

**RESOLUTION**  
**of the Ministry of Health of the Republic of Belarus**  
**No. 55 dated April 23, 2015**  
*On certain measures on realization of*  
**the Resolution of the Council of Ministers**  
**of the Republic of Belarus No. 254 dated April 01, 2015**  
*(Registered in the National Register of Legal Acts*  
*of the Republic of Belarus on June 02, 2015, 8/29947)*

On the grounds of Sub Article 8.14<sup>1</sup> and 8.25<sup>1</sup> of Article 8 and Sub Article 9.1 of Article 9 of the Provision of the Ministry of Health of the Republic of Belarus approved by Resolution of the Council of Ministers of the Republic of Belarus No. 1446 dated October 28, 2011 “On certain issues of the Ministry of Health and measures on realization of Decree of the President of the Republic of Belarus No. 360 dated August 11, 2011” No. 360 dated August 11, 2011, and in pursuit of Article 3 of Resolution of the Council of Ministers of the Republic of Belarus No. 254 dated April 1, 2015 “On state registration (confirmation of the state registration) of medicinal products and pharmaceutical substances and introduction of changes and additions in Regulation of the Council of Ministers of the Republic of Belarus” No. 1269 dated September 2, 2008, the Ministry of Health of the Republic of Belarus RESOLVES:

1. To approve the attached:

Instruction on order of organization and carrying out the range of preliminary technical works related to examinations, inspections of industrial production of medicinal products and pharmaceutical substances, tests and other investigations preceding the state registration (confirmation of the state registration) of medicinal products and pharmaceutical substances, introducing revisions into the registration dossier for a medicinal product, pharmaceutical substance previously registered in the Republic of Belarus;

Instruction on order of organization and carrying out the range of preliminary technical works related to examinations, inspections of industrial production of medical devices and medical equipment, tests and other investigations preceding the state registration (re-registration) of medical devices and medical equipment, introducing revisions into the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus.

2. This Resolution enters into force following its official publication.

**First Deputy Minister**

**Dmitry L. PINEVICH**

Approved by  
Resolution  
of the Ministry of Health  
of the Republic of Belarus  
No. 55 dated April 23, 2015

**INSTRUCTION**

**on order of organization and carrying out the range of preliminary technical works related to examinations, inspections of industrial production of medicinal products and pharmaceutical substances, tests and other investigations preceding the state registration (confirmation of the state registration) of medicinal products and pharmaceutical substances, introducing revisions into the registration dossier for a medicinal product, pharmaceutical substance previously registered in the Republic of Belarus**

1. This Instruction defines the order of organization and carrying out the range of preliminary technical works (hereinafter — preliminary technical works) related to examinations, inspections of industrial production of medicinal products and pharmaceutical substances, tests and other investigations preceding the state registration (confirmation of the state registration) of medicinal products and pharmaceutical substances, introducing revisions into the registration dossier for a medicinal product, pharmaceutical

substance previously registered in the Republic of Belarus by the Center for Examinations and Tests in Health Service Republic Unitary Enterprise (hereinafter — the Enterprise).

2. This Instruction is mandatory for legal entities and individual entrepreneurs carrying out industrial production, realization and medical application of medicinal products manufactured in the Republic of Belarus, realization and medical application of medicinal products that come outside of the Republic of Belarus as well as the conduct of preliminary technical works.

3. In this Instruction the terms and their definitions are used in the meanings determined by Law of the Republic of Belarus dated June, 18 1993 “On healthcare” (Statements of the National Assembly of the Republic of Belarus, 1993, No. 24, Article 290; the National Register of Legal Acts of the Republic of Belarus, 2008, No. 159, 2/1460), Law of the Republic of Belarus dated July 20 , 2006 “On medicinal products” (the National Register of Legal Acts of the Republic of Belarus, 2006, No. 122, 2/1258) and Provision on order and conditions of the state registration (the confirmation of the state registration) of medicinal products and pharmaceutical substances, introduction of revisions into the registration dossier approved by Resolution of the Council of Ministers of the Republic of Belarus No. 254 dated April 1, 2015 “On state registration (confirmation of the state registration) of medicinal products and pharmaceutical substances and introduction of changes and additions in Regulation of the Council of Ministers of the Republic of Belarus” dated No. 1269 September 2, 2008 (the National Legal Internet Portal of the Republic of Belarus, 07.04.2015, 5/40348).

4. Preliminary technical works are carried out on the basis of the Agreement concluded between the Enterprise and the Applicant, and the term of their conduct should not exceed 180 calendar days.

The significant condition of the Agreement, apart from other conditions established by the legislation of the Republic of Belarus is the submission of the documents envisaged by paragraphs 10.13–10.18 of the unified list of administrative procedures conducted by the state authorities and other organizations for legal entities and individual entrepreneurs approved by Resolution of the Council of Ministers of the Republic of Belarus No. 156 dated February 17, 2012 by the Applicant (the National Register of Legal Acts of the Republic of Belarus, 2012, No. 35, 5/35330) (hereinafter — documents). At the same time documents in foreign languages on medicinal products and pharmaceutical substances of foreign production should be accompanied by a translation into Belarusian or Russian.

5. The conduct of the range of preliminary technical works begins with the primary examination of documents that envisage:

examination of completeness and validity of their registration;

examination of compliance of a trade name of a medicinal product, pharmaceutical substance, taking into account similar medicinal products, pharmaceutical substances registered in the Republic of Belarus.

If the result of primary examination of documents is positive, the preliminary technical works are defined, the conduct of which is necessary for the confirmation of safety, efficacy and quality of a medicinal product, pharmaceutical substance.

The term of conduct of primary examination of documents should not exceed 15 calendar days.

6. The safety, efficacy and quality of a medicinal product, pharmaceutical substance is confirmed by carrying out the following preliminary technical works preceding to:

6.1. the state registration of a medicinal product, pharmaceutical substance:

6.1.1. the Inspection of industrial production of a medicinal product on compliance with the requirements of Good Manufacturing Practice (hereinafter — Inspection);

6.1.2. The approbation of the method of quality control of a medicinal product, pharmaceutical substance that will be provided for the state registration for the first time, with the exception of medicinal products and pharmaceutical substances, envisaged in fourth Paragraph of this Sub Article, the quality control of a medicinal product, pharmaceutical substance with the usage of this method as well as analysis of quality of a medicinal product, pharmaceutical substance during the conduct of their clinical trials by the state organizations of health care.

In case if the cost of samples of a medicinal product, pharmaceutical substance, necessary for a conduct of the approbation of the method of quality control, and the quality control of a medicinal product, pharmaceutical substance with the usage of this method on all indicators of a pharmacopoeia monograph of the manufacturer or a regulatory document of the manufacturer, containing the parameters and the method of quality control of a

medicinal product, pharmaceutical substance, exceeds 1000 standard units equivalent to 1000 US dollars at the exchange rate of the National Bank of the Republic of Belarus given at the reporting date of submission of documents by the Applicant, the specified approbation of the method of control and quality control are carried out on individual indicators of a pharmacopoeia monograph of the manufacturer or a regulatory document of the manufacturer used for the confirmation of identity (identification), quantitative content of the drug substances and content of related impurities.

In case of failure of submission of samples of a medicinal product, pharmaceutical substance indicated in the second Paragraph of this Sub Article by the Applicant as well as absence of such technical possibility of the approbation of the method of quality control of a medicinal product, pharmaceutical substance in the state organizations of health care and quality control conducted by the workers of organizations included in the system of the Ministry of Health of the Republic of Belarus, the validation of reproduction of the specified approbation of the method of control and quality control is carried out at the address of the manufacturer of a medicinal product, pharmaceutical substance carrying out the quality control.

The approbation of the method of quality control of a medicinal product, pharmaceutical substance and quality control with the usage of these methods does not apply to:

narcotic drugs and psychotropic substances;

radiopharmaceutical medicinal products;

medicinal products for the treatment of patients with rarely occurring pathology;

medicinal products coming from international organizations to the Ministry of Health of the Republic of Belarus on humanitarian and international technical assistance;

6.1.3. A special examination of documents on compliance of a medicinal product, pharmaceutical substance with the requirements for the safety, efficacy and quality, taking into account their pharmaceutical and clinico-pharmacological peculiarities.

The term of carrying out a special examination of documents should not exceed 60 calendar days.

A special examination of documents is carried out by the experts determined by the Enterprise.

The Expert Conclusion is drawn up by every expert on the basis of the results of a special examination of documents.

With contradictions in Expert Conclusions, the Enterprise appoints a conduct of a special reexamination of documents on the basis of the results of which the expert draws up the Expert Conclusion, including one's viewpoint on encountered contradictions. The term of carrying out reexamination of documents should not exceed 30 calendar days from the date of its appointment.

In the presence of remarks in Expert Conclusions, the Enterprise introduces the Applicant in the written form with the content of Expert Conclusions and with the list of remarks (without specifying the experts).

The Applicant informs the Enterprise of removal of remarks and (or) submits the necessary information (materials) in writing within 40 calendar days from the day of acquaintance with these remarks. After the removal of remarks a final special examination of documents is conducted, the term of conduct of which is no more than 30 calendar days;

6.1.4. The conduct:

of tests on study of bioavailability (bioequivalence) of a generic medicinal product;

of clinical trials of a medicinal product, which will be submitted for the state registration in the Republic of Belarus for the first time, in accordance with the requirements of Good Clinical Practice;

appointed by the Ministry of Health of the Republic of Belarus

6.1.5. other investigations (where necessary) in cases and order, established by the legislation ;

6.2. The confirmation of the state registration of a medicinal product:

6.2.1. Inspection;

6.2.2. a special examination of documents in accordance with Sub Article 6.1.3 of the following article;

6.2.3. other investigations (where necessary) in cases and order, established by the legislation;

6.3. introduction of revisions into the registration dossier for a medicinal product, pharmaceutical substance previously registered in the Republic of Belarus:

6.3.1. Inspection;

6.3.2. The approbation of the method of quality control of a medicinal product, pharmaceutical substance in case of change of tests (quality indicators), specified in the pharmacopoeia monograph or regulatory

document of the manufacturer, containing parameters and methods of quality control of a medicinal product, the conduct of which is carried out in accordance with Sub Article 6.1.2 of the following article;

6.3.3. A special examination of documents, the conduct of which is carried out in accordance with Sub Article 6.1.3 of the following article;

6.3.4. tests on study of bioavailability (bioequivalence) of a generic medicinal product in case of change of its composition, production process, change of the manufacturer of a dosage form and clinical trials of a medicinal product proposed for medicinal application according to the new indications, to a new application method, the appointment of which is carried out in accordance with sub article 6.1.4 of the following article;

6.3.5. other investigations (where necessary) in cases and order, established by the legislation.

7. While establishing the circumstances that prevent the further conduct of preliminary technical works (including submission of documents and samples of a medicinal product, pharmaceutical substance, non-compliant with the requirements of the legislation, or their failure to submit), and taking measures on their elimination by the Applicant, the conduct such works is terminated.

8. On the basis of the results of carrying out preliminary technical works by the Enterprise, the Conclusion on compliance of a medicinal product, pharmaceutical substance with the requirements for the safety, efficacy and quality (hereinafter — Conclusion) is registered in the form according to the Annex to the following Instruction, in which a detailed analysis of information received during the conduct of preliminary technical works is represented.

9. The Conclusion is made in two copies, is signed by the authorized person and affixed by the seal of the Enterprise. One copy of the Conclusion is issued to the Applicant during 5 calendar days from the date of its signing by the authorized person of the Enterprise, the second copy is kept in the Enterprise.

Validity period of the Conclusion — 6 months from the date of its issue.

Annex to

The Instruction on order of organization and carrying out the range of preliminary technical works related to examinations, inspections of industrial production of medicinal products and pharmaceutical substances, tests and other investigations preceding the state registration (confirmation of the state registration) of medicinal products and pharmaceutical substances, introducing revisions into the registration dossier for a medicinal product, pharmaceutical substance previously registered in the Republic of Belarus

Form

CENTER FOR EXAMINATIONS AND TESTS IN HEALTH SERVICE  
REPUBLICAN UNITARY ENTERPRISE

### **CONCLUSION**

**on compliance of a medicinal product, pharmaceutical substance  
with the requirements for the safety, efficacy and quality**

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City of Minsk

This Conclusion is prepared on the basis of the results of the range of preliminary technical works related to carrying out examinations, inspections of industrial production, tests and other investigations

\_\_\_\_\_  
(trade name of a medicinal product, pharmaceutical

\_\_\_\_\_

substance, presentation, name and address of the manufacturer, the applicant)

preceding to \_\_\_\_\_

(the state registration, confirmation

\_\_\_\_\_, including:

of the state registration, introducing revisions into the registration dossier)

1. Results of the primary examination of documents \_\_\_\_\_

2. Results of inspection of industrial production \_\_\_\_\_

3. Results of the approbation of the method of quality control, quality control with the usage of this method, analysis of quality in the appointment of clinical trials \_\_\_\_\_

4. Results of a special examination of documents, including:  
pharmaceutical \_\_\_\_\_

clinico-pharmacological \_\_\_\_\_

5. Results of the tests on bioavailability (bioequivalence) study of a generic medicinal product \_\_\_\_\_

6. Results of clinical trials \_\_\_\_\_

## CONCLUSION

(trade name of a medicinal product, pharmaceutical substance)

(compliant (non-compliant) with the requirements for the

safety, efficacy and quality in the Republic of Belarus)

(possibility (impossibility) of the state registration, confirmation of

the state registration, introduction of revisions into the registration dossier)

This Conclusion is valid during 6 months from the date of issue.

(position of the authorized person) (signature) (Acting, Surname)

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APPROVED  
Resolution  
of the Ministry of Health  
of the Republic of Belarus  
No. 55 dated April 23, 2015

## INSTRUCTION

**on order of organization and carrying out the range of preliminary technical works related to examinations, inspections of industrial production of medical devices and medical equipment, tests and other investigations preceding the state registration (re-registration) of medical devices and**

## **medical equipment, introducing revisions into the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus.**

1. This Instruction defines the order and carrying out the range of preliminary technical works (hereinafter — preliminary technical works) related to examinations, inspections of industrial production of medical devices and medical equipment, tests and other investigations preceding the state registration (re-registration) of medical devices and medical equipment, introducing revisions into the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus by the Center for Examinations and Tests in Health Service Republic Unitary Enterprise (hereinafter — the Enterprise).

2. This Instruction is mandatory for legal entities and individual entrepreneurs carrying out industrial production, realization and application of medical devices and medical equipment as well as the conduct of preliminary technical works.

3. In this Instruction the terms and their definitions are used in the meanings determined by Law of the Republic of Belarus dated June 18, 1993 “On healthcare” (Statements of the National Assembly of the Republic of Belarus, 1993, No. 24, Article 290; the National Register of Legal Acts of the Republic of Belarus, 2008, No. 159, 2/1460) and Provision on the state registration (re-registration) of medical devices and medical equipment approved by Resolution of the Council of Ministers of the Republic of Belarus No. 1269 dated September 2, 2008 (the National Register of Legal Acts of the Republic of Belarus, 2008, No. 213, 5/28269).

4. Preliminary technical works are carried out on the basis of the Agreement concluded between the Enterprise and the Applicant, and the term of their conduct should not exceed 150 calendar days.

The significant condition of the Agreement, apart from other conditions established by the legislation of the Republic of Belarus is the submission of the documents envisaged in paragraphs 10.10–10.12 of the unified list of administrative procedures conducted by the state authorities and other organizations for legal entities and individual entrepreneurs approved by Resolution of the Council of Ministers of the Republic of Belarus No. 156 dated February 17, 2012 by the Applicant (the National Register of Legal Acts of the Republic of Belarus, 2012, No. 35, 5/35330) (hereinafter — documents). At the same time documents in foreign languages on medical devices and medical equipment of foreign production should be accompanied by a translation into Belarusian or Russian.

5. The conduct of the range of preliminary technical works begins with the primary examination of documents that envisage:

- examination of completeness and validity of their registration;

- examination of completeness and relevance of the information given in them;

- specification of the list and the names of medical devices and medical equipment in accordance with the medical devices nomenclature.

If the result of primary examination of documents is positive, the preliminary technical works are defined, the conduct of which is necessary for the confirmation of safety, efficacy and quality of medical devices and medical equipment.

The term of conduct of primary examination of documents should not exceed 15 calendar days.

6. The safety, efficacy and quality of medical devices and medical equipment is confirmed by carrying out the following preliminary technical works preceding to:

- 6.1. the state registration of medical devices and medical equipment:

- 6.1.1. inspection of industrial production of medical devices and medical equipment in order to confirm the possibility to produce medical devices and medical equipment compliant with the requirements for the safety, efficacy and quality (hereinafter — Inspection).

Inspection carried out at the manufacturer, who will introduce medical devices and medical equipment for the state registration in the Republic of Belarus for the first time, with the exception of medical devices and medical equipment of foreign production of the class I of potential risk (except the 1 (sterile) class) and the declared list of which is less than 20 units of medical devices and (or) less than 5 units of medical equipment.

Inspection includes:

- examination of organization of the incoming inspection of raw materials and materials;

- identification and traceability of medical devices and medical equipment;

examination of the control of production processes;  
examination of management of control, measuring and testing equipment;  
study of technological processes of production of medical devices and medical equipment, including examination of documents on the organization of the technological process;  
study of control and test methods at all stages of production;  
examination of storage conditions, types of packaging, labeling of medical devices and medical equipment;

study and assessment of safety, quality and efficacy of medical devices and medical equipment and their compliance with international standards and regulations of the Republic of Belarus (for medical devices and medical equipment of foreign production);

6.1.2. sanitary-hygienic tests of medical devices and medical equipment on compliance with the requirements of sanitary norms and rules of the Republic of Belarus, regulating the requirements for the safety of medical devices and medical equipment;

6.1.3. technical tests of medical devices and medical equipment of domestic production on compliance with the requirements of technical normative legal acts in force in the Republic of Belarus, and (or) technical normative legal acts of the manufacturer, regulating the technical requirements for medical devices and medical equipment and requirements for the safety and quality;

6.1.4. A special examination of documents.

The term of conduct of a special examination of documents should not exceed:

15 calendar days — for medical devices;

30 calendar days — for medical equipment.

A special examination of documents is carried out by the experts determined by the Enterprise.

The Expert Conclusion is drawn up by every expert on the basis of the results of a special examination of documents.

With contradictions in Expert Conclusions, the Enterprise appoints a conduct of a special reexamination of documents on the basis of the results of which the expert draws up the Expert Conclusion, including one's viewpoint on encountered contradictions. The term of carrying out reexamination of documents should not exceed 15 calendar days from the date of its appointment.

In the presence of remarks in Expert Conclusions, the Enterprise introduces the Applicant in the written form with the content of Expert Conclusions and with the of list remarks (without specifying the experts).

The Applicant informs the Enterprise of removal of remarks and (or) submits the necessary information (materials) in writing within 30 calendar days from the day of acquaintance with these remarks. After the removal of remarks a final a special examination of documents is conducted, the term of conduct of which is no more than 10 calendar days — for medical devices and no more than 20 calendar days — for medical equipment;

6.1.5. The conduct of clinical trials, appointed by the Ministry of Health of the Republic of Belarus:

medical devices and medical equipment of domestic production;

medical devices and medical equipment of foreign production in case of adoption of the decision on carrying out clinical trials of the Enterprise by the expert on the basis of the results of a special examination of documents;

6.1.6. other investigations (where necessary) in cases and order, established by the legislation;

6.2. the state re-registration of medical devices and medical equipment:

6.2.1. Inspection in accordance with the requirements of the first and the third part of Sub Article 6.1.1 of the following article in case of availability of information:

from healthcare organizations on the adverse effects associated with associated with causing harm to human life and health when using this medical devices and medical equipment;

from state authorities on manufacturers of medical devices and medical equipment (including the failures of production of medical devices and medical equipment), to be tested in order to establish (confirm) the presence or absence of such information;

6.2.2. sanitary-hygienic tests of medical devices and medical equipment on compliance with the requirements in accordance with Sub Article 6.1.2 of the following article;

6.2.3. technical tests of medical devices and medical equipment of domestic production on compliance with the requirements in accordance with sub article 6.1.3 of the following article;

6.2.4. A special examination of documents in accordance with Sub Article 6.1.4 of the following article;

6.2.5. clinical trials of medical devices and medical equipment of domestic and of foreign production in case of adoption of the decision by the expert of the Enterprise on the basis of the results of a special examination of documents on carrying out clinical trials;

6.2.6. other investigations (where necessary) in cases and order, established by the legislation;

6.3. introduction of revisions into the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus:

6.3.1. The conduct of a special examination of documents in accordance with Sub Article 6.1.4 of the following article;

6.3.2. The conduct of preliminary technical works in accordance with Sub Article 6.1 or 6.2 of the following Article in case if by the results of a special examination of documents is determined that the introduced into the registration dossier changes may influence the safety, efficacy and quality of medical devices and medical equipment;

6.3.3. Other investigations (where necessary) in cases and order established by the legislation.

7. While establishing the circumstances that prevent the further conduct of preliminary technical works (including submission of documents and samples of medical devices and medical equipment, non-compliant with the requirements of the legislation, or their failure to submit), and taking measures on their elimination by the Applicant, the conduct such works is terminated.

8. On the basis of the results of carrying out preliminary technical works by the Enterprise, the Conclusion on compliance of medical devices and medical equipment with the requirements for the safety, efficacy and quality (hereinafter — Conclusion) is registered in the form according to the Annex to the following Instruction, in which a detailed analysis of information received during the conduct of preliminary technical works is represented.

9. The Conclusion is made in two copies, is signed by the authorized person and affixed by the seal of the Enterprise. One copy of the Conclusion is issued to the Applicant during 5 calendar days from the date of its signing by the authorized person of the Enterprise, the second copy is kept in the Enterprise.

Validity period of the Conclusion — 6 months from the date of its issue.

#### Annex

Instruction on order of organization and carrying out the range of preliminary technical works related to examinations, inspections of industrial production of medical devices and medical equipment, tests and other investigations preceding the state registration (re-registration) of medical devices and medical equipment, introducing revisions into the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus

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REPUBLICAN UNITARY ENTERPRISE

#### **CONCLUSION**

**on compliance of medical devices and medical equipment  
with the requirements for the safety, efficacy and quality**



This Conclusion is prepared on the basis of the results of the range of preliminary technical works related to carrying out examinations, inspection of industrial production, tests and other investigations

\_\_\_\_\_ (the name and type of medical devices, medical equipment,

\_\_\_\_\_ the name and address of the manufacturer, the applicant)

preceding \_\_\_\_\_

(the state registration, re-registration,

\_\_\_\_\_, including:

\_\_\_\_\_ introducing revisions into the registration dossier)

1. Results of primary examination of documents \_\_\_\_\_

2. Results of inspection of industrial production \_\_\_\_\_

3. Results of sanitary-hygienic tests \_\_\_\_\_

4. Results of technical tests \_\_\_\_\_

5. Results of a special examination of documents \_\_\_\_\_

6. Results of clinical trials \_\_\_\_\_

## CONCLUSION

\_\_\_\_\_ (the name and type of medical devices, medical equipment)

is related to \_\_\_\_\_ the potential risk class,

\_\_\_\_\_ (compliant (non-compliant) with the requirements for the

\_\_\_\_\_ safety, efficacy and quality in the Republic of Belarus)

\_\_\_\_\_ (possibility (impossibility) of the state registration (re-registration),

\_\_\_\_\_ introduction of revisions into the registration dossier)

This Conclusion is valid during 6 months from the date of issue.

\_\_\_\_\_ (position of the authorized person) (signature) (Acting, Surname)

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