EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No 82** Astana city

on the Adoption of the Common Quality System Requirements for Pharmaceutical Inspectorates of the Eurasian Economic Union Member States

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 10 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 95 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 the Common Quality System Requirements for Pharmaceutical Inspectorates of the Eurasian Economic Union Member States.

2. By 1 July 2016, the competent authorities/organisations of the Eurasian Economic Union Member States shall ensure bringing the quality systems of the Pharmaceutical Inspectorates in the Eurasian Economic Union Member States into compliance with the Common Requirements as approved by this Decision and notify the Eurasian Economic Commission thereof.

3. 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 the Decision of Council of
the Eurasian Economic Commission No. 82
of 3 November 2016

THE COMMON QUALITY SYSTEM REQUIREMENTS for Pharmaceutical Inspectorates of the Eurasian Economic Union Member States

I. General provisions

1. This Common Requirements lay down a single approach to development and implementation of a Quality System in carrying out pharmaceutical inspection by Pharmaceutical Inspectorates by the Eurasian Economic Union Member States (hereinafter referred to as the Union, Member States, respectively).

These Common Requirements define the quality policy of the Pharmaceutical Inspectorates and the procedures for planning, managing, and carrying out pharmaceutical inspections.

2. For the purposes of these Common Requirements, the following terms shall bear the following meaning:

'Pharmaceutical Inspectorate Quality Policy' means assistance to the public health protection by carrying out pharmaceutical inspections of the entities involved in the medicinal product circulation and by means of efficient and rational functioning of the Pharmaceutical Inspectorates in accordance with the legal acts constituting pharmaceutical law of the Union and the applicable legislation of the Member States, as well as by implementing the Pharmaceutical Inspectorates quality system in accordance with a quality manual of the Pharmaceutical Inspectorate.

'Quality system' means the sum of all that is necessary to implement an organisation's quality policy and meet quality objectives (such as organisation structure, responsibilities, procedures, systems, processes and resources) and addressed in different kinds of documents as the quality manual and written documented procedures.

'Pharmaceutical Inspection' means a review of entities involved in medicinal product circulation including healthcare facilities in view of verification of pharmaceutical manufacturing and other activities for compliance with legal acts constituting the law of the Union.

'Pharmaceutical Inspector' means a person authorised to carry out pharmaceutical inspections and named in the Register of Pharmaceutical Inspectors of the Union.

'Pharmaceutical Inspectorate' means a department of the pharmaceutical competent authority/competent organisation of a Member State which carries out pharmaceutical inspections.

3. Pharmaceutical inspections shall be carried out by pharmaceutical inspectors in accordance with the legal acts constituting pharmaceutical law of the Union and applicable legislation of the Member States.

4. The primary purpose of a Pharmaceutical Inspectorate quality system is to ensure harmonisation, high level of pharmaceutical inspections, and mutual recognition of the pharmaceutical inspections results.

5. These Common Requirements are intended for use by Pharmaceutical Inspectorates as a basis for developing their own Pharmaceutical Inspectorate quality system.

6. These Common Requirements have been developed taking into account (PIC/S) PI 002-3 'Recommendation on Quality System Requirements for Pharmaceutical Inspectorates' and ISO 19011-2013 'Guidelines for quality and/or environmental management systems auditing'.

II. Quality Manual

7. The Pharmaceutical Inspectorate should prepare and maintain a quality manual covering the elements described in these Common Requirements. The quality manual must include, or make reference to, the quality system procedures which define the activities of the Inspectorate and the arrangements for maintaining the quality system.

8. The Pharmaceutical Inspectorate quality manual shall be subject to approval by the Director of the Pharmaceutical Inspectorate.

9. The Pharmaceutical Inspectorate quality manual shall establish the Pharmaceutical Inspectorate quality system requirements and procedures for its personnel and involved experts and shall be used to:

a) Demonstrate the Pharmaceutical Inspectorate personnel has sufficient qualification, knowledge, and experience allowing them to meet the requirements as laid down in legal acts constituting law of the Union and legislation of Member States.

b) to determine conditions where the need arises in carrying out internal and external audits of the Pharmaceutical Inspectorate quality systems.

