THE MINISTRY OF HEALTH

Circular No. 09/2010/TT-BYT dated April 28, 2010 of the Ministry of Health on guiding the management of medicine quality

Pursuant to the Government's Decree No. 188/2007/ND-CP of December 27, 2007, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to the June 14, 2005 Law on Pharmacy;

Pursuant to the June 29, 2000 Law on Standards and Technical Regulations;

Pursuant to the November 21, 2007 Law on Product and Goods Quality;

Pursuant to the Government's Decree No. 79/ 2006/ND-CP of August 9, 2006. detailing a number of articles of the Law on Pharmacy;

Pursuant to the Government's Decree No. I27/2007/ND-CP of August I, 2007, detailing a number of articles of the Law on Standards and Technical Regulations;

Pursuant to the Government's Decree No. I32/200S/ND-CP of December 31, 2008. detailing a number of articles of the Law on Product and Goods Quality;

In order to assure the quality of medicines in their manufacture, import, circulation and use, compliance with the Law on Pharmacy, the Law on Standards and Technical Regulations, the Law on Product and Goods Quality, and relevant legal documents regarding medicine quality, and conformity with international practice, and satisfy requirements of international integration of the pharmaceutical sector, the Ministry of Health guides the management of the quality of medicines in the process of manufacture, import, circulation and use in Vietnam.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular regulates activities of managing the quality of medicines in the process of manufacture, import, circulation and use in Vietnam: and provides the rights and responsibilities of medicine traders and consumers and organizations and individuals related to medicine quality.

Article 2. Subjects of application

This Circular applies to organizations and individuals that trade in medicines (below collectively referred to as traders) and agencies, organizations and individuals involved in the management of medicine quality in Vietnam (below collectively referred to as units).

Article 3. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. Medicine means a substance or a mixture of substances used for preventing, treating or diagnosing human diseases or adjusting physiological bodily functions, including finished-product medicine, medicine materials, vaccines and medical biologicals. except functional foods.

2. Vaccine means a preparation containing an antigen which gives a human body an immunological response and is used for prophylactic purposes.

3. Medical biological means a product of biological origin used for preventing, treating or diagnosing human diseases.

4. Medicine material means a substance used as an ingredient in a medicine product in the process of manufacture.

5. Pharmaceutical substance (or active ingredient) means a substance or mixture of substances with a therapeutic effect and used in the manufacture of a medicine.

6. Finished-product medicine means a form of medicine having gone through all stages of manufacture, including final packaging and labeling.

7. Medicine quality standards include regulations on technical specifications and requirements, testing methods, packaging, labeling, transportation and storage and other

requirements related to medicine quality.

Medicine quality standards are expressed in the form of technical documents.

8. Medicine technical regulations means regulations on limits on technical properties and management requirements which medicines and medicine-related activities such as manufacture, testing, storage and transportation must comply with in order to assure the quality and effect of medicines, human safety, hygiene and health; protect animals, plants and the environment: and protect the national interests and security and consumer interests and satisfy other essential requirements.

Technical regulations shall be promulgated by the Minister of Health in the form of documents for compulsory application.

9. Medicine expiry date means final date of a use duration fixed for a lot of medicine after which the medicine may not be used.

An expiry date is usually written in numerals or letters on the medicine label.

10. Lot means a specified quantity of initial materials and packaging materials, or products of the same quality processed through a single stage or a number of stages.

Manufacture lot number means a sign in numerals or letters or a combination of numerals and letters for identifying a medicine lot and tracing the origin of a medicine lot through all stages of manufacture, quality control and distribution of the medicine lot.

11. Quality medicine means a medicine which is up to registered quality standards that are pharmacopoeial standards or manufacturer's institutional standards.

12. Inferior-quality medicine means a medicine which is not up to quality standards already registered with a competent agency.

13. Counterfeit medicine means a product manufactured in the form of a medicine for deceitful purposes because it:

a/ has no pharmaceutical substance;

b/ has pharmaceutical substances but not in registered content;

c/ has pharmaceutical substances different from those indicated on its label;

d/ imitates the name or industrial design of another manufacturer's medicine already registered for industrial properly protection.

14. Good practices means sets of principles and standards promulgated by the Ministry of Health regarding the manufacture, storage, test and circulation of medicines; and culture, harvest and processing of materia medica.

15. Medicine testing means the sampling of a medicine, consideration of technical standards and performance of relevant and necessary tests to determine whether or not materials, semi finished products and finished products are up to quality standards before deciding to accept or reject the medicine.

Article 4. Units of measurement and measuring devices

Units of measurement and measuring equipment and devices used in the pharmaceutical sector must comply with the law on measurement.

Chapter II

ELABORATION. ANNOUNCEMENT AND APPLICATION OF MEDICINE QUALITY STANDARDS

Article 5. Medicine quality standards

1. National standards: the Pharmacopoeia of Vietnam is the set of national standards on medicines.

2. Institutional standards are those elaborated by manufacturers or preparers and applied to their manufactured or prepared products.

3. Quality standards of medicines already permitted by the Ministry of Health for circulation are valid as written commitments of manufacturers or preparers on the quality of manufactured, prepared, circulated or used medicines; and serve as a basis for medicine management or quality control agencies to determine and make conclusions on the quality of medicines in the process of manufacture, circulation and use.

In the management of medicine manufacture and circulation, traders may apply internal quality standards, including medicine quality standards already examined by the Ministry of Health and other additional quality criteria.

4. Application of the Pharmacopoeia of Vietnam:

a/ Medicine manufacturers or preparers may apply the Pharmacopoeia of Vietnam to or elaborate institutional standards for their products on the basis of the Pharmacopoeia of Vietnam and relevant legal documents:

b/ Requirements on quality criteria and levels set forth in each medicine quality standard treatise of the Pharmacopoeia of Vietnam are compulsory. The Ministry of Health encourages establishments to apply testing methods indicated in each medicine quality standard treatise of the Pharmacopoeia of Vietnam;

c/ Requirements on quality criteria and levels and general testing methods set forth in Appendices to the Pharmacopoeia of Vietnam are compulsory. All disparities or inconsistencies must be proved and appraised to ensure their equivalence to the relevant provisions of the Pharmacopoeia of Vietnam;

d/ Institutional standards of medicines must at least meet requirements on quality criteria and levels set forth in the relevant medicine quality standard treatise of the Pharmacopoeia of Vietnam;

e/ Medicine manufacturers or preparers shall update quality standards on their manufactured or prepared medicines in conformity with the effective latest version of the Pharmacopoeia of Vietnam.

