«National Center of Drag and Device expertize»
Medical and pharmaceutical Control Committee of Ministry of Health of Republic of Kazakhstan

Pharmacovigilance and COVID vaccination in Kazakhstan

Dep. head
Abdrakhmanov Malik

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Nur-Sultan

COVID 19 Vaccines

- Gam-COVID Vac (Sputnik V) started 01 of February 2021
- First delivery 20 000 doses under special procedure, from Russia
- At the same time localization of manufacturing via transfer of technology. First 40 000 local doses released 23 of February
- Domestic vaccine - KazCovid under developing (II stage trial)

STATE SUPERVISION SYSTEM MONITORING THE SAFETY, EFFECTIVENESS AND QUALITY OF VACCINES IN KAZAKHSTAN

Vaccines

Passing the state registration procedure

Access to application in the Republic of Kazakhstan

- 65 vaccines are registered in the state register of the Republic of Kazakhstan.
- The National calendar of preventive vaccinations uses vaccines against 11 childhood infections:

tuberculosis, viral hepatitis B, polio, whooping cough, diphtheria, tetanus, measles, rubella, mumps, hemophilic and pneumococcal infections. All vaccines are prequalified by WHO. COVID vaccine under process of WHO prequalification

The safety, efficiency, and quality of vaccines are evaluated: • in the process of expert work during State registration • in the post-registration period

Legislation

- Code «About public health and healthcare system» 07.07.2020 (revised 08.01.2021) – article 261 «Pharmacovigilance and monitoring medical device safety, effectiveness and quality»
- MoH Order dated 04.02.2021 № ҚР ДСМ-16 «On approval of the rules for state registration, re-registration of a medicinal product or medical device, variations to the registration dossier of a medicinal product or medical device»
- MoH Order dated 09.02.2021 № ҚР ДСМ-15 «On the approval of good pharmaceutical practices» - App 6 Good vigilance Practice (GVP)
- MoH Order dated 23.12.2020 № ҚР ДСМ-320/2020 «About the Rules of pharmacovigilance and monitoring medical device safety, effectiveness and quality»
- MoH Order dated 24.12.2020 № ҚР ДСМ-322/2020 «On approval of the rules for registration and investigation, recording and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse manifestations after immunization»
- MoH Order dated 24.12.2020 № ҚР ДСМ-322/2020 «On approval of the Rules for suspension, prohibition or withdrawal from circulation or restriction of the use of medicines and medical devices»

- Eurasian economic Commission Committee decision 03.11.2016 № 87 «On the approval of good pharmacovigilance practice (GVP) Eurasian economic union»

Vaccination steps

Priority:

1) Medical staff (staff of infectious hospitals, ambulance, ICU, primary health care, emergency rooms

healthcare organizations, employees of the sanitary and epidemiological service);

2) Teachers;

3) Local police officers;

4) Students;

