

		
SLUŽBENI GLASNIK BOSNE I HERCEGOVINE <i>Izdanje na hrvatskom, srpskom i bosanskom jeziku</i>	СЛУЖБЕНИ ГЛАСНИК БОСНЕ И ХЕРЦЕГОВИНЕ <i>Издање на хрвајском, српском и босанском језику</i>	
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Based on Article 80 paragraph (4) of the Medicinal Products and Medical Devices Act of Bosnia and Herzegovina ("Official Gazette of BiH", No. 58/08), the Expert Council of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, at the proposal of the Director of the Agency, at the IX session held on April 30th, 2010, adopted

ORDINANCE

ON THE CONDITIONS, CIRCUMSTANCES AND PROCEDURE FOR THE USE OF AUTHORIZED LABORATORIES

TITLE I - Preliminary provisions

Article 1

This Ordinance defines the conditions, circumstances and procedure for the use of authorized laboratories for quality control of the medicinal products, as well as a way of keeping records of inspections conducted in this way.

Article 2

(1) For the purpose of conducting specific analyzes that cannot be completed in the Control Laboratory of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (hereinafter: the Agency) other authorized laboratories may be used.

(2) The Agency is responsible to the applicant for result of the contracted work.

Article 3

The authorized laboratory is a laboratory that has to be a member of "OMCL" network

i.e network of official Medicine Control Laboratories "Official Medicine Control Laboratories".

TITLE II – Determination of the need for the use of authorized laboratories

Article 4

The Agency is responsible for the engagement of the authorized laboratories only when it does not have the right equipment and / or trained staff for the implementation of the specific analysis.

Article 5

Specific analysis referred to in the "Article 4 of this Ordinance" include:

- a) analysis of the quality of risky and other specific categories of medicinal products:
 - 1) medicinal product derived from the blood or plasma (albumin, immunoglobulins and clotting factors)
 - 2) immunological medicinal product (serum, vaccines, toxins and allergens)
 - 3) radiopharmaceutical products,
 - 4) medicinal products obtained by biotechnological procedure,
- b) other analyzes that could not be performed in the Control laboratory, and in accordance with "Article 4 of this Ordinance."

TITLE III - The selection procedure of the authorized laboratories

Article 6

(1) Selection of "OMCL 'laboratory is based on the following requirements:

- a) The laboratory should have qualified equipment to meet the requirements, as well as staff who possess the skills and experience necessary for the implementation of the required tests;
- b) The laboratory should be independent in the work, guarantee the security and confidentiality of data on and should not have a conflict of interest;
- c) The laboratory should implement the standard "ISO / IEC 17025" in the context of its activities;
- d) The laboratory should implement a European Pharmacopoeia in its work, as a

mandatory standard for the quality of medicinal products;

e) The laboratory should participate in the programs and studies of interlaboratory comparisons "PTS".

(2) When selecting the authorized laboratories the financial aspects should be taken in the consideration, as well as the time required for the realization.

(3) When selecting authorized laboratories, recommendations from the management of "OMCL 'network should be taken in the consideration.

Article 7

(1) The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina enters into a contract with the selected authorized laboratory in a written form.

(2) The contract may be entered into on a long-term basis or individually for each sample.

(3) The contract should include the following:

a) type of cooperation with the name of the type and number of samples that are being analyzed as well as the required tests (analytical parameters);

b) the obligations of the Agency as the client (sending samples, responsibility for the accuracy and possible damage to the sample, the payment for delivery of samples);

c) information on the confidentiality and security of data on performed analyzes;

d) the method of payment;

e) persons authorized to represent the client and authorized laboratories;

f) the date when the contract entered into force.

(4) Obligations of the authorized laboratory are to:

a) implement quality control in accordance with the method of the manufacturer, the method of the European Pharmacopoeia or the requirements of the World Health Organization;

b) notify the Agency about the potential withdrawal from the methods;

c) provide data on the used referential substances;

- d) issue a report in which test results are unambiguous;
- e) define the date of receipt of the samples;
- f) define a deadline for the completion of analysis (eg. 30 calendar days from the receipt of samples);
- g) keep samples at least 3 months after the completion of the analysis;

TITLE IV - The procedure of the delivery of and transport of samples

Article 8

Samples and documentation required for certain types of control are provided in accordance with the ORDINANCE ON QUALITY CONTROL OF THE MEDICINAL PRODUCT ("Official Gazette", no. 97/09), which entered into force on 01/10/2009.

Article 9

- (1) The applicant is responsible for the proper delivery of samples to a Control laboratory.
- (2) The Agency is responsible for the transport of samples and the necessary documentation to the authorized laboratory.
- (3) Transport of samples and documentation can be done by express post while respecting the conditions of storage.
- (4) The authorized laboratory is obliged to inform the Agency in writing of the receipt of the shipment.
- (5) The authorized laboratory is responsible for the samples after their admission until the issuance of findings on quality control.
- (6) In the case of the analysis of the medicinal products referred to in "Article 5, item a)," Transport in paragraph (1), (2) and
- (3) Should be conducted using a documented print on storage conditions "data logger".

Article 10

- (1) Transportation is contracted with competent legal person that meets the requirements of special transport.
- (2) Legal person who transports should provide storage conditions which correspond to GMP regulations, as well as a quality management system in accordance with the "ISO

9001".

Article 11

Required documentation includes a detailed description of the method of analysis of the manufacturer with exactly defined quality requirements, except in cases when the manufacturer relies on the regulations of the European Pharmacopoeia or other recognized Pharmacopoeia, and the World Health Organization.

TITLE V - Implementation of tests

Article 12

The authorized laboratory is obliged to conduct quality control of the medicinal product in accordance with the documents submitted by the Agency, or according to pharmacopoeia if the manufacturer relies on the regulations of the European Pharmacopoeia or other recognized Pharmacopoeia.

Article 13

Authorized Laboratory commits itself by the contract that it shall carry out quality control in accordance with "Article 12 of this Ordinance."

Article 14

Before beginning of the analysis, the authorized laboratory is obliged to inform the Agency about the potential withdrawal from the methods "referred to in Article 12 of this Ordinance."

Article 15

(1) The authorized laboratory issues the certificate / findings of the inspection to the Agency.

(2) The certificate shall contain: the studied parameters, the quality requirements and methods, as well as test results.

Article 16

The Agency shall issue the conclusive findings of the inspection to the applicant, with a note that the specific testing parameter was conducted in the authorized laboratory, with the number of certificates issued by the authorized laboratory.

Article 17

(1) The Agency may request the original data on the analysis from the authorized laboratory (diagrams, calibration curves, chromatograms).

(2) The Agency may require the reports on the implementation of quality systems in accordance with the "ISO 17025", as well as the implementation of quality systems in the network according to the scheme "MJA / MJV".

TITLE VI - Final provisions

Article 18

This Ordinance shall enter into force on the day of issuance and shall be published in the "Official Gazette of BiH".

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June 8, 2010

Chairman of the Expert Council
Mr. ph. Ivan Prlic, s. r.