5. Application of international standards and foreign pharmacopoeias:

a/ Vietnam-based medicine traders may directly apply pharmacopoeias widely used in international pharmaceutical trading, such as the European. British. US. International and Japanese ones. The application must cover all regulations on quality criteria and levels and testing methods indicated in those pharmacopoeias;

b/ In case a medicine trader applies a pharmacopoeia different from those specified at Point a of this Clause or institutional standards, minimum applicable quality standards must meet requirements on quality criteria and levels set forth in the relevant medicine quality standard treatise of the Pharmacopoeia of Vietnam or of a widely used pharmacopoeia specified at Point a. Clause 5 of this Article:

c/ In case a widely used pharmacopoeia specified at Point a. Clause 5 of this Article does not contain a relevant medicine quality standard treatise, a medicine trader may apply another pharmacopoeia or institutional standards, which must be evaluated under regulations and approved by the Ministry of Health;

d/ Medicine traders shall promptly update medicine quality standards to satisfy requirements in the latest versions of pharmacopoeias.

Article 6. Elaboration of a set of national standards of medicines and promulgation of the Pharmacopoeia of Vietnam for application

1. The Council for the Pharmacopoeia of Vietnam is tasked to organize the study and elaboration of a set of national standards of medicines according to the Ministry of Health's standardization plan and periodically revise, supplement and amend national standards on medicines.

2. The Vietnam Drug Administration shall assume the prime responsibility for examining, soliciting comments, organizing evaluation, and coordinate with the Council for the Pharmacopoeia in finalizing the dossier of the draft set of national standards on medicines, then transfer it to the Ministry of Science and Technology for examination and announcement; and propose the Minister of Health to promulgate the Pharmacopoeia of Vietnam on the basis of the set of national standards on medicines.

The order of elaboration, examination and announcement of a set of national standards on medicines and promulgation of the Pharmacopoeia of Vietnam complies with Joint Circular No. ll/2008/TTLT/BYT-BKHCN of December 29. 2008. of the Ministry of Health and the Ministry of Science and Technology, guiding the elaboration, examination and announcement of a set of national standards on medicines and promulgation and publication of the Pharmacopoeia of Vietnam.

Article 7. Elaboration and announcement of quality standards of medicines in circulation

1. Medicine manufacturers may apply institutional standards or pharmacopoeia standards.

In case of application of institutional standards, medicine manufacturers shall study and elaborate quality standards (in reference to model institutional standards in Appendix 1 -not printed herein) and examine and prove the conformity of testing methods indicated in institutional standards.

In case of application of pharmacopoeia standards, medicine manufacturers shall assess the conformity of testing methods applicable to their medicines.

2. For pharmaco-chemical medicines, medical biologicals. oriental herbal medicines
and medicines from materia medica:

a/ Medicine manufacturers that attain good manufacture practices (GMP) principles and standards shall enclose documents on quality standards with their medicine registration dossiers sent to the Ministry of Health for examination:

b/ Pharmaco-chemical medicine and medical biological manufacturers that have not yet attained GMP principles and standards shall send documents on quality standards and medicine samples to any of central-level state-owned medicine-testing establishments or medicine-testing service businesses having a certificate of eligibility for pharmaceutical trading for examination and certification of the conformity of applicable testing methods before sending their medicine registration dossiers to the Ministry of Health;

c/ Manufacturers of oriental herbal medicines or medicines from materia medica that have not yet attained GMP principles and standards shall send documents on quality standards and medicine samples to stale-owned medicine-testing establishments or medicine-testing service businesses having a certificate of eligibility for pharmaceutical trading for examination and certification of the conformity of applicable testing methods before sending their medicine registration dossiers to the Ministry of Health.

3. Manufacturers of vaccines and medical biologicals which are sera containing antigens for human disease prevention and treatment shall send documents on quality standards and medicine samples to the National Institute of

Vaccines and Biological Substances for examination and certification of the conformity of quality standards and testing methods and the safety and effects of products before sending their medicine registration dossiers to the Ministry of Health.

4. For biologicals for in-vitro diagnosis:

a/ Manufacturers of these biologicals that attain GMP principles and standards or standard TCVN ISO 13485 shall enclose documents on quality standards with their medicine registration dossiers sent to the Ministry of Health for examination:

b/ Manufacturers of these biologicals that have not yet attained GMP principles and standards or standard TCVN ISO 13485 shall enclose documents on quality standards and samples of their products to the National Institute of Vaccines and Biological Substances for examination and certification of the conformity of testing methods and assessment of the diagnostic effectiveness of products before sending their registration dossiers to the Ministry of Health.

5. For medicines on the list of domestically manufactured medicines, registration dossiers shall be submitted to provincial-level Health Departments:

a/ Manufacturers that attain GMP principles and standards shall enclose documents on quality standards with their medicine registration dossiers sent to provincial-level Health Departments for examination:

b/ Manufacturers that have not yet attained GMP principles and standards shall send documents on quality standards and medicine samples to state-owned medicine-testing establishments or medicine-testing service businesses having a certificate of eligibility for pharmaceutical trading for examination and certification of the conformity of applicable testing methods before sending their medicine registration dossiers to provincial-level Health Departments.

6. Modification of medicine quality standards must be made according to the order and procedures specified in Clauses 2 thru 5 of this Article and current regulations on medicine registration.

Article 8. Elaboration and promulgation of institutional standards of prepared medicines

Institutional standards of medicines prepared by preparing establishments (semi-finished products, pre-packaging finished products, medicines prepared according to prescriptions, prepared medicines for use in hospitals or research institutes with patient beds) shall be elaborated by these establishments and approved and promulgated by their heads.

These prepared medicines may not be distributed and circulated on the market.

Chapter III

MANAGEMENT AND INSPECTION OF THE QUALITY OF MEDICINES IN THE PROCESS OF MANUFACTURE. PREPARATION. CIRCULATION AND USE

Article 9. Conditions for assurance of medicine quality of medicine manufacturers or preparers

Medicine manufacturers or preparers shall satisfy the following requirements of medicine quality management in the course of manufacture:

They apply good practice principles and standards to manufacturing, distributing, storing and testing medicines and/or other appropriate management systems in order to assure that the quality of their products conforms to their quality standards already registered and approved by the Ministry of Health (for medicines in circulation) or announced (for medicines prepared for use).

They register their medicines under the Law on Pharmacy and relevant regulations and label them under regulations on goods labeling.

They comply with technical regulations relevant to the process of manufacture, preparation, quality inspection and storage, quality standards and other relevant regulations.

They submit to inspection by medicine management and state quality inspection agencies under Article 24 of this Circular.

