung cong nghe gen” (Foods involving the use of genetic technology);

k) Producing, trading in foods made of non-food raw materials, failing to ensure food hygiene and safety or being added with chemicals outside the list of those permitted to be added to foods;

l) Wholesaling agricultural products with plant protection drug or chemical fertilizer residues exceeding the permitted levels;

m) Labeling or advertising in any forms on foods with effects substituting for curative medicines;

n) Changing, re-making labels or changing dates of manufacture, dates of expiry on labels of foods already delivered from workshops or circulated;

o) Producing, trading in foods added with mixtures, colors, powders to cover, dye, process with a view to covering up the rottenness or deterioration of foods;

p) Producing, trading in foods composed fully or partially of rotten or deteriorated raw materials or another raw material unsuitable to the foods, regardless of whether such raw materials have been processed or not;

q) Using contaminated means or means already used for transportation of toxins to transport foods;

r) Failing to report on food poisoning upon its occurrence to provincial/municipal Health Services or the nearest People's Committees for taking timely preventive and remedial measures;

s) Failing to apply adequate measures to prevent and handle in time food poisoning upon its occurrence and diseases transmitted via foods.

6. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Advertising for foods, food additives with food hygiene and safety standards not yet announced; foods, food additives of poor quality, failing to ensure hygiene and safety or making advertisements in the absence of written receipts of dossiers of advertisement registration, issued by competent health bodies or making advertisements not according to the registered contents or failing to amend advertisement contents at requests of competent health bodies;

b) Advertising for foods, food additives untruthfully, unclearly, contrarily to the announced

contents; untruthfully or exaggeratedly in terms of characteristics, nature, values, materials, advantageous components, safeness, purity, weight, ratios, origins, composition of foods.

7. Remedial measures: Applying the remedial measures provided for at Point d of Clause 4, Article 7 of this Decree, for violation acts prescribed at Points a, b, c, d, f and g of Clause 4; Points a, b, c, d, e, f, g, i, k, l, n, o, p and q of Clause 5 of this Article.

Article 16.- Violation of regulations on cigarette harm prevention and combat

1. Caution or a fine of between VND 50,000 and 100,000 for one of the following acts:

a) Smoking cigarettes or tobacco at such public places as theatres, cinemas, meeting halls, working rooms, hospitals, libraries, waiting lounges of railway stations, car terminals, airports, ports, mass transit means or at other public places where smoking is prohibited;

b) Selling cigarettes or tobacco to children of under 16 years old.

2. A fine of between VND 4,000,000 and 6,000,000 for acts of violating regulations on labeling cigarette products, regulations on contents of warning and positions for inscription of warning on cigarette boxes.

3. A fine of between VND 20,000,000 and 30,000,000 for acts of producing cigarettes with tar, nicotine contents exceeding the permitted levels.

4. Remedial measures: Applying remedial measures provided for at Point d of Clause 4, Article 7 of this Decree for violation acts prescribed in Clause 3 of this Article.

Article 17.- Violation of regulations on producing, trading in and using products to substitute for mother's milk

1. A fine of between VND 500,000 and 1,000,000 for acts of distributing information and education documents on nurturing newborns, infants in the following cases:

a) Containing pictures or inscriptions encouraging the bottle-feeding or not encouraging breast-feeding of children;

b) Containing names or symbols of products substituting for mother's milk, feeding bottles, rubber nipples, teats.

2. A fine of between VND 3,000,000 and 5,000,000 for one of the following acts:

a) Presenting new mothers or their family members with goods samples encouraging the use of such products as substitute for mother's milk;

b) Trading in mother's milk-substituting products with food hygiene and safety standards not yet announced;

c) Trading in mother's milk-substituting products which fail to ensure the announced food hygiene and safety quality.

3. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Making untruthful information or advertisements on the use of mother's milk substitutes;

b) Comparing mother's milk substitutes as being equivalent to or better than mother's milk;

c) Failing to announce food hygiene and safety quality by establishments producing mother's milk substitutes;

d) Presenting or receiving medical equipment and instruments, feeding bottles, rubber nipples, teats or other utensils with labels of establishments producing and/or trading in mother's milk substitutes; donating or receiving scholarship, financial assistance or funding for scientific research, training, conferences, seminars, training courses, music concerts, via-telephone consultancy services or other forms of financial assistance, aiming to encourage the use of mother's milk substitutes;

e) Advertising for mother's milk substitutes used for children of over six months old without the inscription "Mother's milk is best for the health and growth of newborns and infants".

4. A fine of between VND 10,000,000 and 15,000,000 for one of the following acts:

a) Trading in mother's milk substitutes with use expiry, without labels, origins or without packages;

b) Advertising for mother's milk substitutes used for children from the time of being born to 6 months old, feeding bottles, rubber nipples and teats in any form; advertising with images for mother's milk substitutes used for children from the time of being born to 6 months old.

