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Based on Article 16 and Article 79 paragraph (5) 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 sixth session held on October 1st, 2009, adopted

ORDINANCE
ON QUALITY CONTROL OF THE MEDICINAL PRODUCT

PART ONE

TITLE I-General provisions

Article 1

(Subject of the Ordinance)

This Ordinance shall determine the method of quality control of medicinal products and the content and method of keeping records on the quality control.

Article 2

(Jurisdiction)

(1) Quality control of the medicinal product is conducted by the Division - Control Laboratory of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (hereinafter: Control Laboratory).

(2) Quality control of the medicinal product may also be performed by the laboratory selected or authorized by the Agency in accordance with the Medicinal Products and Medical Devices Act of Bosnia and Herzegovina (hereinafter the Act).

TITLE II Basic control types

Article 3

(Quality control of each batch of produced or imported medicinal product and the substance)

The manufacturer of a medicinal product which is based in Bosnia and Herzegovina, which has a marketing authorization, is obliged to perform quality control of each batch of the medicinal product and the substance, before they are marketed, in the manner as prescribed by the Ordinance on Good Manufacturing Practice for Medicinal Products.

Article 4

(1) The request for quality control of each batch of imported medicinal product, which has a marketing authorization, shall be submitted to the Agency by the wholesale distributor/ importer of the medicinal product.

(2) The Agency shall inform the wholesale distributor/ importer on the quantities of the medicinal product, which are required in order to perform quality control.

(3) The submitted samples shall be accompanied by a certificate of analysis for that particular batch, the reference standards and the corresponding certificate of analysis with traceability to primary standards.

(4) The wholesale distributor / importer of a medicinal product on the market of Bosnia and Herzegovina is responsible for the authenticity of the submitted certificates

(5) The Agency shall perform quality control within 30 days of receipt of the samples. The cost of quality control "referred to in paragraph 1 of this Article" shall be funded by the holder of the marketing authorization, and in the case of an imported medicinal product, wholesalers or importer.

Article 5

(1) The Agency remains the right to require to the extra amount of sample for quality control purposes, and the wholesale distributor / importer is obliged to submit it to the Agency.

(2) The Agency may sample the medicine itself, and the wholesale distributor / importer, which has applied for quality control, is required to enable it to do so.

Article 6

If wholesalers do not provide the Agency with the appropriate certificate of analysis "referred to in Article 3, paragraph 1 of this Ordinance", the Agency shall not conduct the quality control, nor shall it issue a report, and it shall notify the wholesalers that these batches may not be placed on the market.

Article 7

(1) The request for quality control of each batch of the imported medicinal product, which has a marketing authorization, shall be submitted to the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) by the wholesale distributor or importer of the medicinal product.

(2) The application for quality control shall be accompanied by a certificate of analysis of the manufacturer for the mentioned batch with all the prescribed parameters, the reference standards and the corresponding certificate

of analysis with traceability to primary standards, as well as the findings of the Control Laboratory for the first batch of the medicinal product for placing on the market.

(3) The wholesale distributor or importer of the substance shall submit the request for quality control of each imported batch of the active substance to the Agency.

Article 8

(1) The Agency shall verify the quality of the medicinal product according to the analytical procedures accepted in the procedure of issuing the marketing authorization, to the extent determined by the Agency, and it shall issue a report on the conducted quality control.

(2) If the medicinal product has no quality defects, the report shall indicate that the quality of the medicinal product corresponds to the accepted quality requirement, within the shelf life of the medicinal product, in terms of the studied parameters, when the results obtained from the analysis are within the accepted quality limits.

(3) If the obtained result deviates from the accepted quality requirements, the Agency shall send the results to its own and entity inspectors and inspectors of the Brcko District, as well as wholesale distributor, which may not place that batch of the medicinal product on the market.

(4) Quality control of the medicinal product "referred to in Article 4 of this Ordinance" may be conducted by the laboratory authorized or selected by the Agency to perform such control.