Article 10. Conditions for assurance of medicine quality of exporters, importers, wholesalers, retailers, storehouses, transporters or users

Medicine exporters, importers, wholesalers, retailers, storehouses, transporters or users shall satisfy the following quality management requirements:

1. They apply good practice principles and standards to medicine storage and distribution to consumers and other appropriate measures to maintain the quality of medicines in conformity with their quality standards already registered and approved by the Ministry of Health:

a/ Recruiting, training and arranging professionally qualified personnel under regulations;

b/ Equipping devices to store and transport medicines to assure required storage conditions in the course of medicine storage and transportation;

c/ Opening and keeping dossiers and books for monitoring the circulation of medicines they trade in.

For imported medicines, apart from complying with the above provisions, importers shall assure medicine quality under regulations on medicine import.

2. They submit to medicine quality inspection by medicine management and state quality inspection agencies under Article 24 of this Circular.

Article 11. Quality inspection of medicines by medicine traders

1. All medicines (including materials and packages) arc subject to quality inspection. Only medicines that attain quality standards and comply with relevant regulations can be manufactured, prepared and circulated.

2. Heads and professional managers of medicine traders, preparers or users shall take responsibility for the management and inspection of medicine quality at their establishments and for the quality of medicines their establishments trade in, prepare or use.

3. Medicine traders, preparers or users shall organize and conduct the inspection and control of medicine quality at their establishments.

4. Medicine manufacturers or preparers shall have suitable technical devices and professional staffs to test, determine and assess the quality of medicines in the manufacture and ex-works delivery.

5. Medicine exporters, importers, traders, storehouses and users are encouraged to organize, depending on the scope of their operations, the testing of medicines in order to monitor the quality of medicines they trade in.

6. Medicine traders (medicine registrants and importers) shall supply, upon request, documents on medicine quality standards already approved by the Ministry of Health to medicine quality inspection agencies in localities where these medicines are circulated.

Article 12. Contents of quality inspection of medicines by medicine traders

Depending on the scope of their operations, medicine traders shall conduct medicine quality inspection by themselves according to the contents specified in Article 25 of this Circular and their internal regulations in order to assure the quality of manufactured and traded medicines.

Chapter IV

SUSPENSION OF CIRCULATION. RECALL AND HANDLING OF MEDICINES VIOLATING QUALITY REGULATIONS

Article 13. Cases of suspension of circulation or recall of medicines

1. Medicines shall be suspended from circulation or recalled in the following cases:

a/ They are not of right categories due to mistakes in the course of dispensation and delivery;

b/ They are not up to registered quality standards;

c/ They fail to fully satisfy medicine labeling requirements under Article 37 of the Law on Pharmacy and other relevant laws.

d/ Their packaging materials and forms fail to satisfy requirements of medicine quality assurance:

e/ They have no registration numbers or are not yet permitted for import;

f/ There are recall notices of Vietnamese or foreign manufacturers or medicine management or state quality inspection agencies, for the following medicines:

- Counterfeit medicines, smuggled medicines, medicines of unclear origins:

- Medicines manufactured or imported not in accordance with their registration dossiers or import permits:

- Medicines containing substances banned from use in medicine manufacture or containing substances of contents or concentrations exceeding permitted content or concentration limits:

- Finished-product medicines manufactured from materials not up to quality standards or of unlawful origins (smuggled materials, materials of which manufacturers have no certificate of eligibility for pharmaceutical trading, materials not intended for human use or materials without permits for human use):

Medicines manufactured by manufacturers without a certificate of eligibility for medicine trading or failing to satisfy manufacture conditions (failing to satisfy GMP principles and standards or other regulations on pharmaceutical trading conditions):

- Vaccines not preserved under required conditions:

- Expired medicines.

g/ Cases of voluntary recall by medicine traders or under decisions of medicine management or state quality inspection agencies.

2. Forms of recall:

a/ Voluntary recall: Traders themselves detect and recall medicines not up to quality standards.

Upon detecting that medicines of their establishments are of inferior quality or a mistaken category or cause health problems, heads of medicine traders shall promptly report to drug administrations (the Vietnam Drug Administration or provincial-level Health Departments) on the reasons for

and degree of violation, assessing the level of danger and anticipating the extent of recall. After obtaining opinions of management agencies, these establishments shall issue recall notices to localities where their medicines are circulated and recall all medicines circulated on the market, and concurrently monitor and remedy consequences caused by these medicines.

b/ Compulsory recall:

At the request of competent pharmaceutical management and state inspection agencies, trading establishments (circulation permit holders, manufacturers, exporters, importers or import entrusters) shall promptly recall medicines identified as having violated or suspected of having violated regulations, severely affecting the health of users and the community.

3. Degrees of violation:

a/ Bases for determining degrees of violation: Degrees of quality violations shall be determined based on severity of violations, danger of affecting the therapeutic effect and safety of users and undesirable reaction of medicines.

b/ Degrees of violation:

- Degree 1: Violations which are dangerous to the life of medicine users, cause severe injuries or human death.

- Degree 2: Violations which can affect the therapeutic effect and safety of medicines in use.

- Degree 3: Violations which do not affect or slightly affect the therapeutic effect and safety of medicines in use.

4. Levels of notification of circulation suspension and recall of medicines:

a/ Level 1 is applicable to degree-1 violations. Medicine circulation suspension notices shall be urgently sent to medicine circulation license holders, manufacturers, exporters, importers, wholesalers, retailers and pharmacy wards of medicine-using establishments, and concurrently publicized in the mass media for all medicine traders and users to know. Medicine traders that have violating medicines shall urgently take measures to recall all these medicines in a shortest period of time in order to limit bad consequences.

b/ Level 2 is applicable to degree-2 violations. Medicine circulation suspension notices shall be sent to medicine circulation license holders, manufacturers, exporters, importers, wholesalers, retailers.

c/ Level 3 is applicable to degree-3 violations. Medicine circulation suspension notices shall be sent to medicine manufacturers, importers, import entrusters and wholesalers.

d/ Circulation suspension and recall may be conducted for one or several given lots of medicines or a product or all products of one or several medicine manufacturers.

5. Competence to notify a recall

a/ The Vietnam Drug Administration shall issue notices of medicine circulation suspension and recall to be conducted nationwide. These notices shall be sent to provincial-level Health Departments, health care sections of other branches and medicine manufacturers, importers and import entrusters.

b/ Provincial-level Health Departments and health care sections of other branches shall:

- Issue notices of medicine circulation suspension and recall to be conducted under their management for violating medicines detected by local/branch medicine quality inspection agencies:

- Issue notices of circulation suspension and recall to be conducted in their localities in response to recall notices of the Vietnam Drug Administration, handle violations under law and report them to the Vietnam Drug Administration.

c/ Medicine manufacturers, importers or import entrusters shall issue recall notices in cases of voluntary recall.