5. Remedial measures: Forced application of remedial measures provided for at Point d of Clause 4, Article 7 of this Decree, for violation acts prescribed at Point c, Clause 2 and Point a of Clause 4 of this Article.

Article 18.- Violation of regulations on production and supply of iodized salt for users

1. A fine of between VND 300,000 and 800,000 on organizations, individuals producing or trading

in kitchen salt (iodized salt) for committing one of the following acts:

a) Failing to comply with personal-hygiene regulations applicable to laborers;

b) Employing laborers who are being infected with contagious diseases or skin diseases for the direct production of kitchen salt;

c) Failing to organize training on food hygiene and safety for laborers.

2. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Failing to inspect the iodine contents in kitchen salt before delivery from workshops;

b) Failing to provide adequate testing devices and chemicals;

c) Nominating persons who do not possess professional diplomas or possess unsuitable professional diplomas, and testing certificates to positions of professional and technical management or testing in kitchen salt production establishments;

d) Trading in kitchen salt with iodine contents below the prescribed levels.

3. A fine of between VND 3,000,000 and 5,000,000 for acts of failing to publicize goods quality standards as provided for establishments producing and/or trading in kitchen salt.

4. A fine of between VND 5,000,000 and 8,000,000 for one of the following acts:

a) Producing kitchen salt not up to the quality standards set by the State;

b) Using packages labeled with iodized salt for packing common salt (uniodized salt).

5. Remedial measures: Forced re-processing

of kitchen salt which is not up to the quality standards as provided for at Point d of Clause 2 and Point a of Clause 4 of this Article.

Section 3. ACTS OF ADMINISTRATIVE VIOLATION RELATED TO VACCINES, MEDICAL BIO-PRODUCTS, SANCTIONING FORMS AND LEVELS

Article 19.- Violation of regulations on use of certificates of professional practice on vaccine, medical bio-product

1. A fine of between VND 1,000,000 and 3,000,000 for acts of failing to make authorization according to law provisions when heads or professional managers of establishments are absent.

2. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts:

a) Practicing profession without practice certificates or with expired practice certificates;

b) Hiring, borrowing, leasing or lending practice certificates.

3. Additional sanctioning forms: Indefinite deprivation of the right to use practice certificates, for violation acts prescribed at Point b, Clause 2 of this Article.

Article 20.- Violation of regulations on the use of certificates of eligibility for professional practice, professional diplomas

1. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts:

a) Trading in vaccines, medical bio-products without certificates of eligibility for professional

practice on vaccine, medical bio-product or with expired practice certificates;

b) Hiring, borrowing, leasing or lending certificates of eligibility for professional practice;

c) Having no professional diplomas as prescribed for vaccine or medical bio-product professionals.

2. Additional sanctioning forms: Indefinite deprivation of the right to use certificates of eligibility for vaccine or medical bio-product professional practice, for violation acts prescribed at Point b, Clause 1 of this Article.

Article 21.- Violation of regulations on vaccine, medical bio-product production

1. A fine of between VND 5,000,000 and 10,000,000 for one of the acts of producing vaccines, medical bio-products without ensuring preservation equipment, transport means or without ensuring the requirements on fire and explosion prevention and fighting, labor safety and environmental hygiene.

2. A fine of between VND 10,000,000 and 15,000,000 for one of the acts of producing vaccines, medical bio-products without registration numbers or with expired registration numbers or producing vaccines, medical bio-products not in accordance with the registered contents in the approved dossiers for circulation on market.

3. A fine of between VND 15,000,000 and 30,000,000 for acts of producing and circulating on market vaccines, medical bio-products, which are not up to the registered quality standards.

4. Additional sanctioning form: Deprivation of the right to use certificates of eligibility for vaccine,

medical bio-product professional practice for 6 to 12 months, for violation acts prescribed in Clauses 2 and 3 of this Article.

5. Remedial measures:

a) Forced application of remedial measures provided for at Point d, Clause 4, Article 7 of this Decree, for violation acts prescribed in Clauses 2 and 3 of this Article;

b) Payment of expenses for destruction of vaccines, medical bio-products by violating individuals, organizations.

Article 22.- Violation of regulations on preservation, testing of vaccines, medical bio-products

1. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Failing to satisfy the requirements on material and technical foundations and equipment;

b) Failing to acquire adequate technical dossiers, books and vouchers on export, import management by vaccine-, medical bio-product-preserving establishments.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Conducting assays beyond the permitted professional scope;

b) Preserving, transporting vaccines, medical bio-products not yet permitted for circulation.

3. Additional sanctioning forms: Deprivation of the right to use certificates of eligibility for vaccine, medical bio-product professional practice for 6 to 12 months for violation acts prescribed in Clause 2 of this Article.