(5) In the case when the quality control of the medicinal product "referred to in "paragraph 2 of this Article," is performed by an authorized or recognized laboratory, the manufacturer / importer is required to submit to the Agency a sample and the findings of the inspection prior to placing it on the market.

(6) Authorized laboratory is engaged in activities of specific analysis on condition that it is in the General European OMCL Network, and the name of the laboratory is stated in the report under the "Note".

Article 9

(1) The Agency has the right to conduct the quality control of the other quality parameters, except those which are accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(2) The Agency has the right to conduct the quality control of the other analytical procedures, in addition to those accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(3) The reasons for conducting the verification "referred to in paragraph 1 and paragraph 2 of this Article," The Agency shall specify in the report.

Article 10

(1) Quality control of the medicinal products includes verification of data stated on the outer and immediate packaging.

(2) When data on the outer or immediate packaging are not in accordance "with the Article 71 of the Act" Agency shall send the report to all competent inspectors and wholesale distributor, which may not place that batch of the medicinal product on the market.

(3) The manufacturer of the medicinal product may correct the labeling or enclose the correct instructions and

resubmit the request for the quality control of the same batch.

Article 11

(Quality control of the first batch of the medicinal product)

The first batch of the medicinal product is considered to be the first batch of the medicinal product produced after a first or renewed license for the manufacturer of the medicinal product, which is based in Bosnia and Herzegovina, ie the first batch of the medicinal product manufactured and labeled in accordance with the documents adopted in the process of obtaining a first or renewed license for manufacturer of the medicinal products outside Bosnia and Herzegovina, including the labeling in one of the languages which are officially in use in BiH

Article 12

The holder of the marketing authorization is obliged to submit to the Agency for the quality control samples of each of the first batch of the medicinal products before they are marketed, together with comparative substances and documentation relating to the submitted batch and comparative substances.

Article 13

(1) The application for the quality control of the first batch of the medicinal products shall be submitted to the Agency by the marketing authorization holder, and it may also be submitted by the wholesalers or importer under the authorization of the marketing authorization holder (hereinafter: the applicant).

(2) Sufficient amount of sample for analysis shall be enclosed with the application, with reference standards for the implementation of all analytical procedures on the specification for the shelf life and the respective certificates of the analysis for the mentioned batch and reference standard (with reference to the primary standard), data on all integrated raw materials in the first batch of the medicinal product, following the issuance of the marketing authorization, and other information required by the Agency.

(3) Beside the request for a special quality control of the first batch of the medicinal products derived from the human blood or plasma, and immunological medicinal product, other than a certificate and data "mentioned in paragraph 2 of this Article," applicant is obliged to provide detailed information on the original raw material, production protocols, data on the verification of the quality ("summary protocol"), report of an authorized laboratory of the European Union (OCABR) or country of the manufacturer for the manufacturer outside of Bosnia and Herzegovina, and a sufficient number of samples of the source material.

Article 14

Documentation "from the previous Article" shall be original or certified copy or copies of the documents with the statement of the responsible person of the applicant on the credibility of the data.

Article 15

(1) The Agency shall during the quality control of the first batch, prior to placing it onto the market, verify the accepted parameters of the medicinal product quality, according to the analytical procedures accepted in the procedure of issuing the permit for marketing authorization if there are no technical reasons to deviate from that.

(2) The Agency has the right to conduct the quality control of the other quality parameters, in addition to those

accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(3) The Agency has the right to conduct the quality control of the other analytical procedures, in addition to those accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(4) The reasons for conducting the verification "referred to in paragraph 2 and paragraph 3 of this Article," The Agency shall specify in the report.

Article 16

The Agency shall during the quality control of the first batch verify the data stated on the outer and immediate packaging, which have to be in accordance "with Article 71 of the Act".

Article 17

When data on the outer or immediate packaging are not in accordance "with the Article 71 of the Act" the Agency shall send the report to the applicant, which may not place that batch of the medicinal product on the market.