10. The Pharmaceutical Inspectorate quality manual shall be made available to the competent authorities/competent organisations of the Member States and, where the Director of a Pharmaceutical Inspectorate decides so, other stakeholders to demonstrate that the Pharmaceutical Inspectorate has implemented the Pharmaceutical Inspectorate quality system.

III. Administrative Structure of the Pharmaceutical Inspectorate

11. The structure, membership and operation of the Pharmaceutical Inspectorate should be such as to enable it to meet the objectives of quality management and to ensure that impartiality is safeguarded.

The responsibility and authority of the Pharmaceutical Inspectorate should be clearly defined in job descriptions.

12. The pharmaceutical inspectors shall be free from any commercial, financial and other interests.

The Pharmaceutical Inspectorate should ensure that any person cannot influence the result of inspections.

Remuneration of pharmaceutical inspectors shall not depend on the results of pharmaceutical inspections, including where a decision is made to revoke/suspend pharmaceutical manufacturers' certificates of compliance with the Rules of Good Manufacturing Practice of the Union subject to approval by the Eurasian Economic Commission, and manufacturing authorisations of undertakings involved in medicinal product circulation.

Pharmaceutical inspectors document that they refuse to carry out any other paid activities, except for pharmaceutical inspections, which may influence their judgment and freedom of actions while performing their official duties.

Pharmaceutical inspectors shall immediately inform the Pharmaceutical Inspectorate Director of any attempts to undermine the independence of their judgments and actions.

13. The Pharmaceutical Inspectorate quality system shall establish the procedure of communication between the Pharmaceutical Inspectorate and other departments of the competent authority/competent organisation of the Member State and other organisations, including accredited pharmaceutical quality control laboratories, and official authorities of the Member State issuing manufacturing authorisations and supervising medicinal product circulation.

14. The Pharmaceutical Inspectorate quality system shall envisage a written standard operation procedure on communication between the Pharmaceutical Inspectorate of one Member

State and Pharmaceutical Inspectorates of other Member States to ensure information exchange and managing for joint pharmaceutical inspections in accordance with legal acts constituting the law of the Union, and shall determine the list of persons responsible for such communication.

15. A Pharmaceutical Inspectorate shall not provide advisory service to individuals or undertakings to be inspected. The Pharmaceutical Inspectorate staff may take part in open workshops, conferences, or meetings, deliver speeches, and publish the papers in scientific literature.

IV. Organisation and Management of Pharmaceutical Inspectorate Activities

16. The Pharmaceutical Inspectorate quality system shall be established for:

a) scheduling of pharmaceutical inspections, including duration and frequency thereof in accordance with the results of risk analyses and legal acts constituting pharmaceutical law of the Union and the applicable legislation of the Member States in the area of regulation and supervision.

b) carrying out pharmaceutical inspections in accordance with legal acts constituting law of the Union and the applicable pharmaceutical legislation of the Member States, as well as the Pharmaceutical Inspectorate quality system procedures;

c) ensuring accurate and balanced pharmaceutical inspections findings and results, as well as recommendations and future follow-up actions set out in the inspection reports;

d) ensuring carrying out pharmaceutical inspections in accordance with legal acts constituting law of the Union and legislation of the Member States and written procedures of the Pharmaceutical Inspectorate adopted as a written document.

17. The Pharmaceutical Inspectorate shall establish and implement the Pharmaceutical Inspectorate policy and the organisation chart showing subordination to the competent authority/organisation of the Member State and relationships with the departments of the competent authority/organisation of the Member State.

18. The Pharmaceutical Inspectorate senior management shall consist of a Director and deputy directors.

19. In accordance with the Pharmaceutical Inspectorate quality system, the Director shall be responsible for:

a) guiding Pharmaceutical Inspectorate quality policy.

b) assigning obligations and authorities among the Pharmaceutical Inspectorate stuff.

c) allocating resources necessary to implement Pharmaceutical Inspectorate quality policy.

20. The Director of the Pharmaceutical Inspectorate shall revies reports on the functioning of the Pharmaceutical Inspectorate quality system.