Article 23.- Violation of regulations on trading in vaccines, medical bio-products

1. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Trading in vaccines, medical bio-products not at the addresses already permitted by competent bodies;

b) Failing to make authorization according to law provisions when heads or professional managers of establishments are absent;

c) Having no preservation depots, no refrigerators up to the prescribed technical standards for preservation of vaccines, medical bio-products;

d) Having no books to monitor the purchase of vaccines, medical bio-products, books to monitor dates of expiry, vaccinations, product quality control;

e) Failing to ensure adequate conditions on material foundations, equipment and requirements on fire and explosion prevention and fighting, labor safety, environmental hygiene.

2. A fine of between VND 2,000,000 and 5,000,000 for acts of trading in vaccines, medical bio-products beyond the permitted professional scope.

3. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Trading in vaccines, medical bio-products without clear sources of production, with origin packages not left intact;

b) Trading in vaccines, medical bio-products without circulation permits or with expired circulation permits or without circulation permission

of the Ministry of Health;

c) Trading in expired vaccines, medical bio-products.

4. A fine of between VND 10,000,000 and 15,000,000 for one of the following acts:

a) Importing finished products or semi-finished products being vaccines, medical bio-products not yet permitted for lawful circulation;

b) Importing vaccines, medical bio-products of foreign enterprises, which are not yet licensed by the Ministry of Health for operation in the fields of vaccines, medical bio-products in Vietnam;

c) Using vaccines, medical bio-products under the enlarged vaccination program in contravention of regulations of the Ministry of Health.

5. Remedial measures:

a) Forced application of remedial measures provided for at Point d, Clause 4, Article 7 of this Decree, for violation acts prescribed in Clause 3 and Point a of Clause 4 of this Article;

b) Payment of expenses for destruction of vaccines, medical bio-products by violating individuals or organizations.

Article 24.- Violation of regulations on vaccine, medical bio-product information, advertisement

1. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Advertising for vaccines, medical bio-products without written receipts of dossiers of advertisement registration, issued by competent health bodies;

b) Making information, advertisements on vaccines, medical bio-products not yet permitted for circulation in Vietnam;

c) Making information, advertisements on vaccines, medical bio-products untrue to the registered dossiers or failing to amend the advertisement contents at requests of competent health bodies;

d) Making information, advertisements on vaccines, medical bio-products upon the expiry of permits for registration of circulation of vaccines, medical bio-products;

e) Putting into circulation on market vaccines, medical bio-products without labels printed with date of expiry, names and addresses of manufacturers and use instructions in Vietnamese.

2. Remedial measures: Forced compliance with provisions of legislation on goods labels, for violation acts prescribed at Point e of Clause 1, this Article before putting products into circulation on market.

**Section 4. ACTS OF ADMINISTRATIVE
VIOLATION RELATED TO MEDICAL
EXAMINATION AND TREATMENT, INCLUDING
MEDICAL EXAMINATION AND TREATMENT
WITH TRADITIONAL MEDICINES,
SANCTIONING FORMS AND LEVELS**

Article 25.- Violation of regulations on use of practice certificates

1. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

- a) Using expired practice certificates;
- b) Practicing profession without practice certificates;
- c) Hiring, borrowing practice certificates for professional practice;

d) Leasing, lending practice certificates to other persons;

e) Having no suitable professional diplomas or certificates;

f) Failing to make authorization according to law provisions by establishments' heads when they are absent.

2. Additional sanctioning forms: Indefinite deprivation of the right to use practice certificates, for violation acts prescribed at Points c and d, Clause 1 of this Article.

Article 26.- Violation of regulations on conditions for professional practice and use of certificates of eligibility for practice of medicine or traditional medicine (referred collectively to as certificates of eligibility for professional practice)

1. A fine of between VND 300,000 and 1,000,000 for one of the following acts:

a) Conducting professional practice in establishments at variance with the addresses inscribed in the certificates of eligibility for professional practice;

b) Failing to meet the conditions on technical equipment as required;

c) Arranging practicing establishments together with places reserved for family activities or other business activities;

d) Failing to meet housing and environmental hygiene conditions by establishments;

e) Having no signboards for practicing establishments according to regulations;

f) Failing to open statistical books to monitor the number of patients, customers provided with

medical technical services daily, failing to keep books on prescriptions.

2. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Practicing medical examination and treatment, providing medical services without certificates of eligibility for professional practice, granted by competent health bodies;

b) Hiring, borrowing from, or leasing or lending to, other persons, certificates of eligibility for professional practice;

c) Conducting professional practice when certificates of eligibility for professional practice have expired;

d) Failing to post up medical service charge rates or collecting charges higher than posted-up charge rates;

e) Failing to keep books to monitor assorted poisons, psychotropics.

