MINISTRY OF HEALTH

No: 4012/2003/QD-BYT

SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

Hanoi, 30 May 2007 2003

DECISION

MINISTER OF HEALTH

Promulgating regulations on registration of vaccines, medical biologicals

MINISTER OF HEALTH

Pursuant to the Law on Protection of People's Health on July 11, 1989;

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

Pursuant to Letter No. 2942/KGVX on June 20, 1996 the Government Office informed opinion of the Deputy Prime Minister Nguyen Khanh agreed to the Ministry of Health issued the document on management of vaccines and for students product immunity;

The proposal of the Director General of Preventive Health and HIV / AIDS? Ministry of Health,

DECIDES

Article 1. Issued together with this Decision the Regulation on registration Vaccines, medical biologicals.

Article 2. This decision takes effect 15 days from the date of notice and replaces Decision No. 2010/BYT-QD on October 28, 1996 the Minister of Health promulgating the “Regulations on registration of vaccines and immune bio-products.

Article 3. The Mr., Mrs. office chief, Chief Inspector, Director of Department of Preventive Health and HIV / AIDS; Director General of the Department under the Ministry of Health; Director Vietnam Pharmaceutical Management Department; Director Administration Quality, Hygiene, Food Safety; heads of units under the Ministry; Medical Director of the provinces and cities directly under the Central Government; Organizations and individuals producing, trading vaccines and biologicals Health is responsible for implementation of this Decision.

REGULATION

REGISTRATION vaccines and medical bio -

(Issued together with Decision No. 4012/2003/QD-BYT July 30, 2003)

To unify the state management of vaccines, medical biologicals circulated in Vietnam for human use to ensure safety, effectiveness and quality of vaccines, medical bio-products, the Ministry of Health issued "Regulation on registration of vaccines, medical bio-products.

CHAPTER I

GENERAL PROVISIONS

Article 1

1. All vaccines, medical biologicals used for prevention, treatment, diagnosis must be for the Ministry of Health issued registration numbers will be circulated in Vietnam Men.

2. In special cases (vaccines, medical biologicals not have the registration numbers to be used in emergency disaster or epidemic, for a special audience,...), Ministry of Health will consider allowing for each specific case in accordance with Circular No. 06/2003/TT-BYT on May 15, 2003 the Ministry of Health guiding the management and use of vaccines, medical biologicals International has no registration number was circulated aid in case of emergency or imported into Vietnam for use in special cases.

Article 2

In this Regulation, a number of terms below are construed as follows:
1. Vaccines are preparations contain antigens capable of giving the body immune response, which is used for preventive purposes or for other purposes.

2. Medical student (hereinafter referred to as bio-products) is a product of biological origin used for prevention, treatment and diagnosis for people.

3. Vaccines semi-finished products, biologicals semi-finished products are intermediate products from which the preparation of vaccines and biologicals to finished products.

4. Vaccines finished products, finished products are biologicals end product is used for.

**Article 3**

1. The production base, the domestic enterprises has the function of production, trading, import vaccines and biologicals are allowed registration of vaccines, biologicals.

2. Foreign establishments were the Ministry of Health license the operation of foreign companies in the field of vaccines, medical bio-products in Vietnam are allowed to register vaccines, biologicals.

3. Facilities for scientific research in Vietnam as a successful research vaccines and new bio-products, while waiting for transfer of technology basis functions produce vaccines and biologicals, if the research including eligibility and standards produced vaccines and biologicals prescribed by the Ministry of Health is registered to vaccines and biologicals have been studied successfully. Ministry of Health will review and issue of registration under this Regulation.

**Article 4**

Vaccines, biologicals must be registered as:

1. The vaccines, bio-products produced in foreign countries and not granted registration numbers but names on the list of vaccines, medical biologicals Ministry of Health is considering to grant registration number by the Minister of Health annually.

2. Vaccines, biologicals were issued registration numbers but change the formula, composition, content, assigning user, road users, as finished products, quality standards and methods of verification, the legal production, production processes, production facilities.

