

1) CIRCULAR No. 08/2006/TT-BYT OF JUNE 13, 2006,

**GUIDING THE IMPORT OF VACCINES, MEDICAL BIOLOGICALS; CHEMICALS,
INSECTICIDAL OR GERMICIDAL PREPARATIONS FOR DOMESTIC AND MEDICAL USE;
AND MEDICAL EQUIPMENT**

Pursuant to Pharmacy Law No. 34/2005-QH11 of June 14, 2005;

Pursuant to the Government's Decree No. 49/2003/ND-CP of May 15, 2003, defining the functions, tasks, powers and organizational structure of the Health Ministry;

Pursuant to the Government's Decree No. 12/2006/ND-CP of January 23, 2006, detailing the implementation of the Commercial Law regarding activities of international goods trading and activities of goods sale and purchase agency, processing and transit with foreign countries,

The Health Ministry hereby guides the import of vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use, and of medical equipment as follows:

I. GENERAL PROVISIONS

1. Regulation scope

This Circular shall regulate the import of:

1.1. Vaccines, finished and semi-finished medical biologicals, raw materials, packages, auxiliary materials for use, production of, or research into vaccines, medical biologicals.

1.2. Chemicals, insecticidal or germicidal preparations for domestic and medical use.

1.3. Medical equipment, including assorted equipment, instruments, supplies, specialized means of transport in service of medical activities.

2. Subjects of application

This Circular shall apply to traders and organizations operating in the domains related to the import of vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use; and medical equipment.

3. Lists of vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use; and medical equipment

3.1. The list of vaccines, medical biologicals, insecticidal or germicidal preparations for domestic and medical use, which are imported according to demand, shall cover vaccines, medical biologicals and chemicals, insecticidal or germicidal preparations for domestic and medical use, for which the Health Ministry has granted circulation registration permits (for vaccines, medical biologicals) which are still valid, or circulation registration certificates (for chemicals, insecticidal or germicidal preparations for domestic and medical use).

3.2. Medical equipment not specified in Part IV of this Circular and not on the list of goods banned from import provided for in the Government's Decree No. 12/2006/ND-CP of January 23, 2006, detailing the implementation of the Commercial Law regarding activities of international goods trading and activities of goods sale and purchase agency and transit with foreign countries, can be imported according to demand.

4. Customs procedures

4.1. For vaccines, medical biologicals, chemicals, insecticidal or germicidal preparations for domestic and medical use which are on the list of goods permitted for import according to demand: importing traders and organizations shall submit to customs offices copies of valid circulation registration permits (for vaccines, medical biologicals) or circulation registration certificates (for chemicals, insecticidal or germicidal preparations for domestic and medical use) for the imported products, which are signed and sealed for certification by the heads of enterprises who shall bear responsibility before law therefor.

4.2. For vaccines, medical biologicals, chemicals, insecticidal or germicidal preparations for domestic and medical use which are not on the list of goods permitted for import according to demand: importing traders and organizations shall submit to customs offices the original import permits granted by the Vietnam Preventive Medicine Department of the Health Ministry, in case of lump-sum import, or the copies thereof, in case of installment import and must produce the originals for comparison.

4.3. For imported medical equipment requiring permits of the Health Ministry: importing traders shall submit to customs offices the original import permits granted by the Health Ministry, in case of lump-sum import, or the copies thereof, in case of installment import, and must produce the originals for comparison.

II. PROVISIONS ON IMPORT OF VACCINES, MEDICAL BIOLOGICALS

1. Vaccines and medical biologicals requiring no import permit

1.1. Conditions

1.1.1. Traders and organizations dealing in vaccines, medical biologicals must possess the certificates of satisfaction of business conditions, granted by competent bodies. Enterprises which are conducting the import of vaccines, medical biologicals without such certificate must complete these procedures according to the provisions of law.

1.1.2. Foreign enterprises that have permits for operation in the domains of vaccines, medical biologicals and raw materials for production of vaccines, medical biologicals with Vietnam shall be entitled to supply vaccines, medical biologicals for Vietnamese enterprises that import vaccines, medical biologicals within the scope of operation stated in the permits.

1.1.3. Importing enterprises, using units and research units shall themselves bear responsibility before law for the quality and safety of the imported products and their activities.