3. A fine of between VND 3,000,000 and 8,000,000 for acts of practicing profession beyond professional capabilities, beyond the scopes defined in certificates of eligibility for professional practice.

4. Additional sanctioning forms: Indefinite deprivation of the right to use certificates of eligibility for professional practice, for violations prescribed at Point b, Clause 2 and Clause 3 of this Article, committed by practicing establishments.

Article 27.- Violation of professional and technical regulations

1. A fine of between VND 500,000 and 1,000,000 for one of the following acts:

a) Leaving one's on-duty post;

b) Failing to wear badges, uniforms as provided for while performing one's tasks;

c) Failing to make diagnosis for cases of emergency operation;

d) Adopting authoritarian attitude towards, harassing for bribe, causing troubles to patients;

e) Failing to review death cases within 15 days counting from the date the patients died;

f) Failing to conduct 3 examinations and 5 comparisons before permitting patients to use medicines;

g) Failing to sort and gather medical garbage according to regulations.

2. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts;

a) Failing to quickly provide emergency treatment to patients;

b) Failing to possess professional diplomas by professionals, which are suitable to their assigned tasks;

c) Giving prescriptions while selling medicines in excess of the emergency medicine limits prescribed by health bodies (excluding medical examination and treatment with traditional medicine);

d) Giving prescriptions at variance with ailments;

e) Giving unnecessary prescriptions of expensive special medicines to earn profit differences from drug stores;

f) Failing to comply with regulations on sterilization when conducting surgeries, minor operations;

g) Abusing profession to practice superstition;

h) Abusing profession to commit acts of sexual harassment against patients;

i) Failing to treat hospital wastes according to regulations.

3. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Violating professional and technical regulations, causing harms to patients' health;

b) Using medical examination and treatment methods, equipment and facilities, pharmaceuticals without permission of the Ministry of Health;

c) Failing to get permission of the Ministry of Health by foreigners doing professional works at medical or traditional medicine establishments.

4. Additional sanctioning forms:

a) Indefinite deprivation of the right to use practice certificates, for violation acts prescribed at Points e and g of Clause 2 and Point b of Clause 3 of this Article;

b) Deprivation of the right to use practice certificates for 6 to 12 months, for violation acts prescribed at Point a, Clause 3 of this Article.

5. Remedial measures: Forced compliance with the stipulated garbage-treating process, for violation acts prescribed at Point g of Clause 1 and Point i of Clause 2 of this Article.

Article 28.- Violation of other regulations on medical examination and treatment

1. A fine of between VND 400,000 and 1,000,000 for one of the following acts:

a) Failing to participate in medical activities regarding primary healthcare and communications

guiding people on health protection, disease prevention and combat at requests of local health management bodies;

b) Failing to abide by the regime of periodical reporting to health state management agencies according to regulations;

c) Failing to report to local health bodies upon detection of persons suffering from diseases transmitted via sexual intercourse;

d) Failing to take measures according to regulations to manage persons suffering from dangerous contagious diseases.

2. A fine of between VND 500,000 and 2,000,000 for acts of failing to promptly report to State-run medical establishments on detected cases of contagious diseases subject to quarantine, strange ailments, mass poisoning.

3. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Making advertisements at variance with professional capabilities and scope of professional practice provided in certificates of eligibility for professional practice; making advertisements without the written receipts of dossiers of advertisement registration, issued by competent health bodies; making advertisements at variance with the approved registration contents or failing to amend advertisement contents at requests of competent health bodies;

b) Failing to abide by mobilization orders of competent health bodies upon the occurrence of natural calamities or epidemics.

4. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Employing foreigners for medical examination and treatment, who do not know Vietnamese and without interpreters;

b) Employing interpreters for foreigners in medical examination and treatment activities, who fail to ensure the professional or foreign language qualifications according to law provisions;

c) Failing by foreigners who conduct medical examination and treatment to give prescriptions in Vietnamese or foreign languages according to regulations.

Article 29.- Violation of professional and technical regulations in the fields of traditional medicine and pharmacy

1. A fine of between VND 500,000 and 1,000,000 for one of the following acts:

a) Failing to have lids or caps for medicine chests, bottles, failing to inscribe names of medicaments or wrongly inscribing the names of medicaments;

b) Possessing mouldy, worm-eaten medicines.

2. A fine of between VND 1,000,000 and 2,000,000 for one of the following acts:

a) Failing to comply with the regulations on sterilization and disinfection in acupuncture, injection, pricking and other minor operations in medical examination and treatment;

b) Giving prescriptions at variance with ailments.

3. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts:

a) Trading in western medicines by traditional medicine and/or pharmacy establishments;

b) Possessing medicines which are expired, to be recovered on issued orders, have no production registration number or are not yet permitted for import.