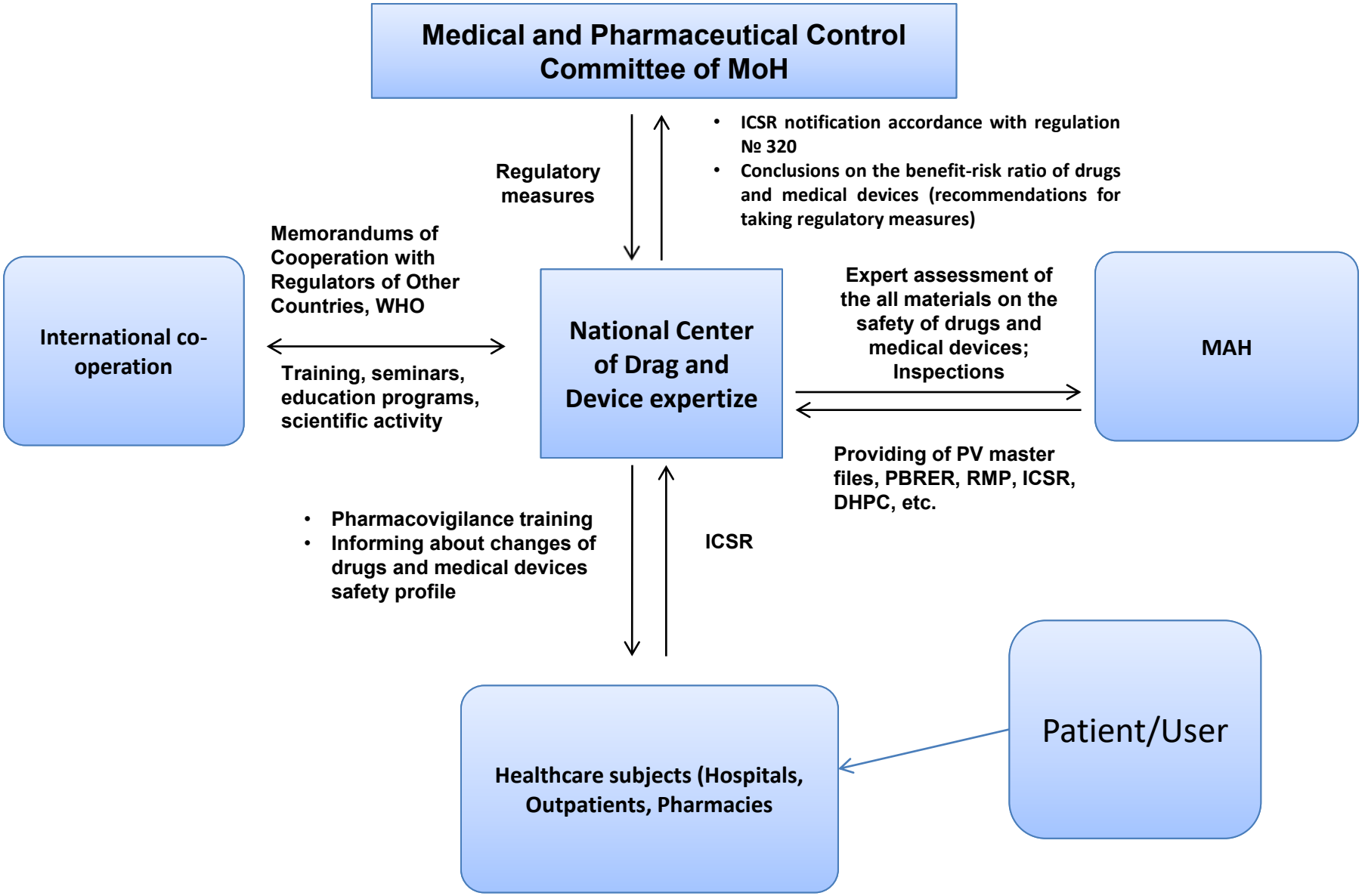
5) Personnel and contingent of medical, social and closed children's institutions;

6) Employees of the Ministry of Emergency Situations, Ministry of Defense, National security Agency, Ministry of Internal Affairs;

7) Government and civil servants, diplomatic, consular offices, accredited in Kazakhstan, members of national sport teams;

8) Other citizens, including persons with chronic diseases (diabetes mellitus, chronic obstructive pulmonary disease, cardiovascular system) .

