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), 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 THE METHODS OF MONITORING OF QUALITY DEFECTS IN MEDICINAL PRODUCT

Article 1

Health workers who come in contact with a medicinal product or medicinal product user, as well as legal and natural persons that produce or distribute the medicinal product, are required to notify the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina in writing about any observed or any established quality defect in a medicinal product (hereinafter: Agency).

Article 2

(1) Health worker, who noticed the quality defect in a medicinal product, before the medicinal product was issued to a user, or after receiving the warning from the user, is obliged to notify the Agency in writing about the noticed defect by filing out the application form, which is given in Annex 1 of this Ordinance and it forms its integral part.

(2) In the application form "mentioned in paragraph (1) of this Article," the health worker should state the name of the medicinal product, the name of the manufacturer / authorization holder, batch number, type and size of packaging, expiry date of the medicinal product, a brief description of the observed quality defect in a medicinal product, name, surname and telephone number of the applicant, and the institution where the applicant works.

(3) According to his or her own assessment, the health worker may specify one of the listed degrees of urgency of the application.

(4) The health worker "mentioned in paragraph (1) of this Article" shall ensure that the same medicinal product (the medicinal product from the same individual packaging, and in the case of suspected quality defect of the whole batch, the medicinal product of the same batch number) is no longer used, and shall keep it for the purposes of pharmaceutical inspection.

(5) The health worker is obliged to submit a completed application form "mentioned in paragraph (2) of this Article" to the Agency within 24 hours from the moment when the quality defect in a medicinal product was noticed.

Article 3

In the case mentioned "in Article 2 paragraph (1) of this Ordinance," the health worker shall not issue the sample of the medicinal product in which the quality defect was noticed, but the health worker shall preserve it for pharmaceutical inspection.

Article 4

(1) The health worker who noticed or suspected the quality defect in a medicinal product during its administration to a patient in a medical institution, is obliged to notify the Agency in writing about the noticed defect or suspicion of the quality.

(2) In the application form "mentioned in Article 2 paragraph (1) of this Ordinance," the health worker shall specify: medicinal product name, manufacturer's name / authorization holder, batch number, type and size of packaging, expiry date of the medicinal product, a brief description of the observed quality defect in a medicinal product or justification for the suspicion of the quality of a medicinal product, patient initials, name, surname and phone number of the applicant, and the institution in which the medicinal product was administered.

(3) According to his or her own assessment, the health worker may specify one of the listed degrees of urgency of the application.

(4) The health worker "mentioned in paragraph (1) of this Article" shall ensure that the same medicinal product (the medicinal product from the same individual packaging, and in the case of suspected defect of the whole batch, the medicinal product of the same batch number) is no longer used, and shall keep it for the purposes of pharmaceutical inspection.

(5) The health worker is obliged to submit a completed application form "mentioned in paragraph (2) of this Article" to the Agency within 12 hours from the moment when the quality defect in a medicinal product was noticed.

Article 5

(1) Marketing authorization holders, manufacturers of medicinal products, importers and wholesalers involved in the production or the wholesale distribution of medicinal products are obliged to inform the Agency in writing about any observed quality defect in a medicinal product, which may result in withdrawal of the medicinal product from the market or restrictions on the use of that medicinal product, that are not listed in the approved summary of medicinal product characteristics and the approved instructions.

(2) Legal entities "referred to in paragraph (1) of this Article" are obliged to submit to the Agency a written notice on a quality defect in a medicinal product within:

a) 12 hours after the identification of a defect, if the defect corresponds to Class I "mentioned in Article 9 of this Ordinance";

b) 24 hours after the identification of a defect, if the defect corresponds to Class II "mentioned in Article 9 of this Ordinance."

(3) If a defect corresponds to class III "mentioned in Article 9 of this Ordinance," legal entities are not obliged to send written notice to the Agency, if the defect does not lead to the withdrawal of the medicinal product.

(4) Legal entities "mentioned in paragraph (1) of this Article" are obliged to implement all the other measures related to the withdrawal of a medicinal product from the market that are prescribed by

the Ordinance on good manufacturing practice and good practice in wholesale distribution of medicinal products and their standard operating procedures.

(5) Legal entities should submit the reports on the implemented measures for the cases "referred to in paragraphs (1), (2) and (3) of this Article" to the Agency within 14 days after taking the measures.

Article 6

(1) The Agency shall appoint a person responsible for monitoring the quality defect in a medicinal product that shall be available to health workers 24 hours a day.

(2) A person responsible "mentioned in paragraph (1) of this Article" is obliged to forward the completed form on the noticed quality defect in a medicinal product "mentioned in Article 2 paragraph (3) and Article 4 paragraph (4) of this Ordinance" to the manufacturer / authorization holder within 24 hours after receiving the written application.

(3) The completed form, which is forwarded to the manufacturer /authorization holder, should not contain information about the applicant of the quality defect in a medicinal product.