4. A fine of between VND 5,000,000 and 8,000,000 for acts of using medical examination and treatment methods, equipment, pharmaceuticals, which are not yet permitted for use by competent health bodies.

5. A fine of between VND 5,000,000 and 10,000,000 on establishments practicing medical examination and treatment with traditional medicine and pharmacy (including establishments involving foreign elements) for committing one of the following acts:

a) Making advertisements beyond the professional capabilities and practicing scope defined in certificates of eligibility for professional practice;

b) Making advertisements without written receipts of advertisement registration dossiers, issued by competent health bodies or making advertisements untrue to the registered contents or failing to amend the advertisement contents at requests of competent health bodies.

6. Additional sanctioning forms: Indefinite deprivation of the right to use practicing certificates, the right to use certificates of eligibility for professional practice, for violation acts prescribed in Clause 4 of this Article.

7. Remedial measures: Forced application of remedial measures defined at Point d, Clause 4, Article 7 of this Decree, for violation acts prescribed at Point b of Clause 1, Point b of Clause 3 and

Clause 4 of this Article.

Article 30.- Violation of regulations on conditions for professional practice of massage, pore rubbing and pressing, medicated inhalation

1. A fine of between VND 300,000 and 500,000 for one of the following acts:

- a) Having no signboards at massage parlors;
- b) Failing by practitioners to wear costumes, possessing no professional certificates issued by competent bodies, failing to wear insignias as provided for.

2. A fine of between VND 500,000 and 1,000,000 for one of the following acts:

- a) Making massage beds not up to the prescribed standards;
- b) Failing to install emergency bells for medicated inhalation rooms;
- c) Failing to ensure adequate light and hygiene as provided for;
- d) Failing to ensure adequate floor space for professional practice as provided for;
- e) Having no emergency means when conducting massage, pore rubbing and pressing, medicated inhalation.

3. A fine of between VND 3,000,000 and 5,000,000 for one of the following acts:

- a) Structuring system of doors of massage, pore rubbing and pressing, acupuncture or medicated inhalation rooms in contravention of regulations;
- b) Failing to comply with professional and technical regulations by massage, pore rubbing and

pressing or acupuncture practitioners;

- c) Failing to ensure safety of medicated inhalation system;

- d) Abusing profession to conduct other activities not for purposes of functional rehabilitation and health improvement.

4. Remedial measures: Forced redressing of the state of unsafety for medicated inhalation system provided for in Clause 2 and Points a, c of Clause 3 of this Article.

Article 31.- Violation of regulations on child birth by scientific methods

1. A fine of between VND 10,000,000 and 15,000,000 for one of the following acts:

- a) Disclosing information on the names, ages, addresses and images of sperm or embryo donors;
- b) Donating or receiving ova; donating or receiving sperms; donating or receiving embryos without permission;

- c) Failing to ensure conditions for performing child delivery supporting techniques according to regulations.

2. A fine of VND 20,000,000 and 30,000,000 for one of the following acts:

- a) Surrogacy;
- b) Human cloning.

3. Remedial measures: Forced redressing the state of failing to ensure conditions for performing child delivery-supporting techniques according to regulations, for violation acts prescribed at Point c, Clause 1 of this Article.

Section 5. ACTS OF ADMINISTRATIVE VIOLATION RELATED TO PREVENTIVE AND CURATIVE MEDICINES FOR HUMAN USE, INCLUDING TRADITIONAL MEDICINES AND COSMETICS DIRECTLY AFFECTING HUMAN HEALTH, SANCTIONING FORMS AND LEVELS

Article 32.- Violation of regulations on use of pharmaceutical practice certificates

1. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Trading in medicines without practice certificates or with expired practice certificates;

b) Hiring, borrowing from, or leasing, lending to, other persons practice certificates or professional diplomas;

c) Failing to make authorization according to law provisions by establishments' heads or professional managers when they are absent.

2. Additional sanctioning forms: Indefinite deprivation of the right to use practice certificates, for violation acts prescribed at Points a, b, Clause 1 of this Article.

Article 33.- Violation of regulations on conditions for professional practice and use of certificates of eligibility for private pharmaceutical practice (referred collectively to as certificates of eligibility for professional practice).

1. A fine of between VND 500,000 and 1,000,000 for one of the following acts:

a) Conducting professional practice not at the right addresses inscribed in the certificates of eligibility for professional practice, or without signboards at practicing establishments as

provided for;

b) Failing to ensure conditions on infrastructure and environmental hygiene;

c) Failing to open statistical books, to keep books, vouchers related to addictives, psychotropics and addictive prescriptions.

2. A fine of between VND 2,000,000 and 5,000,000 for one of the following acts:

a) Practicing profession beyond professional capabilities or practicing scope defined in certificates of eligibility for professional practice;

b) Hiring, borrowing from, or leasing, lending to, other persons the certificates of eligibility for professional practice;

c) Trading in medicines without certificates of eligibility for professional practice or with expired certificates of eligibility for professional practice.