6. Responsibility to recall medicines:

a/ Medicine manufacturers, exporters, importers, import entrusters and wholesalers shall recall all medicines subject to recall. Upon conducting recall or receiving recall notices from the medicine management and state quality inspection agencies or medicine suppliers, they shall:

Notify the recall to medicines wholesalers and retailers and localities where medicines are circulated;

Promptly recall all violating goods items or medicine lots;

Make medicine recall dossiers. A medicine recall dossier, made according to a set form, must show all evidence of the supply of medicines to and recall of medicines from wholesalers, retailers and users that have purchased medicines;

- Send reports, made according to a set form, on the process and results of recall and handling of recalled medicine lots to the Vietnam Drug Administration and relevant functional agencies within 72 hours, for level-1 recalls, and 30 days, for level-2 and level-3 recalls:

- Deal with complications and consequences caused by sub-standard medicines.

b/ Upon receiving recall notices (or information on medicine recall publicized in the mass media), medicines retailers and users shall urgently recall and return medicines to suppliers.

c/ Medicines manufacturers, exporters, importers, wholesalers and retailers shall receive recalled medicines returned by traders, users and consumers that have purchased medicines.

d/ The Ministry of Health (the Vietnam Drug Administration and the Inspectorate), provincial-level Health Departments and health care sections of other branches shall inspect and supervise medicine traders and users in conducting the recall.

e/ The Vietnam Drug Administration shall guide in detail the process of handling and recalling medicines and assess results of medicine recalls conducted by medicine manufacturers and traders.

Article 14. Destruction of medicines (disposal of violating medicines)

1. Medicines of inferior quality and medicines violating labeling regulations shall, depending on the severity of their violations, be recycled or destroyed. Establishments wishing to have their violating medicines recycled shall send written requests enclosed with the recycling process to the Vietnam Drug Administration. Recycling may be conducted only after written approval of the Vietnam Drug Administration is obtained.

2. Counterfeit medicines, smuggled medicines, medicines of unclear origins, expired medicines, medicines containing substances banned from use. medicines manufactured from sub-standard materials, medicines manufactured under poor conditions, and expired medicine samples shall all be destroyed. Traders whose violating medicines are destroyed shall bear all destruction expenses.

3. Heads of establishments having medicines subject to destruction shall issue decisions to set up medicine destruction councils. Such a council must be composed of at least 3 persons, including a manager of the establishment and a pharmacist in charge of technical operations.

4. Medicine destruction must assure the long-term safety for humans, animals and cause no pollution under the law on environmental protection.

5. The destruction of habit-forming medicines, psychotropic drugs, pre-substances used as medicines and radioactive medicines must comply with regulations on medicine destruction applicable to activities related to habit-forming medicines, psychotropic drugs, pre-substances used as medicines and radioactive medicines. Reports on medicine destruction, made according to a set form and enclosed with written records of medicine destruction shall be sent to managing agencies.

Chapter V

MANAGEMENT AND INSPECTION OF QUALITY OF VACCINES AND MEDICAL BIOLOGICALS

Article 15. General provisions

All agencies, organizations, individuals and enterprises involved in the state management, manufacture, trading and use of vaccines and medical biologicals shall comply with this Circulars provisions on management, inspection, manufacture and trading of medicines and other relevant provisions of law.

Article 16. Inspection of the quality of vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment

1. The Ministry of Health assigns the National Institute of Vaccines and Biological Substances to inspect and assess the quality, safety and effect of. and grant ex-works delivery, circulation and use permits for. vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment.

2. Manufacturers and traders of vaccines and medical biologicals shall send samples and manufacture dossiers of vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment to the National Institute of Vaccines and Biological Substances for inspection and assessment before their ex-works delivery, circulation and use. Procedures and dossiers for sending inspection samples are provided in Article 17 of this Circular.

Manufacturers and importers of vaccines and medical biologicals may deliver or put into circulation or use lots of vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment only after obtaining ex-works delivery permits of the National Institute of Vaccines and Biological Substances, certifying that these lots of vaccines and medical biologicals are up to quality standards and safe and effective.

Article 17. Procedures and dossiers for sending samples for inspection and assessment of the quality, safety and effect of vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment

1. For domestically manufactured vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment, their manufacturers shall send manufacture dossiers and samples of product lots (finished or semi-finished products) to the National Institute of Vaccines and Biological Substances. Such a dossier comprises:

a/ A slip of sending samples for inspection;

b/ Vaccine or medical biological product samples (the number of samples as prescribed for each type of vaccine or medical biological product):

c/ A dossier summarizing the manufacture and quality inspection of the vaccine or medical biological product lot (copies bearing the manufacturer's true-copy seal);

d/ An inspection slip of the manufacture lot.

2. For imported vaccines and medical biologicals being sera containing antigens for human disease prevention and treatment, their importers shall send manufacture dossiers and samples of product lots to the National Institute of Vaccines and Biological Substances. Such a dossier comprises:

a/ A slip of sending samples for inspection;

b/ Vaccine or medical biological product samples (the number of samples as prescribed for each type of vaccine or medical biological product):

c/ A dossier summarizing the manufacture and quality inspection of the vaccine or medical biological product lot (a copy bearing the manufacturer's true-copy seal):

d/ Ex-works delivery permit of a competent authority of the importing country or another equivalent authority, enclosed with the imported lot (a copy bearing the importing enterprise's director's true-copy seal):

e/ Evidence of satisfaction of storage conditions (cold storage chain) in the course of transportation of imported lots.

Chapter VI

MEDICINE TESTING SYSTEMS AND MEDICINE TESTING OPERATIONS

Article 18. Medicine testing systems

1. Stale-owned medicine-testing establishments

- At the central level: the Central Institute of Medicine, the Ho Chi Minh City Institute of Medicine, the National Institute of Vaccines and Biological Substances and regional pharmaceutical and cosmetic testing centers.

- At the local level: provincial-level pharmaceutical and cosmetic testing centers.

2. Medicine-testing sections of medicine traders.

3. Medicine-testing service businesses:

independent testing service businesses or testing sections of medicine traders with the function of providing medicine-testing services.

Article 19. Assurance of quality at medicine-testing establishments

Medicine-testing establishments shall, depending on the scope of their operation, apply good laboratory practice principles and standards and/or other appropriate management systems (for example: ISO/IEC 17025...) in order to assure accurate results of sample testing and analysis.

