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Note for the Editors: The mission of the European Pharmacopoeia and the European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe responsible for the Secretariat of the European Pharmacopoeia, is to protect and promote public and animal health through the elaboration of quality standards for medicines for human and veterinary use. Medicines need to be safe, effective and of good quality. The EDQM works closely with its international and European partners to ensure that sub-standard or counterfeit medicines do not reach the marketplace. Its networks collaborate on a daily basis with all authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. For more information, please go to: www.edqm.eu.

The Federal Service for the Supervision of Public Health and Social Development (Roszdravnadzor) is a governmental agency which is responsible for the control and surveillance in the field of healthcare and social development of the Russian Federation. Its functions encompass pharmaceutical activities, control of compliance with state standards of quality of medical care, compliance with state standards, technical requirements for medical products, application of rules in laboratory and clinical practice etc.

The CIS (Commonwealth of Independent States) groups some countries of the former Soviet Union : Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova , Russian Federation, Tajikistan, Ukraine, Turkmenistan and Uzbekistan. These countries have decided to put into common their experience in specific fields such as standardisation and control of pharmaceutical products. They are willing to enhance their cooperation through common groups of experts and an operational central Secretariat. Their objectives are to establish common working rules in the field of standards such as Pharmacopoeia.

QUALITY OF MEDICINES: IMPORTANT PROGRESS MADE TO STRENGTHEN COLLABORATION BETWEEN THE RUSSIAN FEDERATION AND THE EDQM, COUNCIL OF EUROPE

An international conference on “Standardisation of medicines, harmonisation of requirements” took place in Moscow on 23-24 October 2008 with the support of the Federal Service for the Supervision of Public Health and Social Development, the European Directorate for the Quality of Medicines & HealthCare, Council of Europe (EDQM) and the CIS Executive Committee and International Project «Farmsodruzhestvo».

During the conference, the discussion between the leaders of Roszdravnadzor and EDQM focused on current issues of quality assurance of medicines and how to enhance future cooperation. It was agreed to collaborate to implement the provisions of the Declaration of the International Conference «Europe against Counterfeit Medicines» of 24 October 2006 and to expand the comprehensive scientific and practical cooperation.

Reaffirming their common interest in scientific and practical cooperation, the Federal Service for the Supervision of Public Health and Social Development and the European Directorate for the Quality of Medicines & HealthCare expressed the need for further cooperation and defined the following :

1. The parties will organise the research and information liaison for the preparation of the official translation of the European Pharmacopoeia into Russian. The parties also consider it necessary to prepare the Russian translation of the most important publications of the EDQM in particular in the field of OMCL Quality Assurance procedures and guidelines and quality issues in the field of organ transplantations.
2. Roszdravnadzor will continue its active and regular participation in the work of the European Pharmacopoeia Commission and its expert groups. Best practice experience of the European Pharmacopoeia Commission will be taken into account when preparing the new edition of the State Pharmacopoeia of the Russian Federation.
3. Roszdravnadzor, paying tribute to the work of the Council of Europe, the Permanent Mission of the Russian Federation to the Council of Europe, as well as experts from the Council of Europe on the development of the European Convention against counterfeit drugs, medical products and other similar crimes in the pharmaceutical field, considers it necessary to continue work in this area.
4. The parties will continue their cooperation for improving the quality of medicines. The parties will further work together on the accreditation of the Institute of Standardisation and control of medicines FGU «Science Center Medical Application» of Roszdravnadzor to conform to the requirements of the European Network of Official Medicines Control Laboratories (OMCL). Also Roszdravnadzor and EDQM will promote implementation of OMCL network Quality Assurance requirements through the centres for quality control of medicines in the different districts of the Russian Federation.
5. The parties will develop mechanisms for information exchange on the quality of medicines. The parties will seek to establish information channels to inform each other as soon as possible on the quality issues and cases of counterfeit drugs that threaten human life and health.



6. The parties will seek to organise regular activities to improve the skills of professionals in the field of quality control of medicines and fight the proliferation of counterfeit drug products.

7. The Federal Service for Supervision of Public Health and Social Development (Roszdravnadzor) is willing to provide EDQM with technical support in preparing the Russian version of its Internet website

8. The Parties, recognising the importance of an ongoing dialogue between Roszdravnadzor and EDQM, believe it is important to hold regular meetings of representatives of EDQM and Roszdravnadzor devoted to the promotion of the cooperation in these areas.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

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