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Address at the thematic discussion on
"International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines"

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Venue:India

Distinguished participants in the Global Regulators Conclave, dear colleagues, good afternoon.

On behalf of the State Institute of Drugs and Good Practices and myself, I thank the organisers of the Conclave for inviting the Russian delegation to attend the Global Conclave in India.

India and Russia have a long-standing and strategically significant relationship.
In the pharmaceutical sector, India is one of the main suppliers of active pharmaceutical ingredients to Russia, while Russian pharmaceutical companies supply their products to India.

The interaction between our Institute and the Indian regulatory authority has been lasting for many years.In 2018, a delegation of the State Institute of Drugs and Good Practices participated in the India Pharma 2018 conference, which featured a roundtable of regulators from different countries.
In July 2019, I had a meeting with the former head of the Indian GMP inspectorate, Dr S. Eswara Reddy.
In 2020, representatives of the Indian regulator participated in an inspection conducted by Russian inspectors at the vaccine manufacturing site of the Serum Institute of India.In total, more than 400 inspections were carried out by the Russian inspectorate at the production sites of Indian companies.

Furthermore, since 2019experts of the Central Drugs Standard Control Organization of India have been traditionally participating as speakers at GMP Conferences held in Russia.

We live in a large multipolar world.Now the strengthening of existing ties is becoming particularly relevant, and the formation of new alliances acquires a special meaning and significance.

Today, the topic of our discussion is the issues of international regulatory convergence to promote the availability of high-quality medicines.Providing patients with affordable, high–quality and safe medicines is a priority task for each of us.

In addition, formation of mutual trust among regulatory systems of various countries is an issue that is actively discussed at different levels, from international conferences to highly specialised working groups and expert councils.

Convergence and mutual recognition is a multistage process that comprises several steps.Within the Eurasian Economic Union, a common market for the circulation of medicines is being formed, and a supranational regulatory system is being created, including the development of mechanisms for mutual trust and recognition of GMP certificates.For larger associations of countries or various international organisations, the process of convergence and build-up of mutual trust will be longer and more complex in terms of the large number of participants and differences in national legislation.However, the general principles and approaches to the process of convergence and mutual trust remain the same.

Roughly, we can single out five steps towards convergence.

Step one.
Harmonisation of legal provisions and guidelines necessary to determine the basis for licensing activities.

Step two.
Harmonization of legal provisions, guidelines and governing principles necessary to determine the regulatory framework for inspection.

Step three.
Harmonisation of the fundamental principles of the quality system of pharmaceutical inspectorates, commitment and leadership of the top management in the development of the quality system of the pharmaceutical inspectorate.
Elaboration and formation of mechanisms for continued enhancement of the quality system.

Step four.
Harmonisation of requirements for education, work experience, specialisation, functions and responsibilities of personnel authorised for regulatory inspection activities, established and specified in the relevant job descriptions.

Step five.
Creation of the Global Association of Pharmaceutical Inspectorates – a union of representatives of pharmaceutical inspectorates, under which a mechanism for mutual assessment of regulatory systems of association members will be developed, experience exchange, strengthening mutual trust, mutual assistance in the development of regulatory systems and the identification of best practices, principles and approaches to inspection.

At GMP Conference held in early September in Irkutsk (Russia), we had preliminary negotiations with our foreign colleagues from regulatory agencies on the idea of establishing such an organisation.

Following the meeting, it has been decided to form a working group for preparatory work on the organisation of the Association with the participation of experts from national member inspectorates.

It was proposed to draft a governning document that would define the principles of the operation of the Association.
To create a database of reference materials for the inspectorates - members of the association in order to exchange experience and mutually enhance knowledge and competencies.

Such an organisation will give us a real opportunity to interact not only within the framework of some international conferences and forums, but on a permanent basis, enshrined in legal documents, with access to the knowledge base formed through common efforts.

What we are saying is that it will be an open organisation for everyone who wants to grow together and reach a certain level of regulatory development.
The strongest regulatory systems will help colleagues to reach the high level on gratis basis.

We are ready to work with the Indian side on such an interaction in terms of convergence and building mutual trust between our inspectorates, which would be facilitated by the cooperation experience we have already gained.

Colleagues, we are open to proposals to include representatives of various countries in a working group to work on all the aspects of the global association of pharmaceutical inspectorates.

I am confident that in today's world, with its globalisation and international integration, the creation of this Association will bring us closer to mutual recognition among countries, the determination of common principles and approaches to quality control of medicinal products, and therefore to providing the world population with quality and affordable medicines!

Thank you for your attention!