21. The heads of units of the Pharmaceutical Inspectorate bear responsibility for:

a) drawing up plans of pharmaceutical inspections and ensuring their implementation;

b) ensuring that pharmaceutical inspectors follow Pharmaceutical Inspectorate quality system written procedures;

c) enforcing that pharmaceutical inspectors adhere to Pharmaceutical Inspectorate written procedures;

d) taking appropriate measures where irregularities in Pharmaceutical Inspectorate processes are found;

e) drawing up an annual report on implementation of the quality system in the Pharmaceutical Inspectorate departments.

22. The Pharmaceutical Inspectorate personnel shall be responsible for carrying out their duties, adhering requirements of the Pharmaceutical Inspectorate quality manual and written procedures.

23. The Director of the Pharmaceutical Inspectorate shall appoint a person responsible for maintaining the Pharmaceutical Inspectorate quality system.

The person responsible for maintaining the Pharmaceutical Inspectorate quality system shall be a member of the Pharmaceutical Inspectorate senior management and directly subordinated to the Director of the Pharmaceutical Inspectorate and has direct communication channels with the Director of the Pharmaceutical Inspectorate on issues related to the Pharmaceutical Inspectorate quality system.

V. Pharmaceutical Inspectorate quality system performance review

24. A report on the Pharmaceutical Inspectorate quality system performance in the previous year shall be drawn up.

25. The report on the Pharmaceutical Inspectorate quality system performance shall include the following information:

a) pharmaceutical inspections carried out, including the detected number of cases of non-compliance of pharmaceutical undertakings using the main categories (i.e. critical, major, other).

b) the number of pharmaceutical inspections by each pharmaceutical inspector, including external experts, and the number of issues detected by each.

c) the number of joint pharmaceutical inspections carried out in co-operation with pharmaceutical inspectorates of other Member States, including the inspection results.

d) revoked certificates, authorisations/licences.

e) data on complaints, appeals, and petitions, including internal.

f) cases and attempts of external influence on the Pharmaceutical Inspectorate personnel, including external experts.

g) internal and external audits results.

i) corrective actions and preventive actions taken by the Pharmaceutical Inspectorate, including measures taken based on previous review by the management.

k) changes to the Pharmaceutical Inspectorate quality system.

l) personnel training, including external experts.

26. The information provided in paragraph 25 of these Common Requirements shall be presented in comparison with the information for previous years graphically, to assess trends.

In the final part of the report on the Pharmaceutical Inspectorate quality system performance, the Pharmaceutical Inspectorate quality system performance results over the past year shall be compared with the objectives and quality indicators referred to in subsection 1 of Section IX of these Common Requirements. Based on the report on the Pharmaceutical Inspectorate quality system performance, the assessment of the objectives achieved and quality indicators and corrective and preventive actions (CAPA) or changes in the Pharmaceutical Inspectorate quality system shall be included in the report and signed by the Pharmaceutical Inspectorate senior management.

27. Based on the report submitted, the top management shall review the Pharmaceutical Inspectorate quality system performance, assess its efficiency and the implementation of the Pharmaceutical Inspectorate quality policy. Based on the review, the quality indicators shall be updated and the corrective and preventive actions (CAPA) or measures to improve the Pharmaceutical Inspectorate quality system and quality policy shall be established.

28. The report on the Pharmaceutical Inspectorate quality system performance and the performance review shall be retained by the Pharmaceutical Inspectorate for five years.

VI. Pharmaceutical Inspectorate Documentation

The Pharmaceutical Inspectorate shall establish and maintain a system for the control of all documentation relating to the Pharmaceutical Inspectorate quality system. Pharmaceutical Inspectorate quality system documentation shall include:

a) a written Pharmaceutical Inspectorate quality policy.

b) a Pharmaceutical Inspectorate quality manual.

c) written Standard Operation Procedures.

d) texts of legal acts constituting law of the Union and the applicable pharmaceutical legislation of the Member States related to Pharmaceutical Inspectorate performance and its quality.

30. The Pharmaceutical Inspectorate document control system shall ensure that documents referred to in paragraph 29 of these Common Requirements are authorised by appropriate persons prior to issue and that only current versions are used by personnel.