3. Additional sanctioning forms:

a) Deprivation of the right to use certificates of eligibility for professional practice for 6 to 12 months, for violation acts prescribed at Point a, Clause 2 of this Article;

b) Indefinite deprivation of the right to use certificates of eligibility for professional practice, for violation acts prescribed at Points b and c, Clause 2 of this Article.

Article 34.- Violation of regulations on trading in medicines

1. Caution or a fine of between VND 100,000 and 200,000 on medicine sellers for failing to wear working clothes or to wear insignias according to regulations.

2. A fine of between VND 1,000,000 and

3,000,000 for one of the following acts:

a) Failing to reach the prescribed standards by medicine sellers;

b) Failing to authorize or nominate persons by drug store owners, agent owners or pharmaceutical establishments' professional managers to take their places when they are absent.

3. A fine of between VND 500,000 and 2,000,000 for acts of selling wrong medicines.

4. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Selling to be-prescribed medicines without physicians' prescriptions or selling medicines not in accordance with the prescriptions;

b) Trading in non-commercial medicines, or medicines with packages not fully inscribed with the prescribed information.

5. A fine of between VND 3,000,000 and 5,000,000 for one of the following acts:

a) Trading in medicines not permitted for circulation;

b) Trading in medicines below the quality standards or expired medicines with a volume being smaller than or equal to 50 tablets or equal to 10 ampoules or equal to 10 vials or equal to ten times for medicines other than poisons, addictives, psychotropics, pre-substances, radioactive pharmaceuticals.

6. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Trading in medicines not up to the quality standards or expired medicines with a volume of more than 50 tablets, more than 10 ampoules, more than 10 vials or more than 10 bottles, for medicines

other than poisons, addictives, psychotropics, pre-substances, radioactive pharmaceuticals;

b) Trading in medicines not up to quality standards or expired medicines, for medicines being poisons, addictives, psychotropics, pre-substances, radioactive pharmaceuticals.

7. Additional sanctioning forms:

a) Deprivation of the right to use practice certificates, certificates of eligibility for professional practice for 6 to 12 months, for violation acts prescribed in Clause 5 and Point a of Clause 6 of this Article;

b) Indefinite deprivation of the right to use practice certificates, certificates of eligibility for professional practice against practicing establishments for committing the violations prescribed at Point b, Clause 6 of this Article.

8. Remedial measures:

a) Forced application of remedial measures defined at Point d, Clause 4, Article 7 of this Decree, for violation acts prescribed at Point b of Clause 4, Clauses 5 and 6 of this Article;

b) Payment of expenses for destruction of medicines by violating individuals or organizations, except for cases where the medicines must be seized for use as proofs or material evidences for subsequent handling.

Article 35.- Violation of regulations on medicine production

1. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Producing medicines without ensuring conditions on hygiene;

b) Producing medicines without adequate

manufacturing equipment.

2. A fine of between VND 10,000,000 and 20,000,000 for one of the following acts:

a) Producing medicines without registration numbers issued by competent health bodies;

b) Producing medicines when registration numbers have expired;

c) Producing medicines at variance with medicine registration dossiers.

3. A fine of between VND 20,000,000 and 30,000,000 for producing medicines not up to the registered quality standards.

4. Additional sanctioning forms: Indefinite deprivation of the right to use certificates of eligibility for pharmaceutical practice, for violation acts prescribed in Clauses 2 and 3 of this Article.

5. Remedial measures:

a) Forced application of remedial measures provided for at Point d, Clause 4, Article 7 of this Decree, for violation acts defined in Clauses 2 and 3 of this Article;

b) Payment of expenses for destruction of medicines by violators.

Article 36.- Violation of regulations on preservation of medicines, raw materials used for production of medicines and assay of medicines

1. A fine of between VND 1,000,000 and 3,000,000 for one of the following acts:

a) Failing to satisfy the requirements on preservation of medicines and medicinal raw materials;

b) Failing to have technical dossiers and books

recording the delivery and reception of medicines and medicinal raw materials according to regulations.

2. A fine of between VND 5,000,000 and 8,000,000 on establishments providing services on medicine testing, services on medicine preservation for failing to meet the professional and technical requirements.

3. Additional sanctioning forms: Deprivation of the right to use practice certificates for 6 to 12 months, for violation acts defined in Clause 2 of this Article.

4. Remedial measures: Forced application of professional and technical measures to redress violation acts defined in Clause 1 of this Article.

Article 37.- Violation of regulations on export, import of medicines and medicinal raw materials

1. A fine of between VND 20,000,000 and 30,000,000 for one of the following acts:

a) Importing medicines or medicinal raw materials without permission of the Ministry of Health;

b) Importing medicines or medicinal raw materials after the manufacturing countries announce the ban from circulation in the markets;

c) Importing medicines or medicinal raw materials without intact origin packages;

d) Exporting medicines on the list of those banned from export.