1.1.4. Vaccines, medical biologicals on the list of those permitted for import according to demand must have the remaining use duration at least equal to two-third of their use life as from the date of their arrival in Vietnam. For special cases, the Health Ministry shall consider and permit the import of vaccines and medical biologicals with the remaining use duration shorter than prescribed.

1.1.5. Imported semi-finished vaccines, medical biologicals can only be supplied to establishments having the function of, and satisfying the conditions for, production of vaccines and/or medical biologicals in service of production.

1.1.6. Semi-finished vaccines, medical biologicals, after being prepared and packed into finished products, must be granted circulation registration permits by the Health Ministry before being circulated in the market, and must be subject to ex-warehousing procedures for each lot like home-made products.

1.2. Procedures for sending expertise dossiers, samples

1.2.1. Importing enterprises must send ex-warehousing dossiers and samples of the imported goods lots to the National Institute for Expertise of Vaccines and Medical Biologicals, each comprising:

1.2.1.1. To be-expertized samples (the volume of samples shall comply with the regulations applicable to each type of vaccine, medical biological).

1.2.1.2. The to be-expertized sample-sending card.

1.2.1.3. Summarized dossiers on the production and expertise of imported vaccine or medical biological lots (copies with certification seals of producers).

1.2.1.4. Delivery permits of competent bodies of host countries or other equivalent agencies, enclosed with each imported goods lot (copies with certification seals of directors of importing enterprises).

1.2.1.5. Evidences showing the freezing chains in the course of transport of the imported goods lots.

1.2.2. After the customs clearance, vaccines and/or medical biologicals shall be transported to warehouses of enterprises for preservation according to regulations and be put to use only when the National Institute for Expertise of Vaccines and Medical Biologicals certify in writing that the imported vaccines and/or medical biologicals meet the standards of safety on tested animals (for finished vaccines, medical biologicals used for treatment) or that it has fully received the samples and dossiers (for finished medical biologicals used for diagnosis and semi-finished products).

1.2.3. For vaccines and medical biologicals in form of finished products, used for treatment, within 7 working days after the full receipt of samples and dossiers provided for in Section 1.2.1 above, the National Institute for Expertise of Vaccines and Medical Biologicals must give its written replies on the safety of the vaccines or medical biologicals on tested animals to enterprises. For finished medical biologicals used for diagnosis and semi-finished products, within 3 working days after the full receipt of samples and dossiers as provided for, the National Institute for Expertise of Vaccines and Medical Biologicals must give its written certification of full receipt of samples and dossiers to enterprises.

1.2.4. Within 10 days after the import, the importing enterprises shall send reports on the categories and volumes of imported vaccines or medical biologicals for each imported goods lot to the Health Ministry (the Vietnam Preventive Medicine Department).

2. Vaccines and medical biologicals requiring import permit

2.1. Conditions

2.1.1. Traders and organizations dealing in vaccines and/or medical biologicals must possess certificates of satisfaction of business conditions. Enterprises that are conducting the import of vaccines and/or medical biologicals without such certificate shall have to complete these procedures according to provisions of law.

2.1.2 Organizations functioning to research into vaccines and/or medical biologicals are entitled to import vaccines and/or medical biologicals in service of their research.

2.1.3. Vietnam-based representative offices and branches of foreign enterprises shall only be permitted to import samples of vaccines and/or medical biologicals for carrying out the circulation registration procedures.

2.1.4. Traders and organizations shall themselves have to bear responsibility before law for the quality and safety of the imported products and their activities.

2.2. Dossiers and procedures for permit granting

2.2.1. Vaccines and medical biologicals imported for use in special cases (in service of disease prevention and treatment and use for a special group of subjects, foreigners living and working in Vietnam, Vietnamese going abroad to work, study or labor in countries where such diseases exist).

2.2.1.1. Dossiers:

- The application for permission to import vaccines, medical biologicals.
- The needed volumes and categories of vaccines or medical biologicals and vaccinated subjects of the vaccination establishment.
- The written commitment of the vaccination establishment to use, preserve and inject vaccines and/or medical biologicals for proper purposes, to proper subjects, under proper prescription and to bear responsibility for the use of these vaccines or medical biologicals (Appendix 1, not printed herein).
- The written commitments of the distributor and producer to ensure the quality of the vaccines and/or medical biologicals supplied to Vietnam (Appendix 2, not printed herein).
- The written commitment of the importing company to import, preserve and transport vaccines, medical biologicals according to regulations (Appendix 3, not printed herein).
- Enclosed documents (if any), including the written certification that the production establishment has satisfy the GMP standards of the host country, the permit for circulation of vaccines, medical biologicals of the host country, the permit for circulation in a number of other countries where such vaccines and/or medical biologicals have been registered and circulated.

