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**THE MINISTRY OF HEALTH**

**CIRCULAR No. 09/2006/TT-BYT OF JULY 11, 2006, GUIDING AMENDMENTS AND SUPPLEMENTS TO SECTION IV OF AND APPENDIX No. 9 TO THE HEALTH MINISTER'S 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**

To facilitate and conform with the practical state management of import of medical equipment, the Ministry of Health hereby guides amendments and supplements to Section IV on provisions on the import of medical equipment, and Appendix 9 to 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 (hereinafter referred to as Circular No. 08/2006/TT-BYT for short) as follows:

**1. To amend the paragraph at the third em rule, Point 1.2, Clause 1, Section IV of Circular No. 08/2006/TT-BYT on dossiers for import of medical equipment specified in Appendix 7 as follows:**

“The enclosed documents and papers shall include the catalog (the original); use instruction and technical specifications (enclosed with their Vietnamese translations) of each kind of equipment; the quality control certificate (ISO, FDA, EC) or equivalent; the permit for product circulation in the manufacturing country (the original or valid copy) (Appendix 9).”

**2. To amend Clause 2, Section IV of Circular No. 08/2006/TT-BYT on the import of equipment not listed in Appendix 7 as follows:**

"2.1 Traders wishing to import medical equipment not listed in Appendix 7 shall not have to apply for the Health Ministry's import permit, but shall still have to comply with the provisions of Points 1.1 and 1.2, Clause 1, Section IV of Circular No. 08/2006/TT-BYT (enclosed documents and papers)."

"2.2 Medical equipment not listed in Appendix 7, but used for application of new diagnostic or therapeutic methods and imported into Vietnam for the first time shall require the Health Ministry's import permit. Apart from the conditions, dossiers and procedures of application for import permits specified in Clause 1, Section IV of Circular No. 08/2006/TT-BYT, medical equipment to be imported must be accompanied with results of clinical tests and be appraised and permitted for import by the Health Ministry's Science and Technology Council."

**3. To add the following Clause 3 to Section IV of Circular No. 08/2006/TT-BYT:**

"For a number of special medical equipment which have been accredited and recommended for use in other countries by international organizations, the Ministry of Health shall consider and permit their exemption from clinical tests on the basis of conclusions of the Health Ministry's Science and Technology Council."

**4. To amend the enclosed documents of dossiers of application for permission to import medical equipment specified in Appendix 9 to Circular No. 08/2006/TT-BYT as follows:**

"To enclose:

- The catalog (the original) of each kind of equipment;
- Use instruction, technical specifications (enclosed with their Vietnamese translations) of each kind of equipment;
- The quality control certificate (ISO, FDA, EC) or equivalent;
- The permit for product circulation in the manufacturing country (the original or valid copy);
- Written commitment to taking legal responsibility for the quality, quantity and value of the goods to be imported."

**5. This Circular takes effect 15 days after its publication in "CONG BAO."**

To annul the paragraph at the third em rule, Point 1.2, Clauses 1 and 2 of Section IV, and the provisions on documents enclosed with dossiers of application for permission to import medical equipment in Appendix 9 to the Health Minister's Circular No. 08/2006/TT-BYT.

**Minister of Health**  
**TRAN THI TRUNG CHIEN**