A record of all relevant documents and document holders should be maintained in the Pharmaceutical Inspectorate. The document control system should ensure that superseded documents are withdrawn from use. Superseded documents should be retained for an appropriate and defined period.

31. The documentation system should ensure that any changes to documents are made in a controlled manner and are properly authorised. There should be a means of identifying changes in individual documents.

Management of administrative documentation shall be in accordance with a document management procedure established in the Pharmaceutical Inspectorate.

32. The Pharmaceutical Inspectorate should establish and maintain a system of records (a type of documents hereinafter referred to as records) and reports complying with legal acts constituting law of the Union and legislation of the Member States.

33. Records shall provide detailed information on scheduling of inspections, the way in which each inspection is to be conducted, a description of the inspection process.

Pharmaceutical inspections reports shall include observations, results, recommendations follow-up and activities.

34. The mandatory records and reports of the Pharmaceutical Inspectorate include following:

a) pharmaceutical inspections plans.

b) applications for pharmaceutical inspections, including appendices.

c) pharmaceutical inspections programmes.

d) working notes of the pharmaceutical inspectors.

e) pharmaceutical inspections reports.

f) internal audit reports.

g) plans and reports on the implementation of the corrective and preventive actions (CAPA) of the Pharmaceutical Inspectorate.

i) quality system performance report.

j) personnel training records (personal files);

k) personal files of the external experts.

35. Records and reports should be handled in such a way as to prevent their damage or loss.

Records and reports should be retained for an established period. All records should be maintained in confidence. Records and reports may be communicated to Pharmaceutical Inspectorates of other Member States where appropriate Mutual Recognition Agreements exist.

36. Only original records and/or certified copies shall be managed in the Pharmaceutical Inspectorate quality system. All documents need to be identified by their type, name, date, and signature of the responsible person and approving persons.

VII. Pharmaceutical Inspectorate procedures

37. The Pharmaceutical Inspectorate shall conduct inspections of pharmaceutical undertakings and should issue inspection reports using established templates.

38. The Pharmaceutical Inspectorate shall develop and approve written procedures on carrying out pharmaceutical inspections.

39. When more than one inspector is involved in an inspection, a lead inspector should be appointed by the Pharmaceutical Inspectorate Director to co-ordinate inspection activities.

In case of joint pharmaceutical inspections, the lead inspector shall be from the Pharmaceutical Inspectorate of the Member Stated initiated the pharmaceutical inspections.

40. The inspection report should be prepared by the lead inspector and should be agreed by other pharmaceutical inspectors within the inspection group.

Inspection report shall be formatted appropriately and sent to a Qualified Person of the inspected pharmaceutical undertaking.

41. The lead inspector and all concerned inspectors shall participate in assessing the eventual reply or replies to determine the appropriateness of corrective actions and the level of compliance the inspected undertaking with legal acts constituting law of the Union and the applicable pharmaceutical legislation of the Member States.

42. Observations and/or data obtained in the course of inspections shall be recorded in a timely manner to prevent loss of relevant information.

Completed inspections shall be reviewed to ensure that the requirements are met.

VIII. Pharmaceutical Inspectorate resources

The Pharmaceutical Inspectorate shall have it is disposal resources needed to implement Pharmaceutical Inspectorate quality policy.

44. The Pharmaceutical Inspectorate should possess the required personnel to organise and perform pharmaceutical inspections of pharmaceutical undertakings to determine their compliance with the legal acts constituting law of the Union, based on staff schedule.

The Pharmaceutical Inspectorate staff shall be subject to continued training to fulfill its responsibilities.

45. The requirements for personnel education, qualifications, practical experience and tasks and duties shall be established in job descriptions subject to approval by the Pharmaceutical Inspectorate Director.

46. Pharmaceutical inspectors shall:

a) be familiar with the legal acts constituting pharmaceutical law of the Union and Pharmaceutical Inspectorate quality system documentation.

b) have appropriate qualifications, training, experience and knowledge of the inspection process.

c) have the ability to make professional judgements as to the conformance of the inspected party with legal acts constituting pharmaceutical law of the Union and be able to apply an appropriate degree of risk assessment.

d) have other knowledge needed to perform pharmaceutical inspections, including computerised systems and information technology.