**Article 5**

1. Vaccines, medical bio-products have been granted registration numbers, within a valid registration number if you change or supplement one of the following must apply to the Ministry of Health:

   a) change the name of vaccines and biologicals
   b) change the dose
   c) change the basis of registration
   d) change the name of production facilities (location production facilities does not change)
   e) Change location production (production units do not change)
   f) change or supplement the indicated vaccines and biologicals
   g) change shelf life
   h) change or supplement Packing
   i) change the form label vaccines and biologicals

   Ministry of Health to consider and keep the registration number and allow writing.

2. When you change or add one of the provisions in Clause 1 of this Article, the record includes:

   a) An application for change or addition to vaccines and biologicals (Form 8).

   b) Documents related issues for changes or additions.

For vaccines and biologicals abroad: when changing location production facilities have guns certificate production facilities at the new location GMP. When the name change production facilities must have certificates of production facilities with a new name GMP.
Article 6
Registration dossiers vaccines and biologicals must be made in three sets, including one of the original (For the record registration of vaccines and biologicals for foreigners to be written in English with the original and Vietnamese for the two remaining). The following documents must be originals or copies of valid:

a) Certificate of production facilities meet standards set by the authorities in the host country level.

b) Certificate of the competent authorities in host countries to allow circulation or export vaccines, biologicals.

c) the certificate verification results vaccines, biologicals by the National Center Test biologicals medicine Vietnam Men level.

d) certificate of clinical trial results of quality in Vietnam Men.

e) The license of vaccine production facility, bio-products of the authorities in host countries.

The application must be printed clearly on A4 size paper, arranged in the correct order provisions, which separates the parts, which cover and list of documents.

All documents in the file must be the basis of registration confirmation (signature and seal). Where the sample label vaccines, biologicals in the registration dossier is pasted on A4 size it must be stamped on the label adjacent future vaccines and biologicals.

Article 7
Brand vaccines and biologicals comply with the provisions of Circular No. 14/2000/TB-BYT on June 22, 2000 the Minister of Health guiding the implementation of Decision No. 178/1999/QD-TTg 30 / 8 / 1999 of the Prime Minister for labeling goods vaccines and immune bio-products and other provisions of law on labeling of domestically circulated goods, import and export goods.

Information such as barcodes, codes, medals, awards, signs of industrial property to write on the label, they must have copies of legal documents relating to the above information.

Article 8
1. Registration is granted to print labels on vaccines and biologicals.

2. Registration value five years from the date of issue. Basis to registration of vaccines, bio-products for production and circulation in Vietnam Men they must file within 3 months before the registration expires. After the registration expired more than 6 months but not the basis of filing registration, when you want to continue the registration must file a new registration.

3. Shelf labels on the vaccine, bio-products must be in order: day, month and year.

4. For each vaccine, bio-products of the same name, the Ministry of Health registration number for each content.

5. Within three months from the date of receiving the complete dossiers as prescribed, the Ministry of Health will issue registration numbers. If not granted registration, the Ministry of Health will be the reason in writing.

Article 9
Establishments registered circulation of vaccine, bio-products in Vietnam Men must pay fees and charges prescribed by law.

CHAPTER II
APPLICATION vaccines and biologicals
DOMESTIC PRODUCTION

Article 10
1. Registration dossier vaccines and biologicals finished products for prevention and treatment include:

a) An application for registration (Form 3).

b) Certificate of production facilities meet standards set by the Ministry of Health level.

c) The process manufacturing, verification,

d) Quality control and test
e) The certificate verification result of vaccines and biologicals for the National Center for Testing of biologicals medicine for three consecutive lots.

e) The explanations brief introduction process and research results together with the research on the following issues:

Component, composed.

Work, indicated.

Indicated.

Side effects, how to handle.

Stability and the preservation.

Summary record production and test vaccines and biologicals for the third consecutive lot.

Data on the origin of the original strains of bacteria, viruses.

h) Results of clinical quality.

i) label (designed or attached to Form 6) is the official form for circulation, the label directly on the smallest unit of packaging, labels on packages indirect, attached sheet manual.

k) Form vaccines, biologicals: Save at the National Center for Testing of biologicals medicine.

2. Registration dossier biologicals finished products to diagnose include:

a) An application for registration (Form 4)

b) Certificate of production facilities meet standards set by the Ministry of Health level.

c) manufacturing process, verification.

d) Quality control and test

e) The certificate verification result of the National Center for Testing of biologicals medicine.

f) The explanations brief introduction process and research results together with the research on the following issues:

Component, composed.