Article 18

If the manufacturer of a medicinal product is based outside of Bosnia and Herzegovina, and if the data on the immediate packaging of the medicinal product are not in one of the languages which are in official use in BiH, the Agency may issue a report on quality control of the first batch, provided that there is a request for the release of the report on the quality control of the first batch, based on the issued permit for marketing authorization, and that all other requirements for the issuance of that report have been met.

Article 19

(1) The first batch of the medicinal product may be placed on the market only on the basis of the positive report of the Agency.

(2) The report on the quality control of the first batch of the medicinal product is positive when all the prescribed documents have been enclosed and when they contain all the information that are mutually consistent and correspond to the applicable regulations, and the results obtained from the analysis of the medicinal product are within the accepted limits of quality.

Article 20

(Special quality control)

Special quality control includes any series of risky and other specific categories of medicines-medicinal products derived from blood or plasma (especially those containing albumin, immunoglobulin and blood clotting factors), an immunological medicinal product (serum, vaccines, toxins and allergens) and radiopharmaceutical products regardless if they possess a permit for marketing authorization, each batch of medicinal product obtained by biotechnological process, which has a permit for the marketing authorization and other medicinal products that are determined by the Expert Council at the proposal of the Agency.

Article 21

(1) Beside the request for a special quality control of each batch of risky and other specific categories of medicines, the applicant shall submit a sufficient amount of sample for analysis, certificate of analysis for that batch, product documentation of the manufacturer, data on the quality control and report of the authorized laboratory of the European Union or country of the manufacturer for manufacturers outside of Bosnia and Herzegovina, detailed information on the original raw materials, the report on the performed tests, and a sufficient number of samples of the source material.

(2) Documentation "from the previous Article" shall be original or certified copy or copies of the documents with the statement of the responsible person of the applicant on the credibility of the data.

(3) The request for the special quality control of serums and vaccines, in addition to the abovementioned, may be submitted by other institutions such as the Department of Public Health.

Article 22

(1) The Agency is entitled, for the purpose of quality control, to request the additional amount of sample, which the applicant is required to submit to the Agency.

(2) The Agency has the right to sample the medicine itself, and the wholesale distributor / importer, which has applied for quality control, is required to enable it to do so.

Article 23

(1) If the applicant fails to submit the required documentation of the manufacturer, in addition to the submitted sample, the Agency shall not conduct quality control nor shall it issue a report on the quality of the medicinal product.

(2) In the case "referred to in paragraph 1 of this Article," The Agency shall inform the applicant that the batch of the medicinal product may not be placed on the market.

Article 24

The agency is entitled to re-control the quality of the batch of the medicinal products, which already has a report on quality control, in accordance with Article 4 of this Ordinance.

Article 25

(1) The Agency shall verify the quality of the medicinal product according to the analytical procedures accepted in the procedure of issuing the marketing authorization, to the extent determined by the Agency.

(2) The Agency shall issue a report on the conducted quality control.

(3) If the medicinal product has no quality defects, the report shall indicate that the quality of the medicinal product corresponds to the accepted quality requirement, in terms of the studied parameters, when the results obtained from the analysis are within the accepted quality limits.

(4) If the obtained result deviates from the accepted quality requirements, the Agency shall inform the applicant, which may not place that batch of the medicinal product on the market.

Article 26

(1) The Agency has the right to conduct the quality control of the other quality parameters, in addition to those which are accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(2) The Agency has the right to conduct the quality control of the other analytical procedures, in addition to those accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(3) The reasons for conducting the verification "referred to in paragraph 1 and paragraph 2 of this Article," The Agency shall specify in the report.

Article 27

(1) Special quality control of the medicinal products includes verification of data stated on the outer and immediate packaging accepted in the procedure of issuing the permit for marketing authorization.

(2) When data on the outer or immediate packaging are not in accordance with accepted data, the Agency shall send the report to the applicant, which may not place that batch of the medicinal product on the market.

(3) The applicant may correct the labeling or enclose the correct instructions and resubmit the request for the quality control of the same batch.