47. The employed pharmaceutical inspectors (involved in carrying out pharmaceutical inspections) shall participate as trainees in at least five inspections. The pharmaceutical inspectors may be allowed to carry out own inspections after their knowledge has been examined by the Pharmaceutical Inspectorate Director in accordance with the procedure of the Pharmaceutical Inspectorate quality system.

The further training of these pharmaceutical inspectors shall consist of at least 10 days (60 academic hours) of participation in training events per year. The the Pharmaceutical Inspectorate Director shall regularly review training level of each pharmaceutical inspector and determine the need for his/her further training.

48. The training of the pharmaceutical inspectors and its results shall be documented appropriately.

The records of the training and qualification gained shall be retained in the training/personal file of each pharmaceutical inspector.

49. The training/personal file of each pharmaceutical inspector shall include the following personal data:

a) education and specialty according to the education certificate;

b) qualification;

c) practical experience;

d) tasks and responsibilities;

e) specialisation within the Pharmaceutical Inspectorate;

f) information on training and further training, and the final scores received having undergone the training and further training.

50. The information on the position held by the external expert, his/her qualification and information on his/her participation in pharmaceutical inspections shall be recorded in his/her personal file.

51. The Pharmaceutical Inspectorate shall have the equipment necessary to carry out its activity, including premises, furniture, computer and office equipment, communication equipment, information resources and transport.

IX. Internal Audit

52. The Pharmaceutical Inspectorate shall carry out and document periodic an annual internal audit of its operations to assess compliance with the requirements of the quality system.

All Pharmaceutical Inspectorate quality system elements shall be subject to auditing. The audit shall be carried out against criteria laid down in Pharmaceutical Inspectorate quality system.

53. The Pharmaceutical Inspectorate Director shall be responsible for carrying out the internal audit. The audit shall be conducted by Pharmaceutical Inspectorate personnel and senior management in the form of cross-check in such a way that the auditors audit the operations for which they were not responsible.

54. Based on the internal audit results, a report shall be drawn up containing the findings on non-compliance and the corrective and preventive actions (CAPA) taken. The internal audits results and related corrective and preventive actions (CAPA) shall be included in the report on

Pharmaceutical Inspectorate quality system performance and consequently reviewed by the senior management.

55. Internal shall be conducted in accordance with ISO 19011-2013 ‘Guidelines for quality and/or environmental management systems auditing’.

56. Internal audit records should be retained for a five period.

X. Quality Improvement

1. Pharmaceutical Inspectorate quality indicators

57. The person responsible for maintenance of Pharmaceutical Inspectorate quality system shall establish and maintain main quality indicators related to its operations using Pharmaceutical Inspectorate quality policy based on the review of the annual report on Pharmaceutical Inspectorate quality system performance by the Pharmaceutical Inspectorate Director.

58. The Pharmaceutical Inspectorate operations quality indicators include:

a) further training of pharmaceutical inspectors, obtaining a higher qualification category by the pharmaceutical inspectors, presentations at workshops, conferences.

b) adhering to the plan of pharmaceutical inspections.

c) meeting the deadlines of pharmaceutical inspections and submitting reports on pharmaceutical inspections in accordance with legal acts constituting pharmaceutical law of the Union and the Pharmaceutical Inspectorate quality system documentations.

d) average number of days each pharmaceutical inspector participated in pharmaceutical inspections.

e) the degree of equal distribution of the inspection workload among pharmaceutical inspectors.

f) the number and category of the violations of and cases of non-compliance with legal acts constituting pharmaceutical law of the Union revealed by each pharmaceutical inspector during a pharmaceutical inspection and recorded in the documents according to the results of the pharmaceutical inspection;

g) the number of justified complaints (including internal ones) about the operation of the Pharmaceutical Inspectorate and the timeliness of their consideration;

h) effectiveness of the implementation of corrective and preventive actions (CAPA) by the Pharmaceutical Inspectorate.

59. The review of targeting the Pharmaceutical Inspectorate quality indicators is considered as part of the review of the Pharmaceutical Inspectorate quality system.