Article 20. Operations of medicine-testing establishments

1. State-owned medicine-testing establishments at the central level shall:

a/ Inspect and assess medicine quality, assisting the Minister of Health in determining the quality of medicines nationwide under the latter's assignment.

Appraise quality standards of medicines and other products at the request of the Ministry of Health.

b/ Conduct scientific research; provide professional and technical instructions to state-owned medicine-testing establishments in localities.

c/ Train and retrain testing staff in professional skills and testing techniques.

d/ Provide testing services.

e/ Propose to the Minister of Health technical measures to manage medicine quality in accordance with the national socio-economic development conditions.

f/ Perform other operations under relevant laws.

2. State-owned medicine-testing establishments at the local level shall:

a/ Inspect medicine quality, assisting directors of provincial-level Health Departments in determining the quality of medicines circulated in their provinces or centrally run cities.

b/ Appraise quality standards of medicines from materia medica and domestically manufactured medicines registered with provincial-level Health Departments under current medicine registration guidance.

c/ Provide testing services.

d/ Perform other operations under relevant laws.

3. Medicine laboratories of medicine manufacturers and traders:

a/ Medicine laboratory of a medicine manufacturer or trader is a section testing and inspecting the quality of medicines of its establishments and responsible for medicine quality inspection operations at its establishments:

b/ These laboratories shall analyze and test the quality of medicine materials and auxiliary materials, semi-finished products in the process of

manufacture, and finished-product medicines, and participate in assessing and controlling other conditions for medicine quality assurance under regulations of their establishments.

4. Medicine-testing service businesses:

a/ Medicine-testing service businesses must satisfy good laboratory practice standards. In case laboratories of medicine traders wish to provide medicine-testing services, these traders shall carry out procedures for adding the function of providing medicine-testing services in their certificates of eligibility for medicine trading in accordance with law.

b/ Scope of operation: They may provide services of analyzing and testing medicine materials, semi-finished products in the manufacture process and finished-product medicines of medicine manufacturers and traders.

In case medicine-testing service businesses participate in medicine analysis and testing operations serving the state management and inspection of medicine quality, they shall carry out procedures for registering their operation of conformity assessment with the Ministry of Health and the Ministry of Science and Technology under the Ministry of Science and Technology's Circular No. 08/200V1T-PKHCN of April 8. 2009. guiding requirements, order and procedures for registration of the operation of conformity assessment, and relevant regulations.

Article 21. Application of quality standards to medicine testing

1. Medicine testing shall be conducted in accordance with medicine quality standards already registered by medicine manufacturers or importers with medicine circulation permits and approved by the Ministry of Health (the Vietnam Drug Administration).

In case methods other than those indicated in registered standards need to be applied, approval of the Ministry of Health is required. The Ministry of Health assigns the Central Institute of Medicine and the Ho Chi Minh City Institute of Medicine to appraise and accredit applied methods.

2. In case a state-owned medicine-testing establishment has doubts about medicine ingredients or quality, it may apply a method other than those indicated in its registered standards to inspect and produce medicine quality-testing results.

3. Heads of medicine-testing establishments shall be held responsible before law for results of medicine tests conducted by their establishments.

Article 22. Sampling of medicines for quality inspection, notification of testing results, storage of samples, and relevant documents

1. Sampling of medicines for quality inspection:

a/ The sampling of medicines for quality inspection shall be conducted by medicine quality inspection agencies defined in Clause 1. Article 24 of this Circular:

b/ The sampling of medicines for quality testing must comply with the Ministry of Health's Circular guiding the sampling of medicines for quality testing:

c/ Medicine quality inspection agencies shall pay for medicine samples taken for quality inspection under law.

2. Time limit for notifying results of medicine sample analysis or testing:

a/ For medicine samples taken by management agencies or quality inspection agencies for quality inspection: The time limit for notifying analysis or testing results is 30 working days after a testing establishment receives a medicine sample. Within 2 days after issuing an analysis or testing slip, a medicine-testing establishment shall notify analysis or testing results to the management agency, the medicine quality inspection agency and the medicine manufacturer or trader whose medicine is tested. An analysis or testing slip must be made in 3 copies: one to be kept at the testing establishment, one sent to the medicine quality inspection agency and another sent to the medicine manufacturer or trader whose medicine is tested.

When necessary to appraise or re-appraise quality standards or re-assess testing results: equipment, machines, chemicals, reagents and standard agents are insufficient; or there are doubts about medicine ingredients and quality and a testing method other than those indicated in registered quality standards needs to be applied, the time limit for notifying analysis or testing results may be prolonged. Testing establishments shall give explanations about these cases.

b/ For medicine samples sent by organizations and individuals for analysis or testing or appraisal of medicine quality standards: The time limit for notifying analysis or testing results shall be agreed upon by involved parties or stated in internal regulations of medicine manufacturers or traders.

3. Storage of medicine samples:

a/ After quality inspection and quality conclusions are made, inspected medicine samples shall be stored. Medicine samples must be sealed up and stored in proper conditions as indicated in their labels.

b/ Sample storage duration:

- For medicine manufacturers, exporters and importers, finished-product medicine samples shall be stored for at least 12 months after their expiry date:

- For materials being active ingredients used for medicine manufacture, manufacturers shall store material samples for at least 12 months counting from the expiry dale of finished products manufactured from these materials;

- Medicine-testing establishments shall store medicine samples for at least two years (24 months) counting from the time they take or receive the samples;

-Agencies that receive medicine samples for registration shall store these samples for at least 6 months counting from the date they grant registration numbers for medicines.

3. Preservation of dossiers and documents:

a/ Dossiers and documents relevant to medicine quality inspection shall be preserved under regulations;

b/ Dossiers and documents related to habit-forming medicines, psychotropic medicines, pre-substances used as medicines and radioactive medicines shall be preserved for at least 2 years counting from the expiry date of these medicines;

c/ Upon the expiration of their preservation duration, dossiers and documents shall be disposed of under current regulations.

Article 23. Expenses for sampling medicines and testing their quality

1. Expenses for sampling medicines and testing their quality in the course of manufacture, preparation and circulation shall be paid by medicine quality inspection agencies that have decided on sampling and testing under Joint Circular No. 28/2010/TTLT-BTC-BKHCN of March 3. 2010, of the Ministry of Finance and the Ministry of Science and Technology, guiding the management and use of funds for state inspection of product and goods quality.