Interaction between participants



Relationship on ICSR

НАЦИОНАЛЬНЫЙ ЦЕНТР ЭКСПЕРТИЗЫ ЛЕКАРСТВЕННЫХ СРЕДСТВ И МЕДИЦИНСКИХ ИЗДЕЛИЙ

CMPC of MoH

Information about side effects

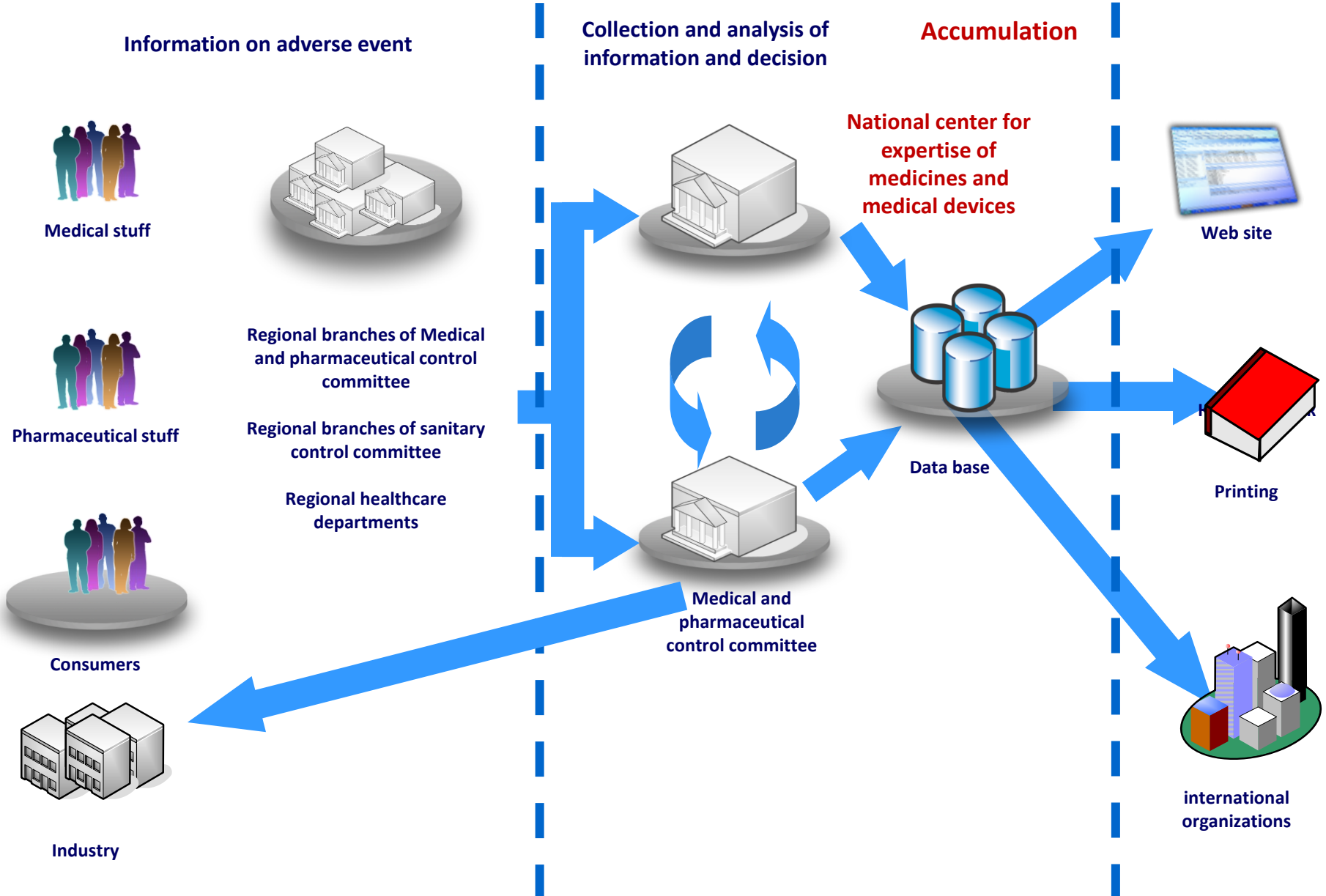
• Within 48 hours, inform about serious adverse reactions (death, threat to life, hospitalization of the patient or its prolongation, persistent / severe disability or disability, congenital anomalies or malformations, the need for medical intervention to prevent the development of these conditions, any unintentional suspected contamination through medicines or device).