2.2.1.2. Procedures:

- Traders and organizations applying for import permit shall send dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).
- Within 15 working days after the full receipt of valid dossiers, the Health Ministry (the Vietnam Preventive Medicine Department) shall consider and reply in writing whether or not to grant the import permit and the requests for sending dossiers and samples to the National Institute for Expertise of Vaccines and Medical Biologicals in case of necessity under the provisions of Section II.1.2 of this Circular.

2.2.2. Vaccines, medical biologicals imported for expertise, field test, use as registration sample (shall only be used for the purpose of circulation registration, not for other purposes).

2.2.2.1. Dossiers:

- The application for permission to import samples for expertise, field test, registered samples.
- The written request of the expertising body or field testing body.

2.2.2.2. Procedures:

- The applying traders and organizations shall send dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).

- Within 15 working days after the full receipt of valid dossiers, the Health Ministry (the Vietnam Preventive Medicine Department) shall consider and reply in writing whether or not to grant the import permit.

2.2.3. Vaccines, medical biologicals used for research, used for programs, projects (shall only be imported for use for the purpose of research at establishments functioning to conduct research, implement projects, not for other purposes).

2.2.3.1. Dossiers:

- The written import request.

- The written approval of the research subject/project by the competent body and the approved research program (for research subjects/projects requiring the approval).

2.2.3.2. Procedures:

- Traders and organizations applying for import permit shall send their dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).

- Within 15 working days after the full receipt of valid dossiers, the Health Ministry (the Vietnam Preventive Medicine Department) shall consider and reply in writing whether or not to grant the import permit.

2.2.4. Vaccines, medical biologicals imported for use in national programs or provided as aid (must be on the lists of those recommended for use by the World Health Organization).

2.2.4.1. Dossiers:

- The certificate of the competent body of the host country, permitting the circulation or export of vaccines and/or medical biologicals.

- The certificates of achievement of GMP standards by production establishments, issued by the host country.

- The testing card proving the compliance with quality standards of vaccines and/or medical biologicals, issued by the national expertising body of the host country or other competent agency for the imported goods lots (with the true-copy certification by the importing enterprise).

2.2.4.2. Procedures:

- The dossiers shall be addressed to the National Institute for Expertise of Vaccines and Medical Biologicals.

- Upon receipt of the prescribed documents, the National Institute for Expertise of Vaccines and Medical Biologicals shall inspect the freezing chains, take samples for storage and evaluate the vaccines and/or medical biologicals at request for:

a/ Test of safety in laboratory regarding the conclusion on achievement of the set standards.

b/ Test of practical safety on humans regarding the conclusion on achievement of the set standards.

Particularly for vaccines and medical biologicals without circulation registration numbers, which are provided as emergency donations to Vietnam by international organizations which have been in regular cooperation with Vietnam in the medical field such as WHO, UNICEF, ..., the National Institute for Expertise of Vaccines and Medical Biologicals shall, depending on each specific case, conduct the inspection of the freezing chain and take samples for storage and test the safety in laboratory.

- After examining the above-said documents and obtaining the expertising and testing results of achievement of the set quality, the National Institute for Expertise of Vaccines and Medical Biologicals shall send a written request to the Health Ministry (the Vietnam Preventive Medicine Department) for the permission for the donation-receiving units to import and put to use the donated vaccines and/or medical biologicals.

- Within 15 working days after the receipt of the request of the National Institute for Expertise of Vaccines and Medical Biologicals, the Health Ministry (the Vietnam Preventive Medicine Department) shall reply in writing whether or not to grant the permit.

- After the importation, the importing units must print or stick papers bearing the phrase "donated vaccines (medical biologicals), not for sale" or "vaccines (medical biologicals) under national programs, not for sale" on the outer packages of products.

2.2.5. Raw materials, packages, auxiliary materials for production of vaccines, medical biologicals (can be imported only for supply to establishments satisfying the conditions for production of vaccines, medical biologicals).

2.2.5.1. Dossiers:

- The written import request.

- The written request of the production establishment.

2.2.5.2. Procedures:

- Traders and organizations applying for import permit shall send their dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).