Article 28

Each batch of an immunological medicinal product and medicinal product derived from human blood or plasma should be placed on the market only on the basis of the positive reports of the Agency on quality control and if it contains a stamp issued by the Agency.

Article 29

The Agency issues the report on special quality control when all the prescribed documents which contain all the necessary data are submitted, which are mutually consistent and correspond to the applicable regulations, and when the results obtained from the analysis of the medicinal product are within the accepted limits of quality.

Article 30

(Regular quality control of medicines that are placed on the market in BiH)

(1) Regular control is a control of all medicinal products that are in circulation in BiH, and it is performed at least once every five years.

(2) It is performed on the basis of the annual plan of regular control of the medicinal products on the market, and it is prepared by a Control Laboratory.

(3) Sampling is conducted by the pharmaceutical inspectorate of the Agency, Inspector submits a sufficient amount of samples for analysis, with a record on sampling.

Article 31

(1) The Agency controls the quality of the medicinal product, according to the analytical procedures accepted in the procedure of issuing the permit for marketing authorization, to the extent determined by the Agency.

(2) The Agency has the right to conduct the quality control of the other quality parameters, in addition to those which are accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(3) The Agency has the right to conduct the quality control of the other analytical procedures, in addition to those accepted in the procedure of issuing the permit for marketing authorization if there are justifiable technical reasons.

(4) The Agency verifies the quality of the galenic preparation according to pharmacopoeial and other internationally accepted standards.

(5) The Agency issues a report on the performed quality control.

(6) If the medicinal product has no quality defects, the report shall indicate that the quality of the medicinal product corresponds to the accepted quality requirement, in terms of the studied parameters, when the results obtained from the analysis are within the accepted (by pharmacopoeia and other internationally recognized standards) quality limits.

(7) If the result obtained deviates from the accepted quality requirements, the Agency shall immediately inform the competent pharmaceutical inspectors, who shall make a ban on marketing of the medicinal product.

(8) The report of the quality control from the circulation is delivered to the pharmaceutical inspection and marketing authorization holder for the medicinal product or a medical institution, or a pharmacy which produced a galenical preparation.

(4) If the obtained result deviates from the accepted quality requirements, the Agency shall immediately inform the competent pharmaceutical inspectors, who shall forbid placing of the medicinal product on the market.

Article 32

(Extraordinary quality control)

(1) Extraordinary control is implemented in order to address the identified problems in the quality of the medicinal products.

(2) In addition to the request for the implementation of extraordinary quality control, it is necessary to state the reason for the request.

Article 33

(1) Extraordinary quality control of the medicinal products is performed at the request of the Agency, during the obtaining a permit for marketing authorization or after its acquisition, to the extent determined by the Agency, according to the analytical procedures accepted in the procedure of issuing a permit for marketing authorization and other analytical procedures, if there are justified professional reasons.

(2) The Agency issues the report on the conducted quality control.

(3) The report shall state the reasons for quality control, the results and opinions on the quality of the medicinal product.

(2) The Agency shall send the report to the competent pharmaceutical inspections and the applicant.

TITLE III-Quality control on other basis

Article 34

Quality control on other basis includes quality control at the request of and by order of the entity and cantonal pharmaceutical inspections, and state, entity and cantonal institutions and institutions of the Brcko District.

Article 35

(1) The applicant shall submit a sufficient amount of sample for testing.

(2) If this control is performed at the request of the inspector, the inspector should, with the sufficient amount of sample for analysis, submit the record of the sampling.

Article 36

(1) The Agency shall verify the quality of the medicinal product according to analytical procedures accepted in the procedure of issuing a permit for marketing authorization, to the extent determined by the Agency.

(2) The Agency verifies the quality of the main or galenic preparation and quality of the substance according to pharmacopoeial and other internationally accepted standards.

Article 37

(1) The Agency shall issue a report about the performed quality control.

(2) If the results obtained from the analysis are within the accepted limits of quality, the report shall indicate that the quality of the medicinal product corresponds, in terms of the studied parameters.

(3) If the obtained result deviates from the accepted quality requirements, the Agency shall immediately inform the competent pharmaceutical inspectors, who shall forbid placing of the investigated batch of medicinal products or substance on the market of Bosnia and Herzegovina.

(4) The report on quality control from the circulation is delivered to the applicant.

PART TWO

TITLE I-The method of implementation of quality control

Article 38

Quality control includes:

- a) submission / receiving of samples for quality control of medicinal products,
- b) receiving of samples and reference materials for quality control of medicinal products,
- c) receipt of documentation related to the submitted samples and reference materials,
- d) testing of compliance of primary and secondary packaging with the documentation accepted in the licensing procedure,
- e) analytical testing and expert evaluation of the submitted documents,
- f) the issuance of the report.

Article 39

(1) Places of sampling for quality control of the medicinal products are:

- a) the manufacturer, its storage of medicinal products and means of transport, after the person responsible of the manufacturer put the medicinal product on the market;
- b) legal persons that are wholesalers which trade in medicinal products and their storage and transportation equipment;
- c) pharmacies.

(2) Sampling is carried out in accordance with the principle of random selection of samples, in a manner that provided a representative sample, according to the defined procedure for sampling.

(3) The number of samples is determined on the basis of documentation for obtaining a permit for marketing authorization.

Article 40

(1) A person who takes samples should maintain the record during their taking, in accordance with the procedure for sampling and should issue a certificate of taken samples to a legal or natural person.

(2) A certificate of taken samples shall contain data for the sampling procedure, quantity of the medicinal product, the date of taking, environmental conditions, the signature of the persons who conducted the sampling and signature of the persons where the sampling was performed.

Article 41

(1) The Agency shall issue a report on quality control, which consists of the administrative section and the section for entering the test results.

(2) The administrative section contains the following information:

- a) Title of the document (eg. "Findings", "Testing Report"),
- b) Name and address of the laboratory, and the locations where the tests were conducted, if they differ from the address of the laboratory,

- c) Unique identification of test reports and identification of each side which will ensure the recognition that it is the part of the test report, and a clear identification of the end of the test report PK number,
- d) Name and address of the holder of the marketing authorization,
- e) The legal or natural person, who sent the samples for the verification, or from which the samples were taken,
- f) The purpose of the test,
- g) The name of the medicinal product, pharmaceutical form, strength and packaging,
- h) International nonproprietary name
- i) The declared composition of the medicinal product,
- j) The series and the name of the manufacturer,
- k) Shelf life,
- l) The date of receipt of the sample,
- m) Date of creating the report,
- n) Date of issuing the report.

(3) Section for entering the test results contains:

- a) The results of the verification of labeling of the immediate and outer packaging, instructions and data regarding the additional equipment for use of the medicinal product,
- b) The results of the analytical tests (test parameters, the methods used, quality requirements, and results)
- c) The name and surname, position and signature of the person authorized to report on quality control,
- d) Note- refers to laboratory, with which the analysis is subcontracted and the reasons for the use of other analytical procedures,
- e) Comment on the medicinal product -relating to the labeling of the outer and immediate packaging,
- f) Remark - refers to the non-compliance of packaging. The existence of remark indicates the fact that deficiencies do not endanger the health of the patient, but should be removed,
- g) The conclusion in the part of laboratory testing

Article 42

Report on quality control of the medicinal product the Agency shall issue in sufficient number of copies for all parties.

Article 43

During the quality control of the medicinal product, the procedures stated in the documentation on the medicinal product accepted in the procedure of issuing the marketing authorization are applied, and for medicinal product that is not approved for marketing authorization, and the Agency decided that the quality control of the medicinal product is required, the procedures are adopted by the Agency.

Article 44

(1) The manufacturer of the medicinal product, wholesalers and each importer of the medicinal product on the regular, extraordinary, special, quality control of each batch and the first batch of the medicinal product are required to keep records.