2. In case medicine quality inspection agencies conclude that medicine samples are not up to quality standards, manufacturers and traders of these medicines shall refund all sampling and testing expenses to quality inspection agencies under Articles 10. 12, 14. 16 and 41 of the 2007 Law on Product and Goods Quality. Joint Circular No. 28/2010/TTLT-BTC-BKHCN of March 3. 2010. of the Ministry of Finance and the Ministry of Science and Technology, guiding the management and use of funds for state inspection of product and goods quality, and other relevant legal documents.

3. In case complaints and denunciations about medicine quality arc concluded by inspection agencies to be groundless, complainants and

denouncers shall refund sampling and analyzing and testing expenses to inspection agencies defined in Clause 1 of this Article.

4. Expenses for sampling medicines for quality inspection and for testing medicine samples shall be incorporated in operation expenditure estimates of state medicine quality inspection agencies under Joint Circular No. 28/2010/TTLT-BTC-BKHCN of March 3. 2010, of the Ministry of Finance and the Ministry of Science and Technology, guiding the management and use of funds for state inspection of product and goods quality.

Chapter VII

STATE INSPECTION AND SCRUTINY OF MEDICINE QUALITY

Article 24. State inspection of medicine quality

1. Medicine quality inspection agencies:

a/ At the central level, the medicine quality inspection agency is the Vietnam Drug Administration under the Ministry of Health:

b/ At the local level, medicine quality inspection agencies are provincial-level Health Departments;

c/ The Vietnam Drug Administration shall direct and coordinate with provincial-level Health Departments and other concerned agencies in inspecting medicine quality.

2. Annually, the Vietnam Drug Administration (in coordination with the Central Institute of Medicine, the Ho Chi Minh City Institute of Medicine, the National Institute of Vaccines and Biological Substances) and provincial-level Health Departments shall base themselves on collected information on dangers of inferior-quality medicines and the actual quality of medicines manufactured, imported or circulated on the market to work out plans on sampling medicines for quality inspection, then submit them to the Ministry of Health or provincial-level Peoples Committees for consideration, approval and allocation of budgets for implementation according to their competence.

3. The state inspection of medicine quality shall be conducted by inspection teams or quality controllers. Powers and tasks of inspection teams and quality controllers are provided in Articles 48 thru 51 of the 2007 Law on Product and Goods Quality.

a/ Inspection teams shall be set up by heads of medicine quality inspection agencies (the Vietnam Drug Administration or provincial-level Health Departments) under approved inspection programs or plans or in case medicine manufacturers, preparers or traders commit systematic or serious violations of regulations on medicine quality or medicine manufacture or

trading conditions, or in other unexpected cases. Inspection contents are specified in Clauses 1 and 2. Article 25 of this Circular;

b/ Medicine quality controllers shall inspect the quality of medicines manufactured, exported. imported or circulated on the market. Inspection contents are specified in Clause 2, Article 25 of this Circular.

Article 25. Contents of quality inspection by medicine quality inspection agencies

1. Quality inspection of medicines in the course of manufacture or preparation covers:

a/ Inspection of the application of good practice principles and standards to medicine manufacture, testing and storage and the observance of relevant laws:

- Inspection of manufacture preparations: quality and origin of materials, auxiliary materials and packaging materials before they are used in the course of manufacture:

- Inspection of the assurance of manufacturing and testing conditions and observance of the manufacturing technology process and processes of testing, cleaning workshops and machines and keeping personal hygiene;

- Inspection of semi-finished products, unpackaged products and finished products;

- Inspection of products before warehousing and ex-works delivery;

- Inspection of the observance of regulations on export, import, storage, dispensation and assurance of quality of medicines.

b/ Inspection of the registration of medicines. research of medicine stability, research and development of products, and labeling of medicines under regulations.

c/ Sampling of medicines and testing of medicine samples according to registered quality standards or applicable institutional standards (for medicines prepared according to prescriptions or medicines prepared for use in hospitals) and to other relevant regulations.

2. Quality inspection of medicines exported, imported, circulated or distributed on the market covers:

a/ Inspection of the observance of good practice principles in medicine distribution, storage and preservation, conditions for medicine quality assurance and relevant regulations on conditions for medicine storage, transportation, circulation and distribution. Inspection of the issuance and implementation of regulations on the inspection and control of medicine

origin and quality in the course of warehousing, storage, transportation and ex-warehousing;

b/ Inspection of medicine registration numbers or medicine import permits, and the observance of regulations on medicine labeling and use instructions;

c/ Inspection of compliance with medicine recall notices of quality inspection agencies and medicine manufacturers, importers, import entrusters and wholesalers;

d/ Sampling of medicines for quality analysis and testing and testing of medicine samples according to medicine quality standards indicated in medicine registration dossiers/import dossiers of medicines without registration numbers already accepted by the Ministry of Health.

Article 26. Specialized scrutiny of medicine quality

Scrutiny of medicine quality shall be conducted by the Pharmaceutical Inspectorate.

The Pharmaceutical Inspectorate shall:

a/ Inspect and scrutinize the observance of the law on medicine quality, propose measures to prevent, remedy and terminate violations of the law on medicine quality;

b/ Consider and settle disputes over and complaints and denunciations about medicine quality:

c/ Handle or sanction administrative violations under law.

3. Provincial-level Health Departments and health care sections of other branches shall inspect and scrutinize the medicine quality management, and handle violations in their respective localities or branches.

4. Procedures, order and measures for conducting inspection or scrutiny and forms of handling or sanctioning administrative violations must comply with regulations on handling of administrative violations.

Article 27. Responsibilities of medicine quality management, inspection and scrutiny agencies in the prevention and combat of counterfeit medicines

1. To receive information reported by concerned organizations and individuals. To publicize necessary contact addresses (hotline telephone numbers, fax numbers, email addresses).

2. To communicate and disseminate to the public and businesses information about harmful effects of counterfeit medicines, signs for distinguishing genuine medicines from counterfeit ones, measures to detect

counterfeit medicines, methods of reporting suspicious cases of counterfeit medicines to state management agencies.

3. To notify cases of counterfeit medicines uncovered on the market and results of handling these cases.

4. To conduct or coordinate with concerned functional agencies in conducting market inspection and supervision to promptly uncover counterfeit medicines in circulation.

5. To coordinate with and support functional agencies in investigating into and tracing sources of counterfeit medicines.

6. To handle violations of manufacturing or trading in counterfeit medicines or medicines of unclear origin or smuggled medicines.

7. The Vietnam Drug Administration shall act as a focal point for coordination, liaison and exchange of information on counterfeit medicines with relevant international organizations (WHO,...) and drug administrations of foreign countries.