2. Additional sanctioning forms: Deprivation of the right to use practice certificates for 6 to 12 months, for violation acts defined at Points a, b and d of Clause 1 of this Article.

3. Remedial measures:

a) Forced application of remedial measures defined at Point d, Clause 4, Article 7 of this Decree, for violation acts defined at Points a, b, c and d, Clause 1 of this Article, excluding precious and rare medicines (both western and eastern medicines) defined at Points a, c of Clause 1, being certified by medicine-expertising agencies as meeting the use quality;

b) Payment of expenses for destruction of medicines by violating individuals or organizations.

Article 38.- Violation of regulations on poisons, addictives, psychotropics, pre-substances, radioactive pharmaceuticals

1. A fine of between VND 4,000,000 and 8,000,000 for acts of prescribing and using poisons, addictives, psychotropics, pre-substances, radioactive pharmaceuticals not in accordance with regulations of the Ministry of Health.

2. A fine of between VND 20,000,000 and 30,000,000 for acts of producing, preparing, preserving, trading in poisons, addictives, psychotropics, pre-substances, radioactive pharmaceuticals at variance with the regulations of the Ministry of Health.

3. Additional sanctioning forms: Deprivation of the right to use certificates of eligibility for professional practice for 6 to 12 months, for violation acts defined at Clauses 1 and 2 of this Article.

Article 39.- Violation of regulations on information and advertisement on medicines and medicine labels

1. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Advertising for medicines in the absence of written receipts of advertisement registration dossiers, issued by competent health bodies;

b) Providing information, advertisements on medicines not yet permitted for circulation in Vietnam;

c) Providing contents of medicine information, advertisements at variance with the registered dossiers or failing to amend advertisement contents at requests of competent health bodies or printing, distributing or advertising for medicines when medicine registration numbers have expired;

d) Using medicine labels not approved by competent health bodies or printing medicine labels not in accordance with the approved models;

e) Putting into circulation on market medicines without labels printed with dates of expiry, names and addresses of producers, names of importers and serial numbers of import permits (medicines without registration numbers), for foreign medicines and without slips of use instructions in Vietnamese or auxiliary labels as provided for medicines imported from foreign countries.

2. Additional sanctioning forms: Deprivation of the right to use certificates of eligibility for professional practice for 6 to 12 months, for violation acts defined at Points a, b of Clause 1, this Article.

3. Remedial measures: Forced application of remedial measures defined at Point d, Clause 4, Article 7 of this Decree, for violation acts defined at Points d, e of Clause 1 of this Article.

Article 40.- Violation of regulations on cosmetics directly affecting human health

1. A fine of between VND 3,000,000 and 5,000,000 for one of the following acts:

a) Forging labels of other products already permitted for circulation;

b) Making cosmetic labels without adequate prescribed contents;

c) Producing, trading in cosmetics not yet registered for circulation or with their quality standards being not yet announced according to regulations.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Producing, importing cosmetics which fail to ensure quality;

b) Producing, trading in cosmetics composed of substances banned from use in cosmetics or in excess of permitted limits for substances requiring use concentration, contents;

c) Advertising for cosmetics without circulation registration numbers, with quality standards not yet announced or untrue to registration dossiers;

d) Providing contents of information, advertisement on cosmetics untrue to the registered dossiers or failing to amend advertisement contents at requests of competent health bodies;

e) Trading in cosmetics without ensuring their quality, with expired dates, cosmetics without registration numbers;

f) Advertising for cosmetics in the absence of written receipts of advertisement registration dossiers, issued by competent health bodies;

g) Importing, trading in cosmetics without intact packages of origin.

3. A fine of between VND 10,000,000 and 15,000,000 for acts of importing cosmetics or raw materials for production of cosmetics, which are banned by producing countries from circulation on market.

4. Remedial measures:

a) Forced application of remedial measures prescribed at Point d, Clause 4, Article 7 of this Decree, for violation acts prescribed at Points a, b, c, d, e, g of Clause 2 and Clause 3 of this Article;

b) Payment of expenses for destruction of cosmetics by violating individuals or organizations.

Article 41.- Violation of regulations on medicine price control

1. A fine of between VND 200,000 and 500,000 for acts of failing to post up medicine prices according to regulations.

2. A fine of between VND 500,000 and 2,000,000 for acts of selling medicines at prices higher than the posted prices.

3. A fine of between VND 5,000,000 and 10,000,000 for acts of taking advantage of difficult circumstances, natural disasters or other special plights to raise medicine prices, to press medicine prices, causing damage to consumers.

