EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No 91** Astana city

on the Adoption of the Procedure for Performing of Joint Pharmaceutical Inspections

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 10(1) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 100 of Appendix No 1 to the Regulations of the Eurasian Economic Commission as approved by Decision No. 98 of the Supreme Eurasian Economic Council of 23 December 2014, and by Decision No. 108 of the Supreme Eurasian Economic Council of 23 December 2014 on the Implementation of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union, the Council of the Eurasian Economic Commission has decided:

1. To adopt the attached Procedure for Performing of Joint Pharmaceutical Inspections.

2. This Decision shall enter into force on the 10th day following that of entry into force of the Protocol of 2 December 2015 on the Accession of the Republic of Armenia to the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, but not earlier than on the 10th day following that the official publication of this Decision.

Members of the Board of the Eurasian Economic Commission:

From the Republic of Armenia	From the Republic of Belarus	From the Republic of Kazakhstan	From the Republic of Kyrgyzstan	From the Russian Federation
V. Gabrielyan	**V. Matyuschevsky**	**A. Mamin**	**O. Pankratov**	**I. Shuvalov**

ADOPTED
by Decision No. 91 of the Council of
the Eurasian Economic Commission
of 3 November 2016

the P R O C E D U R E
for Performing of Joint Pharmaceutical Inspections

I. GENERAL PROVISIONS

1. This Procedure has been developed to implement Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014 and Article 10(1) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014 and paragraph 100 of Appendix No 1 to the Regulations of the Eurasian Economic Commission as approved by Decision No. 98 of the Supreme Eurasian Economic Council of 23 December 2014 and lays down the rules of performing of joint pharmaceutical inspections by the pharmaceutical inspectorates of the Eurasian Economic Union Member States (hereinafter referred to as the Union, Member States) to verify compliance with Good Pharmaceutical Practices within the Union.

II. JOINT PHARMACEUTICAL INSPECTIONS CAN BE EITHER SCHEDULED OR UNSCHEDULED

Scheduled joint pharmaceutical inspections may be performed by pharmaceutical inspectorates of the Member States as part of promoting cooperation and exchange of experience.

Unscheduled joint pharmaceutical inspections (hereinafter unscheduled inspections) may be performed by pharmaceutical inspectorates of the Member States for dispute resolution purposes or mutual recognition of inspections of manufacturing, non-clinical or clinical tests/studies, pharmacovigilance or distribution systems for compliance with the Union rules of good pharmaceutical practices by the Member States.

3. Manufacturers of active substances, bulk or finished products, non-clinical or clinical test/study sites and wholesale distributors of medicinal products (hereinafter referred to as inspected parties) shall be subject to unscheduled inspections.

4. A joint pharmaceutical inspection shall be performed and an inspection report shall be drawn up in accordance with the Rules for performing pharmaceutical inspections subject to approval by the Eurasian Economic Commission and with legislation of the Member State whose competent authority has initiated such an inspection.

5. Scheduled and unscheduled inspections, including payment of the inspection costs (including travel and other costs), shall be ensured as laid down in legislation of the Member States.

The costs related to an unscheduled inspection may be covered at the expense of an inspected party only as related to the pharmaceutical inspectorate of the Member State whose competent authority has initiated such an inspection.

II. Arrangement of an unscheduled inspection

6. An unscheduled inspection shall be conducted based on the recommendation of the Expert Committee on Medicinal Products (hereinafter referred to as the Expert Committee) adopted based on the results of review of the application from the Member State’s pharmaceutical competent authority or of the inspected party, for dispute resolution purposes.

7. The pharmaceutical inspectorate that initiated an unscheduled inspection shall assemble an inspection group and assign the lead inspector within 10 business days taking into account proposals of other pharmaceutical inspectorates involved in the unscheduled inspection.

The lead inspector shall assign functions to inspection group members, coordinate pre-inspection measures, and, in coordination with other pharmaceutical inspectorates, recruit assessors, as necessary.

Before inclusion into the inspection group, the assessors involved shall sign a confidentiality agreement related to information they will get access to during the unscheduled inspection.

Details on the date of the unscheduled inspection and contact information of inspection group members shall be forwarded to the Expert Committee.

8. When preparing the unscheduled inspection, the lead inspector shall:

a) determine the date of inspection together with the inspected party at least 40 calendar days before the date the unscheduled inspection commences and inform that party on the inspection costs, as applicable;

b) send the information on the agreed inspection date to the pharmaceutical inspectorates involved in the unscheduled inspection;

c) send a notification on the unscheduled inspection using the template provided in the Appendix to the pharmaceutical competent authority of the Member State where the inspected party is located;

d) request from the inspected party to provide copies of documents needed for confirmation of the inspected party's compliance with the Union rules of good pharmaceutical practices;

e) develop the program of the unscheduled inspection and prepare check lists;

f) forward the program of the unscheduled inspection to the inspected party.

9. A lead inspector and members of the inspection group shall preliminarily examine the documents and other information related to the inspected activities and the inspected party within 30 calendar days after their receipt.

10. If necessary, consultations of inspection group members with the inspected party may take place, including in the form of a face-to-face meeting or videoconference.

III. UNSCHEDULED INSPECTION RESULTS

11. Upon completion of an unscheduled inspection, the lead inspector shall send an inspection report to the competent authorities of the Member States, inspected party, and Expert Committee within the established period, but in 30 calendar days at the latest.

12. Having reviewed the inspection report, the Expert Committee, within the established period, shall prepare recommendations for dispute resolution and send it to the Member State's competent authorities that involved in mutual recognition of the results of inspections of manufacturing, non-clinical or clinical tests/studies of medicinal products and pharmacovigilance systems for compliance with the Union rules of good pharmaceutical practices and/or the Rules for granting a marketing authorisation and assessment of medicinal products for human use subject to approval by the Eurasian Economic Commission.

A copy of this recommendation shall be sent to the inspected party.

APPENDIX
to the Procedure for Performing
of Joint Pharmaceutical Inspections

(template)

NOTIFICATION
on a joint pharmaceutical inspection by pharmaceutical inspectorates of the Eurasian Economic Union Member States

No.	Inspected pharmaceutical party	Reasons for inspection	Inspection site	Planned inspection date	Pharmaceutical inspectorate		Full name of the appointed inspector
					initiated inspection	involved in inspection	
1	2	3	4	5	6	7	8