(2) The Agency shall keep a record of each performed control quality.

(3) The records "referred to in paragraph 1 and 2 of this Article" shall be kept a year longer than the shelf life of the medicinal product to which they relate and should be kept in a safe place and have the status of confidential document.

(4) If the records are in an electronic medium, there should be defined procedure for the protection of electronic records and their backups, which would prevent unauthorized access, or their amendments.

TITLE II-Final Provisions

Article 10

The grammatical terminology of using masculine gender in this Ordinance implies the inclusion of both genders.

Article 11

(1) Amendments to this Ordinance shall be made in a manner of and according to the procedure for its adoption.

(2) This Ordinance shall constitute annexes 1,2 and 3 which are the appropriate application forms.

Article 12

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

No 01-07-2877-1 / 09

Chairman of
the Expert Council of the Agency:
Mr ph. Ivan Prlic

Date: 17.11.2009.

Annex 1

Applicant:

Name and address: _____

Phone / fax:

Contact person:

Date:

Name and address of manufacturer of the active substance / holder of the marketing authorization:

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Control Laboratory of the Agency

Sarajevo, Marsala Tita 9,

Tel: 033 279 352, 279 350, Fax: 033 211 279

REQUEST

for conducting quality control of each batch of the active substance imported into Bosnia and Herzegovina

Name of the active Substance	Manufacturer	Size and type of packaging	Batch number	Expiry date	Quantity of substance which is imported	Quantity of substance for analysis	Number of approval for the import of substance

The quality control of the following batches of the active substance should be done:

Along the completed application, it is necessary to submit:

The manufacturer`s certificate of analysis for the active substance of the imported batch

Form IIb is an integral part of the quality system document SOP OKL 4/05

Annex 2

Applicant:

Name and address: _____

Phone / fax:

Contact person:

Date:

Name and address of the manufacturer of the active substance / holder of the marketing authorization:

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Control Laboratory of the Agency

Sarajevo, Marsala Tita 9,

Tel: 033 279 352, 279 350, Fax: 033 211 279

REQUEST

for conducting quality control of each batch of the risky and other specific categories of the medicinal products (special control) in Bosnia and Herzegovina

The quality control of the following batches of the medicinal product should be done:	Name of the medicinal product	INN	Pharmaceutical form, strength, size and type of packaging	Batch number	Expiry date	Quantity of a medicinal product which is imported	OCABR certificate number

Number of license for the import of risky medicinal products

Along the completed application, it is necessary to submit:

The manufacturer`s certificate of analysis for the medicinal product of the specified batch

Summary protocol- summary protocol for the batch (Data on the original raw material, product documentation of the manufacturer, data on the quality control)

Report of an authorized laboratory for the specified batch (OCABR for the European Union or equivalent certificate for countries outside the European Union)

The amount of medicine for the analysis / number of samples is determined by the Control Laboratory of the Agency

Form Ic is an integral part of the quality system document SOP R 4/01

Annex 3

Applicant:

Name and address: _____

Phone / fax:

Contact person:

Date:

Name and address of the manufacturer of the active substance / holder of the marketing authorization:

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Control Laboratory of the Agency

Sarajevo, Marsala Tita 9,

Tel: 033 279 352, 279 350, Fax: 033 211 279

REQUEST

for conducting quality control of each batch of the medicinal product imported into Bosnia and Herzegovina

Name of the medicinal product	INN	Pharmaceutical form, strength, size and type of packaging	Batch number	Expiry date	Quantity of a medicinal product which is imported	For analysis

The quality control of the following batches of the imported medicinal products should be done:

Number of license for the import of the medicinal product

Along the completed application, it is necessary to submit:

The manufacturer`s certificate of analysis for the medicinal product of the imported batch

The certificate of analysis for the reference standard

Control Laboratory`s report for the first batch

The amount of medicine for the analysis / number of samples is determined by the Control Laboratory of the Agency

Form IIa is an integral part of the quality system document SOP OKL 4/05