- Within 15 working days after the full receipt of valid dossiers, the Health Ministry (the Vietnam Preventive Medicine Department) shall consider and reply in writing whether or not to grant the import permit.

III. PROVISIONS ON IMPORT OF CHEMICALS, INSECTICIDAL AND GERMICIDAL PREPARATIONS FOR DOMESTIC AND MEDICAL USE

(hereinafter referred to as chemicals and preparations for short)

1. Chemicals and preparations requiring no import permit

Chemicals or preparations with circulation registration certificates granted by the Vietnam Preventive Medicine Department, the Health Ministry, which are still valid, can be imported according to demand, without restriction on volume, value, for which import procedures shall be carried out at customs offices and the Health Ministry's approval is not required. Importing enterprises shall bear responsibility before law for their respective activities.

Chemicals, insecticidal or germicidal preparations for domestic and medical use, which are on the list of those imported according to demand must have the remaining use duration at least equal to two-third of their use life, counting from the date of their arrival at Vietnam. In special cases, the Health Ministry shall consider and permit the import of chemicals, insecticidal or germicidal preparations for domestic and medical use with their remaining use duration being shorter than prescribed.

2. Chemicals and preparations requiring import permit

2.1. Chemicals and preparations without circulation registration certificate which are imported for use as production raw materials.

2.1.1. Dossiers:

- The application for import permission.
- A notarized copy of the business registration certificate.
- The written commitment to ensure quality, safety and effect of chemicals (Appendix 5, not printed herein).
- Copies of circulation registration certificates of chemicals, preparations turned out from the to be-imported chemicals.
- The plan on the use of the imported chemicals, preparations.

2.1.2. Procedures:

- Traders and organizations applying for import permit shall send their dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).
- Within 15 working days after the full receipt of valid dossiers, the Health Ministry (the Vietnam Preventive Medicine Department) shall give its written reply whether or not to grant the import permit.

2.2. Chemicals, preparations imported for assay, test (after the Health Ministry permits the assay thereof in Vietnam).

2.2.1. Dossiers:

- The application for import permission (Appendix 6, not printed herein).

2.2.2. Procedures:

- Traders and organizations applying for import permit shall send their dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).
- Within 15 working days after the full receipt of valid dossiers, the Health Ministry (the Vietnam Preventive Medicine Department) shall give its written reply whether or not permitting the import thereof.

2.3. Chemicals, preparations without circulation registration numbers which are imported for research, as donation or for use for other particular purposes

2.3.1. Dossiers:

- The application for import permission.
- A notarized copy of the business registration certificate or other papers proving the legal person status of the applying unit.
- The written commitment to ensure quality, safety and effect of chemicals, preparations.
- Technical documents of chemicals, preparations.
- The research program (for chemicals, preparations imported for research) or documents explaining the purposes of using the imported chemicals, preparations (for chemicals, preparations imported for particular purposes).
- The enclosed documents (if any), including the GMP certificate, ISO certificates of factories, the permit for circulation of chemicals, preparations of the host country, the permits for circulation in other countries where such chemicals and/or preparations have been registered and sold.

2.3.2. Procedures:

- The traders and organizations applying for import permission shall send their dossiers to the Health Ministry (the Vietnam Preventive Medicine Department).
- Within 15 working days after the full receipt of valid dossiers, the Vietnam Preventive Medicine Department shall give its written reply whether or not permitting the import.

IV. PROVISIONS ON IMPORT OF MEDICAL EQUIPMENT

1. Medical equipment listed in Appendix 7 to this Circular

1.1. Conditions:

Traders wishing to import medical equipment listed in Appendix 7 must satisfy the following conditions:

1.1.1. Having adequate legal documents under the Enterprise Law, the Cooperative Law or the Law on Investment in Vietnam.

1.1.2. Having technical staff and material foundations that satisfy the requirements:

- The chief technician must possess one of the following diplomas: university diploma in medico-biological electronics; university diploma in techniques; university diploma in medicine or pharmacy and certificates of specialized training in medical equipment issued by a lawful medical equipment training establishment or equivalent certificates issued by foreign countries, with the training duration of at least one month.
- For persons possessing the above-mentioned diplomas and having directly worked with medical equipment or managed medical equipments at medical establishments for 3 years or more as certified by the heads of their working units, the certificate of specialized training in medical equipment is not required.
- Having technical cadres and personnel capable of guiding the installation, maintenance of medical equipment dealt in by traders (having been annually trained by equipment producers).
- On the technical foundations:

Having headquarters, proper warehouses which satisfy the conditions on good preservation of medical equipment, having adequate tools, technical equipment and facilities for performance of the installation, maintenance of medical equipment; having adequate fire- and explosion-preventing and -fighting equipment and having to ensure environmental safety and sanitation under the provisions of law.

1.2. Dossiers:

- The application for permission to import medical equipment.
- Relevant documents specified at Point 1.1, Clause 1, Section IV.
- The enclosed documents and papers, including catalogue (the original) of each kind of equipment; the quality control certificate of producer ISO-9001, ISO 14,000 or the equivalent; the permit for product circulation in the producing country.

1.3. Procedures:

- The dossiers of application for permission to import medical equipment shall be sent to the Health Ministry (the Medical Equipment and Works Department being the standing unit) for synthesis and submission to the council for consideration and grant of permits within 15 working days after the full receipt of valid dossiers.
- Traders granted the permits must pay import fees prescribed in Decision No. 44/2005/QĐ-BTC of July 12, 2005, of the Finance Ministry.

2. Medical equipment not listed in Appendix 7 to this Circular

Medical equipment not listed in Appendix 7 but used for application of new diagnostic and therapeutic methods and imported into Vietnam for the first time shall require an import permit of the Health Ministry. In addition to the conditions, dossiers and procedures of application for import permits specified in Clause 1, Section IV of this Circular, the to be-imported medical equipment must be accompanied with results of clinical tests, and be appraised and permitted for import by the Scientific and Technological Council of the Health Ministry.

V. ORGANIZATION OF IMPLEMENTATION

1. The Health Ministry shall announce lists of vaccines, medical biologicals and insecticidal or germicidal preparations for domestic and medical use which can be imported according to demand. Annually, the Health Ministry shall consider, supplement and adjust the list of medical equipment in Appendix 7 to suit the practical situation.
2. The Vietnam Preventive Medicine Department shall, within the ambit of its competence, receive dossiers and grant import permits for vaccines, medical biologicals, insecticidal or germicidal preparations for domestic and medical use. The Medical Equipment and Works Department shall act as the standing body of the Health Ministry, having the responsibility to make review reports and submit them to the Council for consideration and grant of permits for import of medical equipment.
3. The Health Ministry's Inspectorate shall coordinate with various departments and functional sections of the Health Ministry in examining and inspecting nationwide activities of trading in, import of vaccine and medical biologicals, insecticidal or germicidal preparations for domestic and medical use as well as medical equipment.

4. Provincial/municipal Health Services shall examine and inspect the activities of trading in and import of vaccines, medical biologicals; insecticidal or germicidal preparations for domestic and medical use as well as medical equipment in their respective localities.

5. The National Institute for Expertise of Vaccines and Medical Biologicals, the Health Ministry, shall base itself on the documents accompanying the import goods lots, the stored samples and the registered quality standards to perform the function of inspecting and supervising the quality of vaccines, medical biologicals circulated in the market.

6. Establishments using vaccines, medical biologicals shall bear responsibility for the use of assorted vaccines and biologicals and send periodical and irregular reports on the use of vaccines: side effects, complications due to the use of vaccines and other abnormal cases in the course of use.

7. Traders and organizations importing, dealing in, researching into vaccines, medical biologicals and chemicals, insecticidal or germicidal preparations for domestic and medical use shall have to strictly observe the provisions of law and bear responsibility for their respective activities.

8. Quarterly, importing traders and organizations shall report on the import of vaccines, medical biologicals, insecticidal or germicidal preparations for domestic and medical use to the Health Ministry (the Vietnam Preventive Medicine Department), and report on the import of medical equipment to the Medical Equipment and Works Department.

VI. IMPLEMENTATION PROVISIONS

1. This Circular takes effect 15 days after its publication in "CONG BAO." To annul the Health Ministry's Circular No. 09/2001/TT-BYT of May 21, 2001, guiding the import and export of vaccines, immune biologicals for human use in the 2001-2005 period; Circular No. 06/2003/TT-BYT of May 15, 2003, guiding the management and use of vaccines and medical biologicals without circulation registration numbers, which are provided as emergency donations or imported into Vietnam for use in special cases; Circular No. 13/2001/TT-BYT of June 18, 2001, guiding the export and import of chemicals, insecticidal and germicidal preparations for domestic and medical use in the 2001-2005 period; and Circular No. 06/2002/TT-BYT of May 30, 2002, guiding the import and export of medical equipment subject to specialized management in the 2002-2005 period.