Work, indicated.

Stability and the preservation.

Experimental results.

h) label (designed or attached to Form 6) is the official circulation models, labels directly on the smallest unit of packaging, labels on packages indirect, attached sheet manual.

i) Model vaccines, biologicals: Save at the National Center for Testing of biologicals medicine.

3. Registration dossier vaccines semi-finished products, semi-finished products, including biologicals:

a) An application for registration (Form 3)

b) Certificate of production facilities meet standards set by the Ministry of Health level.

c) manufacturing process, verification.

d) Quality control and test

e) permit the registration of the product

e) the certificate verification result of vaccines, bio-products of the National Center for Testing of biologicals medicine for three consecutive lots of semi-finished products.

h) The brief explanations referral process and research results together with the research on the following issues:

Component, composed.

Effects and indicated.
Indicated.
Side effects, how to handle.
Stability and the preservation.
Technical production process and for the final.
Data on racial origin origin

i) Brand is the official form for circulation, the label directly on the smallest unit of packaging, labels on packages indirect, attached sheet manual.

k) Form vaccines, biologicals: Save at the National Center for Testing of biologicals medicine.

4. Record registration of vaccines, bio-products: procedures documents as stipulated in Clause 1, Clause 2, Clause 3 of this Article, except Section H, Clause 1.

CHAPTER III
APPLICATION vaccines and biologicals
PRODUCTION IN FOREIGN

Article 11
1. Registration dossier vaccines and biologicals finished products for prevention and treatment include:

a) An application for registration (Form 3).
b) Certificate of production facilities meet GMP standards by the competent authority in country level.
c) Certificate of the competent authorities in host countries to allow circulation or export vaccines, biologicals.
d) certificate or a copy of the certificate of national verification agencies in other countries where vaccines and biologicals for registration duon sale or distribution (case no verification agencies in these countries or vaccines, biologicals first time abroad, and must specify).
e) The certificate verification result of vaccines and biologicals by the National Center for Testing of biologicals medicine Vietnam Men for a batch of products.
f) Results of clinical trial quality in Vietnam Men (for the product was first used in Vietnam Men).
h) production process, control of vaccines and biologicals
i) Quality control and test
j) documents to:
Origin and history of the original strains of bacteria, viruses.
Documents related to copyright and other applicable certificates produced vaccines and biologicals
Statement production status last.

l) The documents on stability of vaccines and biologicals:
Summary records of each lot produced three consecutive lots.
Factory production license of the agency competent host countries for each batch of three lots of vaccines, biologicals consecutive test results together with the verification of the room production facilities.
m) label (designed or attached to Form 6) is the official form for circulation, the label directly on the smallest unit of packaging, labels on packages indirect, attached sheet manual.
n) Form vaccines, biologicals: Save at the National Center for Testing of biologicals medicine.

2. Registration dossier biologicals finished products to diagnose:

a) An application for registration (Form 4)
b) Certificate of production facilities meet standards set by the authorities in the host country level.
c) Certificate of the competent authorities in host countries to allow circulation or export biologicals.
d) certificate verification result by the National Center for Testing of biologicals medicine Vietnam Men level.
e) The process manufacturing and test.
e) Quality control and test
h) The brief explanations referral process and research results together with the research on the following issues: Component, composed.
  Work, indicated.
  Stability and the preservation.
Experimental results.
i) label (designed or attached to Form 6) is the official circulation models, labels directly on the smallest unit of packaging, labels on packages indirect, attached sheet manual.
k) Form vaccines, biologicals: Save at the National Center for Testing of biologicals medicine

3. Registration dossier vaccines semi-finished products, semi-finished products, including biologicals:
a) An application for registration (Form 3).
b) Certificate of production facilities meet GMP standards by the competent authority in country level.
c) Certificate of the competent authorities in host countries to allow circulation or export finished products.
d) certificate or a copy of the certificate of national verification agencies in other countries where semi-finished products registered for sale or distribution duon. Where there is no verification agencies in these countries or product first time abroad, must also clearly state.
d) certificate verification results vaccines, biologicals semi-finished products by the National Center for Testing of biologicals medicine Vietnam Men level.
e) The process manufacturing, verification.
h) Quality control and test
i) documents to:
  Origin and history of the original strains of bacteria, viruses.
Documents related to copyright and other applicable certificates produced
  Statement production status last.
l) The documents on stability:
  The result of verification room production facilities for three consecutive lots of semi-finished products.
l) Brand is the official circulation models, labels directly on the smallest unit of packaging, labels on packages indirect, attached sheet manual.
m) Form vaccines, biologicals: Save at the National Center for Testing of biologicals medicine.

4. Record registration of vaccines, biologicals: Procedures documents as stipulated in Clause 1, Clause 2, Clause 3 of this Article, except Section E, Clause 1.

CHAPTER IV
PROVISIONS ON THE CLINICAL TESTING vaccines, medical biologicals

Article 12
All vaccines and biologicals will be studied in water or used in other countries but first used in Vietnam, the clinical trial must be prescribed by the Ministry of Health before issuing registration numbers.

CHAPTER V
HANDLING OF VIOLATIONS

Article 13.
Vaccines and biologicals have been granted registration number, valid period will be suspended or withdrawn from circulation registration numbers if they violate one of the following cases:

a) suspend the circulation of vaccine lots for the bio-products do not meet quality standards as registered.
b) Withdrawal of registration of vaccines and biologicals on the market circulation records were not properly registered; vaccines and biologicals production three lots did not meet quality standards in a year or once a violation of the seriously.
c) clinical test vaccines and biologicals without permission in writing by the Ministry of Health shall be handled in accordance with the law.
d) Vaccines, biologicals breach of industrial property will be handled according to regulations.

**Article 14.**

1. Ministry of Health announced to suspend the circulation of vaccines, biologicals, or withdrawal of registration and withdrawal of vaccines and biologicals poor quality, vaccines and biologicals produced incorrect registration dossiers in the whole country.
2. When a decision to suspend the circulation and recovery of vaccines, biologicals, agencies function testing, processing facilities and sanctioning violations in accordance with current legislation.

**Article 15.**

1. Upon receiving the decision, suspending and withdrawing from circulation, the production base, business, imported vaccines, bio-products must comply with the following provisions:
a) expeditiously implementing recovery measures, immediately notify the management agency and the client know.
b) Lap record recovery.
c) revoke statement, explanation, evolutions and consequences of vaccines and biologicals recovered triggers.
d) To make the process and expedite the process of vaccines and biologicals were withdrawn under current regulations.
2. Establishments vaccines and biologicals were withdrawn to be responsible about what kind of vaccines and biologicals that bear all forms of treatment prescribed by law.

**Article 16.**

1. Those who violate this statute, depending on the seriousness of their violations, be disciplined, handling administrative violations or criminal process, if causing damage, pay compensation in accordance with the law.
2. The sanctioning of administrative violations in the field of State management of vaccines and biologicals shall comply with current regulations.

**CHAPTER VI IMPLEMENTATION**

**Article 17.**

1. Evaluation Council registration of vaccines, biologicals by the Minister of Health decided, the function of advising the Minister of Health to review and issue of registration of vaccines, bio-products in the country and abroad.
2. Department of Preventive Health and HIV / AIDS is a standing body of the Council vaccine evaluation registration biologicals tasked organizations receiving registration dossiers vaccines and biologicals, evaluation, organization Council meetings and resolve employment-related.
3. Based on the conclusions and recommendations of the Council, Minister of Health will determine the level of registration and processing forms and types of vaccines and biologicals.

**FORM 1**

APPLICATION vaccines, medical biologicals

1. Name and address base register:
2. Full name owner base register:
3. Name and address of production facilities:
4. Full name owner production facilities:
5. Name vaccines, bio-products:
6. Form sin vaccine, bio-products:
7. Purposes:

FORM 2
LIST APPLICATION vaccines and biologicals
Chamber treatment DOMESTIC PRODUCTION

1. Application for registration (Form 3)

2. Certificate production facilities meet standards set by the Ministry of Health issued

3. Production processes, verification
4. Quality standards and test

5. Certificate verification results vaccines, biologicals of
Testing of the National Center biologicals medicine for the third consecutive lot

6. The explanations brief introduction process and outcome research
together with the research on the following issues:
a) Composition, construct.
b) The effect and indicated.
c) Indications.
d) Side effects, how to handle.
e) The stability and the preservation.

e) From the original data on the origin strains of bacteria, viruses

7. Results of clinical trial quality in Vietnam Men
8. Brand and written manuals
9. Model vaccines, biologicals

FORM 3
APPLICATION FOR REGISTRATION vaccines and biologicals
Chamber treatment

To: Ministry of Health Department of preventive medicine and HIV / AIDS
138A Giang Vo, Hanoi
1. Trade names: Common name:
2. Name of Manufacturer:
Director of production facilities:
Address:
Phone: Fax:
3. Price:
4. Types of vaccines, bio-products:
5. Unit:
6. Uses:
7. Indicated, dose:
8. Road use:
9. Stability and the preservation of:
10. Shelf:
11. Indications, side effects:
12. Original strains used to produce vaccines and biologicals:
13. Package Type:

Director of production facilities On .... May ..... in 200
(signature and seal) Director establishments registered
(signature and seal)

FORM 4
STUDENT REGISTRATION APPLICATION PRODUCTS DIAGNOSTICS

To: The Ministry of Health Department of preventive medicine and HIV / AIDS
138A Giang Vo, Hanoi
1. Trade names: Common name:
2. Name of Manufacturer:
Director of production facilities:
Address:
Phone: Fax:
3. Price:
4. Form biologicals:
5. Unit:
6. Uses:
7. Indicated, dose:
8. Usage:
9. Stability and storage conditions:
10. Shelf:
11. Package Type:

Director of production facilities (signature and seal)  On .... May ..... in 200

Director establishments registered (signature and seal)

FORM 5

List registration dossiers biologicals finished products to diagnose

1. Application for registration (Form 4)

2. Certificate production facilities meet standards set by agencies competent authorities

3. Production processes, verification
4. Quality standards, verification

5. Certificate verification result by the Center for Testing of national bio-products for medicine
6. The explanations brief introduction process and outcome research together with the research on the following issues:
   a) Composition, construct.
   b) The effect and indicated.
   c) The stability and the preservation.
   d) Results of experiments

7. Label attached sheet manual

8. Model biologicals
**FORM 6**  
**CONTENT blood**

1. Name vaccines, bio-products: Registration :....................
2. Manufacturer:
3. Number of series production:
4. Number of units:
5. Production date:
6. Shelf:
7. Usage:
8. Storage:
   Director of production facilities  
   (signature and seal)

**FORM 7**  
**LIST APPLICATION vaccines and biologicals**  
**Chamber treatment FOREIGN**

1. Unit Registration (Form 3)

2. Certificate production facilities meet GMP standards by the competent authority in country level.

3. Certificate of the competent authority in the country for circulation or export

4. Certificate or certified copy of the agency's verification of the other countries where vaccines and biologicals for registration of the sale or distribution

5. Certificate verification results vaccines, biologicals by the National Center for Testing of bio-products for medicine

6. Results of clinical trial in Vietnam Men

7. Production processes, verification

8. Quality standards and test
9. Documents to:
   a) Origin and history of the original strains of bacteria, viruses
   b) documents related to copyright and other applicable certificates produced
   c) statement production status last

10. Documents on the stability of vaccines and biologicals:
    a) Documents produced a summary of each series of three consecutive lots of finished products.
    b) export permits factory national authorities for each series of three lots of vaccines, biologicals consecutive test results together with the verification of the room production facilities

11. Label attached sheet manual

12. Model vaccines, biologicals

   FORM 8
   APPLICATION REQUEST FOR CHANGES AND SUPPLEMENTS TO
   Vaccines, medical biologicals

   To: The Ministry of Health Department of preventive medicine and HIV / AIDS
   138A Giang Vo, Hanoi

   1. Trade names: Common name:
   2. Name of Manufacturer:
      a. Address:
      b. Phone: Fax:
   3. Name of the register:
      a. Address:
      b. Phone: Fax:
   4. Types of vaccines, bio-products:
   5. Unit Validated
   6. Uses:
   7. Indicated, dosage, how to use:
   8. Road use:
   9. Stability and storage conditions:
   10. Shelf:
   11. Indications, side effects:
   12. Original vaccine strains, bio-products:
   13. Content proposed changes and supplements:
Director of production facilities
(signature and seal)

On .... May ..... in 200
Director establishments registered
(signature and seal)

MINISTER
(Signed)

Tran