• causal relationship and benefit risk balance conclusion

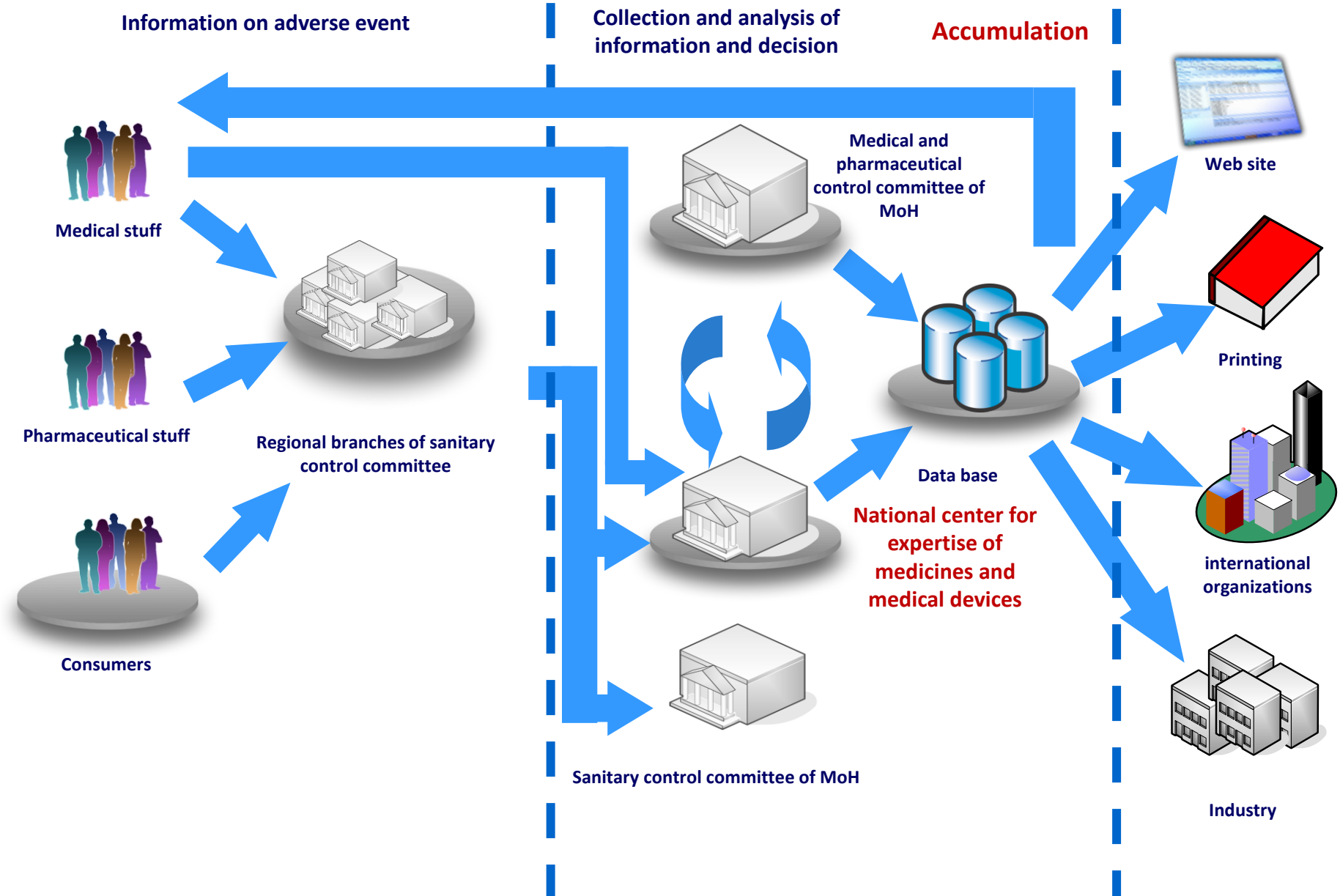
Regulatory measures

- Selection and seizure of samples
- Suspension of medical use of a batch (batch)
- Variation of SMPC and PL/Manual (instruction)
- Inspection
- Marketing authorization recall with prohibition of medical use and withdrawing product from market