2. The Vietnam Preventive Medicine Department, the Medical Equipment and Works Department, the Health Ministry's Inspectorate, the National Institute for Expertise of Vaccines and Medical Biologicals, provincial/municipal Health Services, units using vaccines and/or medical biologicals, traders and organizations importing vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use and medical equipment shall have to strictly observe the provisions of this Circular.

3. Problems arising in the course of implementation should be reported to the Health Ministry's departments for consideration and solution.

Minister of Health

TRAN THI TRUNG CHIENtc "This Circular takes effect 15 days after its publication in CONGBAO.-"

Appendix 7

LIST OF MEDICAL EQUIPMENT (BRAND NEW) TO BE IMPORTED UNDER PERMITS OF THE HEALTH MINISTRY

(Promulgated together with the Health Ministry's Circular No. 08/2006/TT-BYT of June 13, 2006)

Ordinal number	List of medical equipment
	Image diagnosis equipment
1	Assorted X-ray diagnosis machine
2	CT scanners of various kinds (spiral, single-layer, multi-layer)
3	PET-CT system of various kinds
4	Black and while, color ultrasonic diagnosis machines of various kinds
5	Angiography of various kinds
6	Magnetic resonance imaging system of various kinds (electric magnet and superconductor of between 0.06 Tesla and 3.0 Tesla)
	Operation theatre equipment
7	Electronic scalpels of various kinds
8	Laser scalpels of various kinds
9	Ultrasonic scalpels of various kinds
10	Marcotizers of various kinds
11	Marcotizer-respirators of various kinds
12	Artificial heart-lung apparatus
13	Laser excimer, Phaco
14	Endoscopic surgery equipment and instruments of various kinds
	Ward equipment
15	Medical gas system
	Emergency intensive care equipment
16	Patient monitors of various kinds
17	Electric shock apparatus
18	Breathing support apparatus of various kinds
19	Cardia fibrillation breakers and cardia rate makers
20	Assorted ambulances
21	Specialized ambulance vehicles (accompanied with medical equipment) of various kinds
	Function examination equipment
22	Electro-cardiographic apparatus of various kinds
23	Electro-encephalographic apparatus of various kinds
24	Electro-mechanical meters of various kinds
25	Electro-retompgraph
26	Endoscopic diagnosis equipment of various kinds
27	Respiratory function metering and analyzing equipment
	Nuclear medicine equipment
28	Assorted nuclear medicine equipment
29	Radio-therapy measuring equipment
30	Preventive radio-therapy measuring machine
31	Assorted SPECT machines
	Preclinical equipment (testing)
32	Biochemical testing apparatus of various kinds
33	Hematologic testing apparatus of various kinds
34	Immune testing apparatus of various kinds
35	Bacteria and virus-identifying apparatus
	Radio-therapeutic equipment
36	Cancer treatment Cobalt machine (with Co 60)
37	Linear accelerator for cancer treatment with different energy intensity

38	Gammar operation knives of various kinds
39	Close radio-therapeutic apparatus of various kinds
	Other therapeutic equipment
40	Lithotripsy apparatus
41	Hepaticolithiasis-breaker
42	Urolith-breaker
43	Assorted prostate treatment apparatus
44	High-grade oxygen apparatus
	Long-term grafting and culture materials
45	Artificial heart valves of various kinds
46	Assorted stent
47	Assorted crystalline lens
48	Assorted absorbable suture
49	Artificial bone
50	Stainless steel splints, screw
51	Composite materials for healing skulls, artificial joints
52	Assorted probes implanted for long term
53	Other long-term grafting and culture materials
	Other common medical equipment and supplies
54	Medical glasses of various kinds (myopia, hypermetropia, astigmatism)

2) Circular No. 09/2006/TT-BYT date July 11, 2006 of the Ministry of Health guiding amendments and supplements to Section IV of and Appendix No.9 to the Health Minister's Circular No. 08/2006/TT-BYT dated June 13, 2006, guiding the import of vaccines, medical biological; chemicals, insecticidal or germicidal preparations for domestic and medical use; and medical equipment

