Russian Federation
Government Decree No. 673 of September 3, 2010
"Approval of Rules for Import and Export of Biological Materials Obtained in Clinical Trials of a medicinal product for medical use into and from the Russian Federation"

Pursuant to Article 40 of Federal Law "On Circulation of Medicines", the Government of the Russian Federation hereby decrees:

The attached "Rules for Import and Export of Biological Materials Obtained in Clinical Trials of a medicinal product for medical use into and from the Russian Federation" are hereby approved and enacted.

Vladimir Putin,
Prime Minister of the Russian Federation

APPROVED
by RF Government Decree No.
673 of September 3, 2010

RULES

for Import and Export of Biological Materials Obtained in Clinical Trials of a medicinal product for medical use into and from the Russian Federation

(with amendments, approved by RF Government Decree No.1001 of December 05, 2011)

1. These Rules regulate the procedure to import and export biological materials (samples of biological liquids, tissues, secretion and products of human life, physiological and pathological discharge, smears, swabs, streaks, microorganisms, biopsy materials) obtained in a clinical trial of a medicinal product for medical use (hereinafter referred to as "import (export) of biological materials") into and from the Russian Federation.

2. Biological materials shall be imported (exported) to be researched inside or outside of the Russian Federation, based on permits issued by the Ministry of Healthcare and Social Development of the Russian Federation.

Permits to import/export biological materials shall be issued for the time of clinical trials of a medicinal product for medical use expected to produce biological materials.

Permits to import (export) biological materials shall be issued for presentation to the customs agencies of the Russian Federation.

3. The following corporate entities that organize through the established procedure clinical trials of medicines (hereinafter referred to as "petitioning organization") are authorized to import and export biological materials into/from the Russian Federation, obtained in clinical trials of a medicinal product for medical use:

a) developer of the medicinal product or its representative corporate entity authorized to organize clinical trials of a medicinal product for medical use;

b) educational institutions of higher and/or additional professional education, whose activities envisage participation in organization or conduct of clinical trials of a medicinal product for medical use;

в) research centres whose activities envisage participation in organization or conduct of clinical trials of a medicinal product for medical use.

4. To receive a permit for import (export) of biological materials, the petitioning organization shall submit to the Ministry of Health and Social Development of the Russian Federation the following documents in hard copy or electronic form:

(as amended by Government Decree of December 5, 2011, No.1001)

a) request to permit import (export) biological materials, disclosing the following:

- information about clinical trials of a medicinal product for medical use with a reference to a protocol on a clinical trial and stated purposes of the clinical trials of a medicinal product for medical use, time schedule of a clinical trial expected to produce biological materials;
- name of the nation state where the clinical trials of a medicinal product for medical use are to be conducted; place of residence and full name of the organization recipient of imported (exported) biological materials;
- purpose of import (export) of biological materials;
- type of imported (exported) biological material;
- number of units of each type of imported (exported) biological material;
- type of packing for each type of imported (exported) biological material;

b) back up calculation for the number of units of each type of imported (exported) biological material based on the report of clinical trials of a medicinal product for medical use and the number of patients involved (to be involved) in the clinical trials of a medicinal product for medical use;

c) a copy of officially issued permit to conduct clinical trials of a medicinal product for medical use, expected to produce biological materials, if such trials are to be in the Russian Federation;

d) copies of incorporation documents and statutory registration of corporate entity, certificate of tax registration of the petitioning organization. If the petitioning organization is a foreign corporate entity while the clinical trials of a medicinal product for medical use are conducted in the Russian Federation, documents must be presented to confirm accreditation of a foreign corporate entity’s representative in the Russian Federation.

4.[1]. The Ministry of Health and Social Development of the Russian Federation shall not have the right to request that the petitioning organization submits a copy of the permit provided for by subclause "c" of clause 4 of these Rules and copies of the certificate of state registration of legal entity and

certificate of registration of the applicant company with the tax body provided for by subclause "d" of clause 4 of these Rules.

The petitioning organization shall have the right to submit copies of the said documents on its own initiative.

(as amended by Government Decree of December 5, 2011, No.1001)

5. Within 10 business days from acceptance of the documents required by Par. 4 hereof, the Ministry of Healthcare and Social Development of the Russian Federation shall:

a) Checks completeness and reliability of the data specified in the submitted documents, and in case the petitioning organization does not submit a copy of the permit provided for by subclause "c" of clause 4 of these Rules, checks existence of the said permit according to the data in the register on the permits issued for conduct of clinical trials of medicinal products,

(as amended by Government Decree of December 5, 2011, No.1001)

a^1) Requests and receives information on the fact of inclusion of data on the petitioning organization into the Unified State Register of Legal Entities and on the fact of registration of the petitioning organization with the tax body from the Federal Tax Service according to the procedure for interauthority information cooperation, in case the petitioning organization being a Russian legal entity does not submit a copy of the certificate of state registration of legal entity and certificate of registration with the tax body.

(as amended by Government Decree of December 5, 2011, No.1001)

b) make a decision whether a permit to import (export) biological materials is granted or refused;

c) issued to the petitioning organization a permit to import (export) biological materials or notify the petitioning organization in writing that permit to import (export) biological materials is refused, stating the reasons.