Chapter VIII

RESPONSIBILITIES OF STATE MANAGEMENT AGENCIES IN CHARGE OF MEDICINE QUALITY

Article 28. Responsibilities of the state management agency in charge of medicine quality at the central level

The Vietnam Drug Administration is answerable to the Minister of Health for performing the state management of medicine quality:

1. To work out and submit master plans and plans on medicine quality management to the Minister of Health for approval, and organize implementation of approved plans.

2. To elaborate and submit to the Minister of Health for promulgation legal documents on medicine quality management and assurance (good practice principles and standards).technical regulations and quality standards, and guide the implementation of these documents.

To assume the prime responsibility for examining and appraising the set of national standards of medicines and proposing it to the Ministry of Science and Technology for appraisal and announcement; to propose the Minister of Health to promulgate the Pharmacopoeia of Vietnam for application.

To assume the prime responsibility for submitting the National Book of Pharmaceuticals of Vietnam to the Minister of Health for promulgation.

3. To manage the registration of standards of medicinal products of licensed medicine traders.

To provide scientific and technical information on medicine quality assurance.

4. To be responsible for inspecting the quality of medicines manufactured, prepared, circulated and used nationwide. To direct and supervise the medicine-testing system nationwide. To make conclusions on medicine quality based on results of medicine testing conducted by state-owned medical-testing establishments at the central level, and relevant dossiers.

To monitor, make statistics on and review the management of medicine quality.

5. To inspect and grant certificates of attainment of GMP principles and standards to medicine manufacturers: certificates of attainment of good laboratory practice principles and standards to medicine-testing establishments, and certificates of good storage practice principles and standards to medicine storage service providers.

6. To assume the prime responsibility for. And coordinate with concerned functional agencies in, communicating, disseminating and guiding relevant laws: to assist medicine manufacturers and traders in getting access to information on medicine quality.

To provide professional directions and guidance to medicine quality management staff of the heath sector and conduct professional training and retraining courses in medicine standards, measurement and quality.

7. To coordinate with the Ministry of Health's Inspectorate in performing the state inspection and scrutiny of medicine quality and handling violations in medicine quality according to its competence.

8. To coordinate with concerned functional agencies in implementing treaties and international agreements on mutual recognition in conformity assessment: certification of attainment of GMP principles and standards, clinical trial results and recognition of results of bio-equivalence and bio-availability tests.

Article 29. Responsibilities of local state management agencies in charge of medicine quality

1. Provincial-level Health Departments shall direct the comprehensive management of medicine quality in their localities.

- To take the initiative in organizing the inspection and handling of medicine quality-related issues in their localities under law.

- To be responsible for inspecting the quality of medicines manufactured, prepared, circulated and used in their localities. To make conclusions on medicine quality based on results of medicine sample testing conducted by local slate medicine-testing establishments, and relevant dossiers.

2. To disseminate, guide and organize the implementation of legal documents on medicine quality management in their localities.

To monitor, make statistics on and review the actual management of medicine quality in their localities. To make periodical reports on management of medicine quality to the Ministry of Health (the Vietnam Drug Administration).

To report to the Ministry of Health (the Vietnam Drug Administration) on cases of uncovered or confiscated inferior-quality or counterfeit medicines in their localities.

3. To perform the state inspection and scrutiny of medicine quality and handle medicine quality-related violations in their localities.

Chapter IX

RIGHTS AND RESPONSIBILITIES OF MEDICINE TRADERS AND RIGHTS OF CONSUMERS REGARDING MEDICINE QUALITY

Article 30. Rights and responsibilities of medicine traders

1. Medicine traders shall apply good practice principles and standards to medicine manufacture, quality inspection and storage and take appropriate quality management measures specified in Articles 9 and 10 of this Circular in order to assure the quality of medicines in the process of manufacture, import, storage, circulation and distribution, and ensure that only quality medicines arc delivered to users.

2. Manufacturers, importers and import entruslers shall guarantee that their manufactured or imported medicine lots attain registered standards, and publicize truthful information on medicine quality and take responsibility for the quality of medicines they manufacture, import or entrust others to import.

3. Medicine wholesalers and retailers may only trade in medicines of lawful origins and up to quality standards and shall be held responsible before law and their customers for medicine quality, publicize truthful information on medicine quality, and promptly stop selling medicines upon detecting that these medicines are not up to quality standards or receiving notices of these medicines' inferior quality from medicine quality management or inspection agencies.

4. Medicine manufacturers and traders shall/ may:

a/ Submit to the medicine quality inspection or scrutiny by state quality management, inspection or scrutiny agencies, and comply with requests of these agencies;

Pay expenses for medicine sampling, analyzing or testing medicine samples when medicine quality management or inspection agencies conclude that medicine samples are not up to quality standards or if they make groundless complaints or denunciations about medicine quality under Clauses 2 and 3, Article 23 of this Circular.

b/ Lodge complaints with inspection or scrutiny agencies or superior management agencies about results of quality analysis or testing of medicine samples taken by state quality management or inspection agencies, or complaints about conclusions on medicine quality and handling measures taken by medicine quality management or inspection agencies.

Receive compensation for damage under Section 2. Chapter V of the Law on Product and Goods Quality and other relevant laws.

Article 31. Responsibilities of medicine traders in the prevention and combat of counterfeit medicines

1. To buy medicines only from lawful pharmaceutical traders with invoices and vouchers clearly identifying their sources of supply.

To sell medicines with invoices and vouchers.

2. To trade only in medicines with registration numbers or import permits granted by the Ministry of Health.

3. When detecting counterfeit medicines in their medicine supply networks, to promptly separate them from other medicines and record them in writing. To label and separately store counterfeit medicines or medicines suspected to be counterfeit in order to prevent them from circulation and distribution.

4. To promptly notify medicines confirmed or suspected to be counterfeit to medicine quality management or inspection agencies, other concerned state agencies and medicine

manufacturers and suppliers.

5. To provide truthful and accurate information and coordinate with functional agencies in
tracking down origins of counterfeit medicines.

Article 32. Rights of consumers

Consumers have the right to access information on medicine quality and medicine use and storage instructions: shall abide by instructions for the safe and rational use and storage of medicines; have the right to lodge complaints about and claim compensations from medicine manufacturers and traders under law for damage caused by their inferior-quality medicines.