2. Corrective and preventive actions (CAPA)

60. The Pharmaceutical Inspectorate should establish and maintain a procedure for the investigation of non-compliances with the quality system which are identified through internal or external audit of its activities. The procedure should include the prescribing, implementation and verification of corrective action. The procedure should cover also corrective actions arising from the investigation of complaints and other observations relating to the activities of the Inspectorate.

Where, in the course of investigation of a non-compliance related to the Pharmaceutical Inspectorate operation, a pharmaceutical inspector’s error is suspected to be the cause of the non-compliance, it shall be documented to confirm that an existing procedural, process or system error or a problem was detected that caused this non-compliance.

61. Based on the quality system review, minutes of meetings, other documents and records of the senior management and in case of amendments to legal acts constituting pharmaceutical law

of the Union or applicable legislation of the Member States or other legal requirements, measures to improve the Pharmaceutical Inspectorate quality system shall be taken.

The measures taken to improve the Pharmaceutical Inspectorates quality system shall comprise of corrective and preventive actions (CAPA) and be managed within a single Pharmaceutical Inspectorate quality system.

62. The corrective and preventive actions (CAPA) and the information on the measures taken to improve the Pharmaceutical Inspectorate quality system shall be recorded in a log of corrective and preventive actions (CAPA) by the person responsible for maintaining the Pharmaceutical Inspectorate quality system, specifying the type of non-compliance, a reference to the records determining the corrective and preventive actions (CAPA), the content of the corrective and preventive actions (CAPA), persons responsible for performing the corrective and preventive actions (CAPA), the deadlines, performance control results, notes on completion, references to the records containing confirmation of completion.

When drawing up a report on Pharmaceutical Inspectorate quality system performance, the efficiency of the corrective and preventive actions (CAPA) shall be assessed. The corrective and preventive actions (CAPA) shall be considered efficient if no new non-compliance arise having the same cause against which the previous corrective and preventive actions (CAPA) were taken.

3. Complaints

63. The Pharmaceutical Inspectorate should establish and maintain a procedure for dealing with complaints relating to its activities, or those of its personnel, and any contracted persons or organisations. The procedure should describe the application and verification of corrective action and preventative action (CAPA) arising from the investigation of complaints.

64. Records should be maintained of all complaints received and actions taken and should be retained for a period defined by the Pharmaceutical Inspectorate.

XI. Liaison of the Pharmaceutical Inspectorate with Certified Laboratories and External Experts

65. The Pharmaceutical Inspectorate quality system shall have a procedure for communication between the Pharmaceutical Inspectorate and the laboratories certified in accordance with legal acts constituting law of the Union, related to exchange of information on the quality control of medicinal products.

66. The Pharmaceutical Inspectorate may hire persons working in accredited laboratories to perform sampling and testing of medicinal products during pharmaceutical inspections.

67. The Pharmaceutical Inspectorate may invite independent experts to take part in pharmaceutical inspections.

The invited experts shall perform specific tasks during a pharmaceutical inspection but shall not be responsible for accuracy and objectivity of the pharmaceutical inspection results.

The invited experts shall be familiar with the requirements of the Pharmaceutical Inspectorate quality system documentation.

68. In selecting experts, independence from the inspected pharmaceutical company and freedom from possible conflict of interest between this expert and the inspected pharmaceutical company shall be taken into account. Prior to a pharmaceutical inspection, the invited experts shall sign a declaration on the independence of the inspector from the inspected pharmaceutical company for the previous 2 years and on confidentiality of the documents and results of the pharmaceutical inspection, as well as the absence of any financial interests and obligations to the owners or management of the inspected party.

XII. Publications

69. The Pharmaceutical Inspectorate shall publish the following information on the official web-site of the competent authority/competent organisation:

a) a list of pharmaceutical undertakings inspection procedures.

b) a plan and schedule of pharmaceutical inspections.

c) a decision-making procedure based on the results of pharmaceutical inspections.

d) a procedure for communication with inspected parties.

e) pharmaceutical inspections carried out and results thereof and the lists of holders of certificates issued following the pharmaceutical inspections.