6. A permit to import (export) biological materials shall be issued on the blank form available in Appendix 1.

No fees shall be charged for issue of permits to import (export) biological materials.

7. Failure to present all documents and/or unverifiable/false information in the materials presented by the petitioning organization shall constitute grounds to refuse permit to import (export) biological material.

8. Request for permit to import (export) biological materials, and the resulting decision by the Ministry of Healthcare and Social Development of the

Russian Federation on the request shall be recorded in the registry of issued permits to import (export) biological materials, and decisions to refuse permits to import (export) biological materials, which the Ministry of Healthcare and Social Development of the Russian Federation shall keep in the set form.

9. If there is need to increase the quantity of imported (exported) biological material under the same clinical trial of a medicinal product for medical use, the petitioning organization shall file with the Ministry of Healthcare and Social Development of the Russian Federation a request to import (export) additional quantity of biological materials, prepared as described in Par. 4 hereof.

10. Within 10 business days from receipt of such request to import (export) additional quantity of biological materials prepared as described in Par. 4 hereof the Ministry of Healthcare and Social Development of the Russian Federation shall:

a) verify and validate the information contained in the request;

b) make a decision to grant or refuse permit to import (export) biological materials, stating the reason of refusal;

c) issue a supplement to the petitioning organization's permit to import (export) biological materials, or written notice of refusal stating the reasons.

11. Supplements to permits to import (export) biological materials shall be issued using the form of Appendix 2.

No fee shall be charged for issue of supplements to permits to import (export) biological materials.

12. Failure to present all documents and/or unverifiable/false information contained in the materials presented by the petitioning organization shall be grounds to refuse supplements to permits to import (export) biological material.

13. Request for permit to import (export) additional quantity of biological materials, and the resulting decision by the Ministry of Healthcare and Social Development of the Russian Federation on the request shall be recorded in the registry described in Par. 8 hereof.

14. Should the clinical trials of a medicinal product for medical use be suspended or terminated, Ministry of Healthcare and Social Development of the Russian Federation shall rule that the effect of the respective permit to import (export) biological materials, with related supplements, be suspended until the clinical trial is resumed, or terminate the effect of the permit to import (export) biological materials and related supplements.

15. Decision by the Ministry of Healthcare and Social Development of the Russian Federation to suspend or terminate the effect of a permit to import (export) biological materials shall be communicated to the petitioning organization and the Federal Customs Service within 5 business days from the time of such decision.

16. Decision by the Ministry of Healthcare and Social Development of the Russian Federation to resume the effect of a permit to import (export) biological materials with related supplements, shall be communicated in writing to the petitioning organization and the Federal Customs Service within 5 business days from the time of such decision.

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APPENDIX 1

To Rules to import into and export from the Russian Federation biological materials obtained in a clinical trial of a medicinal product for medical use

FORM

Coat of arms of the Russian Federation

MINISTRY OF HEALTHCARE AND SOCIAL DEVELOPMENT OF THE RUSSIAN FEDERATION

PERMIT No. _____

to import (export) biological materials obtained in a clinical trial of medicine _____ of medical use

Issued to _____

(name of the petitioning organization to import (export) biological materials)

based on request of _____ No. _____

(date)

to import (export)

_____

(type of imported (exported) biological material)

_____,

(number of units of each type of imported(exported) biological material, type of packing for each type of imported (exported) biological material)

obtained in a clinical trial of medicine _____ of medical use, as authorized by the Ministry of Healthcare and Social Development of the Russian Federation by permit of _____ No. _____

(date)

according to clinical trials report _____

(title of report)

for _____.

(objective to import (export) biological materials, name of the nation state, location and full name of organization to receive imported (exported) biological materials)

This Permit is valid until _____

(date)

_____ _____ _____

(position) (signature) (full name)

‘_____’ _____ 201__ stamp here

_____

APPENDIX 2
To Rules to import into and export from the Russian Federation biological materials obtained in a clinical trial of a medicinal product for medical use

FORM

Coat of arms of the Russian Federation

MINISTRY OF HEALTHCARE AND SOCIAL DEVELOPMENT OF THE RUSSIAN FEDERATION

SUPPLEMENT TO PERMIT No. _____
to import (export) biological materials obtained in a clinical trial of medicine _____ of medical use

Issued to _____
(name of the petitioning organization to import (export) biological materials)

based on request of _____ No. _____
(date)

to import (export)_____
(type of imported (exported) biological material)

_____,
(number of units of each type of imported (exported) biological material,
type of packing for each type of imported (exported) biological material)

obtained in a clinical trial of medicine _____ of medical use, as authorized by the Ministry of Healthcare and Social Development of the Russian Federation by permit of _____ No. _____
(date)

according to clinical trials report _____
(title of report)

for _____.
(objective to import (export) biological materials, name of the nation state, location and full name of organization to receive imported (exported) biological materials)

This Supplement to Permit is valid until _____
(date)

_____ _____ _____
(position) (signature) (full name)

‘_____’ _____ 201__ stamp here

_____