Chapter X

HANDLING OF VIOLATIONS

Article 33. Handling of violations detected in the course of quality inspection of medicines in manufacture

In the course of quality inspection of medicine products in manufacture, upon detection of manufacturers' failure to satisfy the conditions on medicine manufacture, testing and storage; to attain medicine quality standards or to satisfy requirements of medicine labeling and relevant technical regulations applicable to medicine products, such violations shall be handled as follows:

1. The inspection team shall request the manufacturer to take remedying or repairing measures to assure quality of medicines before circulation on the market:

2. In case the manufacturer breaches principles and standards of pharmaceutical trading conditions (good medicine manufacture, storage and testing practice principles and standards), or testing results show that products are not up to quality standards, posing a danger to the safety and life of users, the medicine quality inspection agency shall issue a notice to terminate the circulation and recall the products, revoke their circulation registration numbers or suspend their manufacture, and request a competent management agency to suspend or revoke the certificate of eligibility for pharmaceutical trading.

3. In case the manufacturer disagrees with sample testing results, it may. within 3 days after receiving a notice of medicine sample testing results showing that medicine samples are not up to quality standards, request the state quality management and inspection agencies to designate another testing establishment to analyze or test medicine samples to obtain medicine quality testing results on the principle that such testing establishment satisfies conditions at least equivalent to the first testing establishment.

Article 34. Handling of violations detected in the course of quality inspection of imported medicines

In the course of quality inspection of imported medicines, upon detection of these medicines' failure to satisfy the requirements on labeling, registration numbers, satisfaction of medicine storage and transportation conditions and application of quality management measures according to relevant technical regulations, such violations shall be handled as follows:

1. For imported medicines with quality test slips but failing to satisfy labeling requirements, the product and goods quality inspection agency shall request the importer or import entruster to satisfy such requirements

before giving certification for import procedures to be carried out with the customs office.

2. For medicines permitted by the Ministry of Health for import and satisfying all labeling requirements but accompanied by quality test slips containing insufficient quality standard indicators but having damaged or broken packings or their appearances changed or failing to meet required storage conditions, the product and goods quality inspection agency shall request the importer to select one among designated or accredited assessment organizations to assess the medicines and grant quality test slips at the border gate of importation.

3. In case quality testing or assessment results show that medicines are not up to registered quality standards, the inspection agency shall, depending on the nature and severity of violations, request a competent state agency to take either or both of the following handling measures:

a/ To request the importer to re-export or destroy these imported goods;

b/ The quality inspection agency shall consider intensifying inspection at border gates or request a competent state agency to suspend or terminate the importation, revoke circulation registration numbers of violating medicines or all medicines of the violating manufacturer or supplier: and concurrently take handling measures against the manufacturer, supplier and importer under current regulations.

Article 35. Handling of violations detected in the course of quality inspection of medicines in market circulation

1. In the course of quality inspection of medicines in market circulation, upon detecting that medicine products fail to satisfy requirements on labeling, registration numbers, application of quality management measures according to relevant technical regulations and satisfaction of storage and distribution conditions, such violations shall be handled in the following steps:

a/ The inspection team or quality controller shall request the trader to suspend the sale of medicines and report such violation within 24 hours to the medicine quality inspection agency for handling according to its competence:

b/ For medicines violating regulations on medicine labeling, registration and quality, the inspection agency shall request the manufacturer. exporter, importer or import entruster to lake measures to handle, remedy or repair consequences or recall the medicines:

c/ In case the medicine trader violates regulations and standards on pharmaceutical trading conditions (good medicine-trading practice principles and standards), affecting the quality of traded or stored

medicines, the inspection team or quality controllers shall send a report thereon to a competent management and inspection agency, proposing it to suspend the medicine trading operation and request the trader to take repairing or remedying measures before it can resume its operation. In case the trader fail to remedy its violation, the competent management agency shall revoke its certificate of eligibility for medicine trading under current regulations on sanctioning of administrative violations in the health sector.

2. In case testing results show that medicine samples are not up to quality standards registered or indicated in the applications for circulation permits or violate regulations on medicine quality, the quality inspection agency shall, depending on the nature and severity of violations, issue a notice of medicine recall, requesting the manufacturer, exporter, importer, import entruster or wholesaler to recall these medicines under Chapter IV of this Circular.

3. In case a trader disagrees with medicine sample testing results, it may. within 3 days after receiving a notice of testing results showing that medicine samples are not up to quality standards, request the state quality management or inspection agency to designate another testing establishment to conduct analysis and testing for obtaining medicine quality testing results on the principle that this testing establishment has conditions at least equal to those of the first testing establishment.

Article 36. Handling of traders of counterfeit medicines, medicines of unclear origins or smuggled medicines

1. Manufacturers or traders of counterfeit medicines shall, depending on the severity of their violations, administratively handled or examined for penal liability.

2. Traders of medicines of unclear origins or without valid invoices and vouchers, smuggled medicines or medicines banned from circulation shall be administratively handled or sanctioned at the highest sanctioning level and subject to additional sanctions under law.

Chapter XI

IMPLEMENTATION PROVISIONS

Article 37. Transitional provisions

1. Central and provincial-level state medicine-testing establishments shall continue sampling medicines for quality testing until medicine quality controllers at all levels are appointed.

a/ The Central Institute of Medicine, the Ho Chi Minh City Institute of Medicine and the National Institute of Vaccines and Biological Substances shall, within the ambit of their functions, tasks and operation, be assigned

and responsible for sampling medicines for testing and determining the quality of medicines manufactured, circulated and used nationwide;

b/ Regional pharmaceutical and cosmetic testing centers and provincial-level pharmaceutical and cosmetic testing centers shall sample medicines for testing and determining the quality of medicines manufactured, circulated and used in their localities.

2. During implementing Clause 1 of this Article, medicine-testing establishments shall estimate, receive and use annual budget allocations for sampling and testing medicines.

Article 38. Effect

1. This Circular takes effect on July 1. 2010.

To annul the Minister of Health's Decision No. 2412/1998/BYT-QD of September 15.1998. promulgating the Regulation on management of medicine quality.

2. The director of the Vietnam Drug Administration shall guide the implementation of this Circular.

3. The chief of the Office, the chief inspector, directors of the Department of Science and Training and Department of Planning and Finance, the director of the Vietnam Drug Administration, directors of the Central Institute of Medicine, the Ho Chi Minh City Institute of Medicine, the National Institute of Vaccines and Biological Substances, and provincial-level Health Departments, heads of health care sections of other branches, the director general of the Vietnam Pharmaceutical Corporation, medicine traders and concerned organizations and individuals shall implement this Circular.

4. Any problems arising in the course of implementation should be promptly reported to the Ministry of Health (the Vietnam Drug Administration) for consideration and settlement.-

FOR THE MINISTER OF HEALTH
DEPUTY MINISTER

Cao Minh Quang