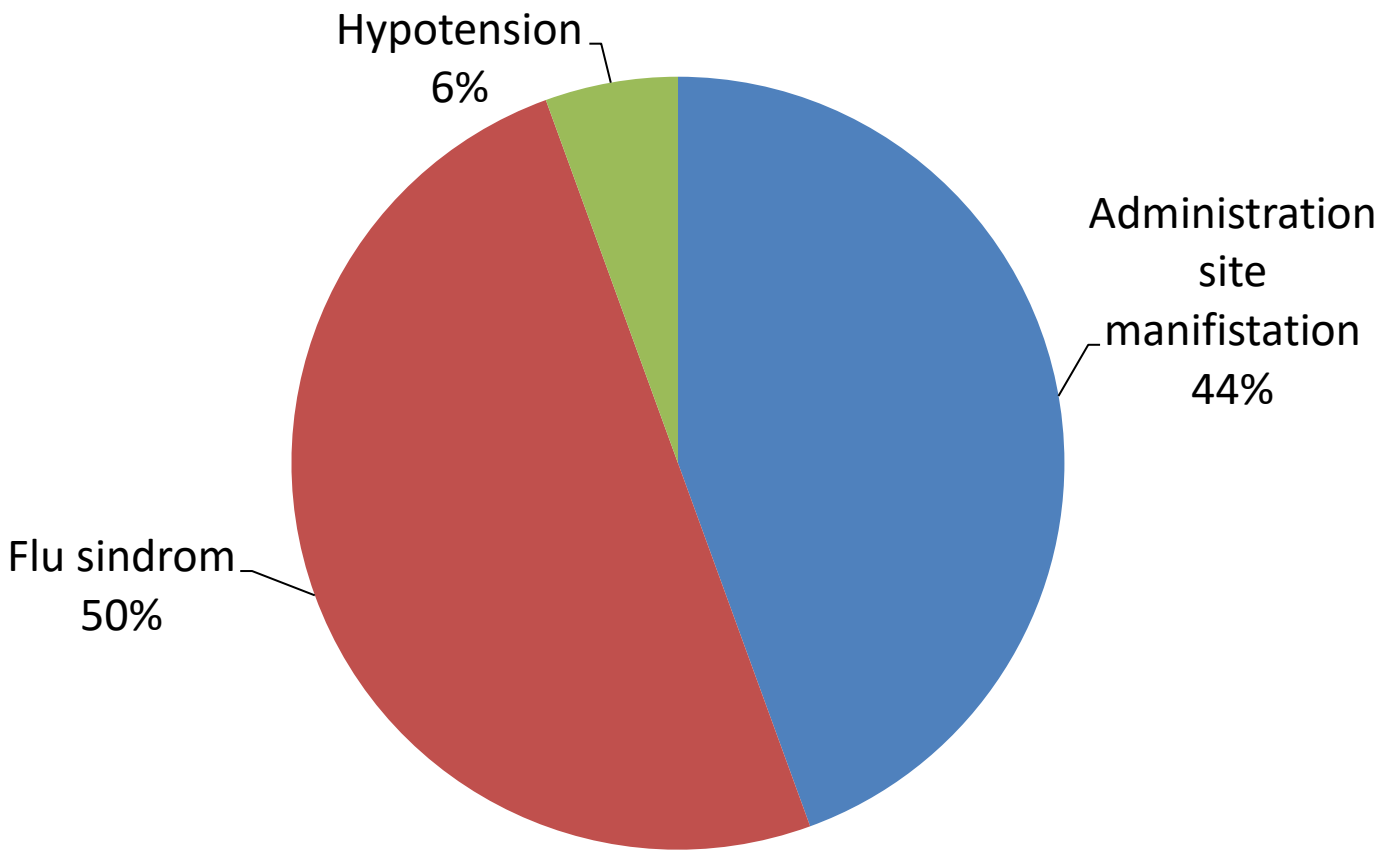
Adverse events reporting system



Vaccination adverse events reporting



Reactions profile



Thank you for attention!