4. A fine of between VND 8,000,000 and 12,000,000 for acts of violating regulations on the State's policies on medicine price subsidies.

5. A fine of between VND 10,000,000 and 20,000,000 for acts of selling medicines at prices exceeding the prices set by competent bodies.

6. Additional sanctioning forms:

a) Indefinite deprivation of the right to use certificates of eligibility for professional practice, for violation acts prescribed in Clauses 3, 4 and 5 of this Article, committed by practicing establishments;

b) Indefinite deprivation of the right to use pharmaceutical business registration certificates when establishments twice committed the violations prescribed in Clause 4 of this Article;

c) Confiscation of the entire amount of money difference resulting from selling medicines at higher prices as provided for in Clauses 2, 3, 4 and 5 of this Article.

Section 6. ACTS OF ADMINISTRATIVE VIOLATION RELATED TO MEDICAL EQUIPMENT, SANCTIONING FORMS AND LEVELS

Article 42.- Violation of regulations on conditions for professional practice on medical equipment

1. A fine of between VND 3,000,000 and 8,000,000 for one of the following acts:

a) Failing to comply with regulations on medical equipment business registration;

b) Having material and technical foundations and personnel for medical equipment production and trading not in accordance with regulations of the Ministry of Health;

c) Failing to post up prices or posting up prices but selling medical equipment at prices higher than the posted prices.

2. A fine of between VND 5,000,000 and

10,000,000 for one of the following acts:

a) Trading in medical equipment having no circulation registration numbers; being not permitted for import by the Ministry of Health or having unclear origins;

b) Trading in fake medical equipment;

c) Doing business beyond the permitted scope.

3. Additional sanctioning forms: Confiscation of medical equipment, for violation acts defined at Points a and b of Clause 2, this Article.

Article 43.- Violation of regulations on production of medical equipment

1. A fine of between VND 2,000,000 and 5,000,000 for acts of producing medical equipment without certificates of eligibility for professional practice on medical equipment or using expired certificates.

2. A fine of between VND 5,000,000 and 10,000,000 for one of the following acts:

a) Producing medical equipment without registering product circulation numbers;

b) Producing medical equipment when product circulation numbers are no longer valid for circulation on market;

c) Producing medical equipment not in accordance with the announced standards and quality.

3. Remedial measures: Forced application of remedial measures defined at Point d, Clause 4, Article 7 of this Decree, for violation acts prescribed at Points a and c, Clause 2 of this Article.

Article 44.- Violation of regulations on

remedial measures defined at Points a, b and d, Clause 4, Article 7 of this Decree.

2. The presidents of the district-level People's Committees are competent to impose caution, fines of up to VND 20,000,000, to confiscate material evidences and/or means used for commission of administrative violations; to deprive of the right to use practice certificates, certificates of eligibility for professional practice, issued by the Ministry of Health or provincial/municipal Health Services, business registration certificates; to apply remedial measures defined at Points a, b and d, Clause 4, Article 7 of this Decree.

3. The presidents of the provincial-level People's Committees are competent to impose caution, fines of up to VND 30,000,000 for acts of administrative violation in the field of health, to deprive of the right to use practice certificates, certificates of eligibility for professional practice, issued by the Ministry of Health of provincial/municipal Health Services, business registration certificates; to confiscate material evidences and/or means used for commission of administrative violations; to apply remedial measures defined in Clause 4, Article 7 of this Decree.

Article 47.- Sanctioning competence of other agencies

1. In addition to the persons defined in Articles 45 and 46 of this Decree, other persons defined by the Ordinance on Handling of Administrative Violations shall, within the scope of their respective functions and assigned tasks, be competent to sanction acts of administrative violation prescribed in this Decree when detecting them within the domains or geographical areas under their respective management.

2. Where an administrative violation falls under the handling competence of many agencies, the handling thereof shall be undertaken by the agency that accepts the case first.

Article 48.- Procedures for sanctioning of administrative violations

The procedures for sanctioning administrative violations shall comply with the Ordinance on Handling of Administrative Violations and Chapter IV on procedures for sanctioning of administrative violations of Decree No. 134/2003/ND-CP of November 14, 2003 of the Government, detailing the implementation of a number of articles of the 2002 Ordinance on Handling of Administrative Violations.

Chapter IV

IMPLEMENTATION PROVISIONS

Article 49.- Implementation effect

This Decree takes effect 15 days after its publication in the Official Gazette. To annul Decree No. 46/CP of August 6, 1996 of the Government on sanctioning of administrative violations in the field of state management over health.

Article 50.- Implementation responsibility

The ministers, the heads of the ministerial-level agencies, the heads of the Government-attached agencies and the presidents of the provincial/municipal People's Committees shall have to organize the implementation of, and implement, this Decree.

On behalf of the Government
Prime Minister
PHAN VAN KHAI