Thông tư số: 09/2006/TT-BYT ngày 11 tháng 7 năm 2006
Hướng dẫn sửa đổi, bổ sung Mục IV và Phụ lục 9 của Thông tư số 08/2006/TT-
BYT ngày 13/6/2006 của Bộ trưởng bộ Y tế
hướng dẫn nhập khẩu vắc xin, sinh phẩm y tế; hoá chất, chế phẩm diệt côn trùng,
diệt khuẩn dùng trong lĩnh vực gia dụng và y tế và trang thiết bị y tế

Để tạo điều kiện thuận lợi và phù hợp với tình hình thực tế trong công tác quản lý nhà nước về nhập khẩu trang thiết bị y tế, Bộ Y tế hướng dẫn sửa đổi, bổ sung Mục IV. Quy định về nhập khẩu trang thiết bị y tế và Phụ lục 9 của Thông tư số **08/2006/TT-BYT** ngày 13/6/2006 hướng dẫn nhập khẩu vắc xin, sinh phẩm y tế; hoá chất, chế phẩm diệt côn trùng, diệt khuẩn dùng trong lĩnh vực gia dụng và y tế và trang thiết bị y tế (sau đây gọi tắt là Thông tư số 08/2006/TT-BYT) như sau:

1. Sửa đổi đoạn gạch đầu dòng thứ 3, điểm 1.2, khoản 1, Mục IV của Thông tư số 08/2006/TT-BYT về hồ sơ đối với nhập khẩu trang thiết bị y tế thuộc Phụ lục 7 như sau:

“Tài liệu, giấy tờ kèm theo bao gồm: Catalogue (bản gốc); tài liệu hướng dẫn sử dụng, tài liệu kỹ thuật (kèm theo bản dịch tiếng Việt Nam) của từng loại thiết bị; Chứng chỉ chất lượng (ISO, FDA, EC,...) hoặc tương đương; Giấy phép lưu hành sản phẩm tại nước sản xuất (bản gốc hoặc bản sao hợp lệ) - (Phụ lục 9)”.

2. Sửa đổi khoản 2, Mục IV của Thông tư số 08/2006/TT-BYT về nhập khẩu trang thiết bị ngoài danh mục thuộc Phụ lục 7 như sau:

“2.1 Thương nhân muốn nhập khẩu trang thiết bị y tế ngoài danh mục quy định tại Phụ lục 7 này không phải xin giấy phép nhập khẩu của Bộ Y tế nhưng vẫn phải đảm bảo các quy định tại điểm 1.1 và 1.2 khoản 1, Mục IV của Thông tư số **08/2006/TT-BYT** (phần tài liệu, giấy tờ kèm theo)”.

“2.2. Trang thiết bị y tế ngoài danh mục nêu tại Phụ lục 7 nhưng trang thiết bị đó ứng dụng các phương pháp chẩn đoán, điều trị mới và lần đầu tiên nhập khẩu vào Việt Nam phải xin phép nhập khẩu của Bộ Y tế. Ngoài các điều kiện, hồ sơ, thủ tục xin giấy phép nhập khẩu như quy định tại Khoản 1, Mục IV của Thông tư số **08/2006/TT-BYT**, trang thiết bị y tế xin nhập khẩu phải có kết quả đánh giá thử nghiệm lâm sàng và được Hội đồng Khoa học - Công nghệ của Bộ Y tế thẩm định, cho phép thì mới được phép nhập khẩu”.

3. Bổ sung Khoản 3 vào Mục IV của Thông tư số 08/2006/TT-BYT như sau:

“Đối với một số trang thiết bị y tế đặc biệt đã được các tổ chức quốc tế chấp nhận và khuyến cáo sử dụng ở các nước, Bộ Y tế sẽ xem xét cho phép miễn thử nghiệm lâm sàng dựa trên kết luận của Hội đồng Khoa học – Công nghệ của Bộ Y tế”.

4. Sửa đổi phần tài liệu kèm theo của hồ sơ xin nhập khẩu trang thiết bị y tế tại Phụ lục 9 của Thông tư số 08/2006/TT-BYT như sau:

Nguồn: <http://vnexim.com.vn/forum/bai-viet/10499-TT-so-09-2006-TT-BYT-V-v-sua-doi-TT-so-08-2006-TT-BYT-ve-huong-dan-NK-vac-xin-sinh-pham-y-te-#ixzz1oNjGyOII>