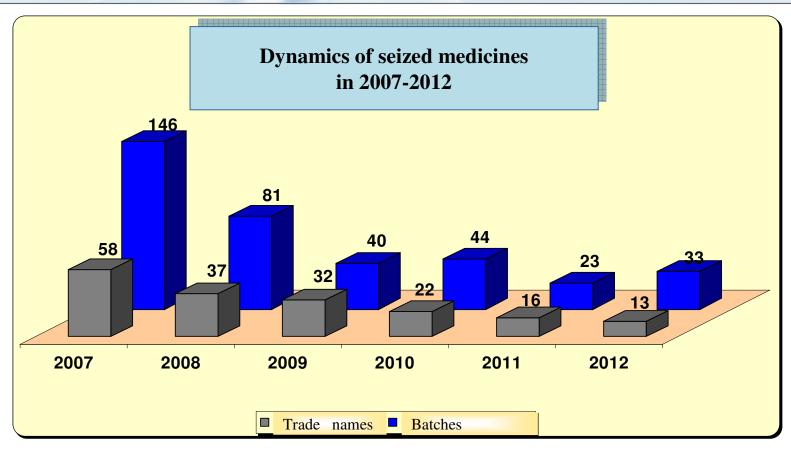
### Federal Service on Surveillance in Healthcare



# Counteraction to falsified and counterfeited medicines circulation in the Russian Federation.

### The scale of a problem with counterfeit medicines in Russia





About 1% from circulated on the market is officially detected by Roszdravnadzor as counterfeited, fraudulent and manufactured from counterfeited APIs.

### The system of state quality control of medicines



#### The state system of quality control of medicines









Efficacy and safety assessment, setting the quality standards for marketing approval

Selective quality control of marketed medicines

**Quality, safety and efficacy monitoring** 

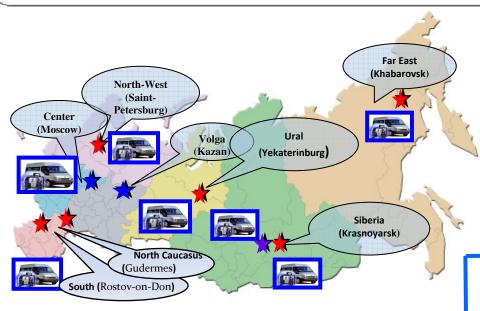
**Inspections** 

#### Alongside with Roszdravnadzor, the state control of medicines involves:

- → Regional offices of Roszdravnadzor
- Quality control laboratories
- → United electronic information resource
- Quality assurance systems of manufacturers, wholesalers and retailers

## Basic elements of the reform of the state quality control of medicines



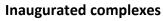


Modern high-tech laboratory complexes began operating **in 8 federal districts of the Russian Federation**: Gudermes Rostov-on-Don, Yekaterinburg, Krasnoyarsk, Khabarovsk St. Petersburg. The construction of the laboratory of the Central Federal District is underway in Moscow.





Federal laboratory complexes performing quality control of biologicals



Federal laboratory complexes with projected facilities for control of biologicals



**Complexes possessing mobile control laboratories** 



Since the introduction the NIR spectroscopy authenticity screening in 2009 the spectra database has acquired more then 390 profiles of marketed medicines. The mobile control laboratories are operating in 8 federal districts.











#### Medicines Quality Control Laboratory Complex





Physico-chemical, spectrophotometric, chromatographic (GC, HPLC, TLC), biochemical methods, methods of titration, dissolution, disintegration microscopy, K. Fischer water determination, and residual moisture.



Sterility tests,
microbiological purity tests,
LAL-test, monitoring of the
environment.

#### Pharmacological Lab

Pharmacological, toxicological, pharmacokinetic studies, bioequivalence studies.

### Medical Immuno-biological preparations control Lab (MIBP)

Virological studies, and immunochemical analysis of enzyme immunoassay, polymerase chain reaction (PCR), the museum of strains and cultures, working with cell cultures and bacterial agents



Areas of application:

Quality control of drugs

Preclinical studies

Consulting



### **Mobile Express Laboratories**







The pilot project for screening the quality of medicines with the Near Infra Red Spectrometry based on the mobile express laboratories; screening the quality of drugs using non-destructive method. These mobile labs are operating in all Federal Districts of the Russian Federation.

The NIR spectrometry for drug identification was introduced in the state system of quality control of medicines in 2009. Since that time, a library of spectra containing 390 medicines was accumulated. The work on the expansion of this library is under way.

### Within its competence, Roszdravnadzor maintains inter-agency, institutional and international cooperation.



#### Law-enforcement agencies

Regular (monthly) information exchange on substandard, falsified and counterfeited medicines with the Ministry of Interior.

#### **Non-governental institutions**

Bilateral cooperation agreements are signed with:

- •Association of the Russian Pharmaceutical Manufacturers (*ARPM*, APΦII),
- •Union of Professional Pharmaceutical Organizations (*UPPO*, СПФО),
- •Association of International Pharmaceutical Manufacturers (AIPM),
- •Association of manufacturers of Pharmaceutical products and medical devices (APII).

#### **International cooperation**

- ❖ The international cooperation provides Roszdravnadzor with valuable data on quality of medicines contributing to efficient struggle against counterfeit and low-quality products.
- \* Roszdravnadzor singed bilateral memoranda and maintains effective cooperation with the drug regulators from China, European states, USA, Ukraine and others.
- ❖ Roszdravnadzor was involved into elaboration of CoE's Medicrime convention. Russia singed the Convention on the day of its opening for signature (October, 28<sup>th</sup>, 2011).

### Federal Service on Surveillance in Healthcare



### Thank you for your attention!