Article 7

(1) When the Agency, after processing the received written reports and / or notifications from the legal or natural person about a quality defect or suspected quality defect in a medicinal product, establishes that the reported defect belongs to class I, and that it is urgent to withdraw one or more batches of a medicinal product from the market, which has a marketing authorization, the Agency shall take immediate inspection measures within its jurisdiction and notify in writing entities` retail pharmaceutical inspections and competent authority inspection of Brcko District.
(2) In the case "referred to in paragraph 1 of this Article," pharmaceutical inspector of the Agency shall prohibit a legal entity "mentioned in Article 5 paragraph (1) of this Ordinance" to deliver medicinal products, shall order withdrawal of certain batches of a medicinal product from the market, and shall send the written notice about the taken measures to the Director of the Agency, entities` Ministries of health and the Department of Health of Brcko District.
(3) If the Agency in the case "referred to in paragraph (1) of this Article" determines that it is necessary, in order to protect the health of the population, to inform the population about the determined quality defect in a medicinal product, it shall submit the proposal of the notice for the population to the Ministry of Civil Affairs of Bosnia and Herzegovina, entities` Ministries of health and the Department of Health of Brcko District.
(4) The Agency is obliged to submit the proposal "mentioned in paragraph (3) of this article," within 8 hours since making a decision on withdrawal, along with the request that the information is publicly announced.

Article 8

(1) When the Agency determines, based on the reported suspicion of the quality of medicinal product, that it is necessary to carry out verification of the quality of a sample of medicinal product, it shall order the extraordinary quality check and take inspection measures within its jurisdiction, and it shall notify entities` retail pharmaceutical inspections and competent authority inspection of Brcko District.
(2) When it comes to the samples of medicinal product submitted by pharmaceutical inspectors, the Agency shall act in accordance with the Ordinance on the method of quality control.

Article 9

Reports on the quality defect in a medicinal product or suspicion of the quality are classified according to the degree of urgency, as it follows:

a) Class I includes reports on defects that are life-threatening or have serious health consequences, such as: wrong medicinal product (labeling and composition / ingredients of the medicinal product do not refer to the same medicinal product), wrong strength of medicinal product that can cause serious medical consequences, microbiological contamination in the "sterile" injections / infusions or preparations for the eyes, chemical pollution that may cause serious medical consequences, wrong active substance in medicinal product with more ingredients that may cause serious health consequences.

b) Class II includes reports on defects that can cause diseases or wrong treatment and they do not belong to the class I, for example, wrong labeling (incorrect or omitted text or data), the lack of instruction or the wrong instruction, microbiological contamination in sterile medicinal products which are not for use as injection / infusion or preparations for the eyes with possible medical consequences, chemical or physical contamination (higher levels of pollution, pollution by other medicinal products), inadequate quality of a medicinal product (content, stability or charge / mass in packaging for single dosage that do not correspond to the demands), unsafe closing of a medicinal product with serious health consequences (cytotoxic medicinal products, medicinal products with safety closures, medicinal products with strong effects);

c) Class III includes reports on defects that may not cause serious health consequences, but the medicinal product can be withdrawn from the market for other reasons (eg, lack or wrong indication of the serial / control number or expiration date, faulty closure, microbiological or mechanical contamination).

Article 10

The grammatical terminology of the use of male gender throughout this Ordinance implies the inclusion of both genders.

Article 11

Amendments to this Ordinance shall be conducted in a manner of and according to the procedure for its adoption.

Article 12

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

No 01-07-2878-1 / 09

Date: November 17th, 2009

Chairman of

The Expert Council of the Agency

Mr ph. Ivan Prlic

(Entered into force on October 1st, 2009)

Annex 1

APPLICATION FORM FOR REPORTING QUALITY DEFECTS IN MEDICINAL PRODUCT

Phone number of the person responsible for monitoring quality defects in medicinal products appointed by the Agency (In the period from 08 am till 4 pm):	+387 XX XXX XXX
Mobile phone number of the responsible person (Only in the period from 4 pm till 8 pm):	+387 XX XXX XXX
Fax:	+387 XX XXX XXX

Fills out the medical institution / other legal and natural person	Fills out the Agency for Medicinal Products and Medical Devices
	Date and time of receipt of the application:
THE REPORT OF DEFECT IS: VERY URGENT URGENT NO INDICATION OF URGENCY	CLASSIFICATION OF URGENCY: Class I, Class II, Class
Name of the medicinal product:	
Form of the medicinal product:	
Strength of the medicinal product:	
Type and size of packaging:	
Batch number:	

<table>
<tr><td colspan="2">Expiration date:</td></tr>
<tr><td colspan="2">Manufacturer / Authorization holder</td></tr>
<tr><td>Description of the defect:</td><td rowspan="3">Description of the defect:</td></tr>
<tr><td>Person / Health worker who reports the defect:

Name, surname and signature:

Phone number:

Company / institution (and address):</td></tr>
<tr><td>Date and time of the noticed defect:</td></tr>
<tr><td>The number of available samples of the defective medicinal product:</td><td>Delivered samples of medicinal product:
YES / NO
Number of samples:
Delivered by:</td></tr>
<tr><td>Undertaken measures regarding the user / patient`s initials</td><td></td></tr>
<tr><td>Date and time of the report:</td><td>Date and time of the processing:</td></tr>
</table>

	Name and surname, signature of the person responsible in the Agency: