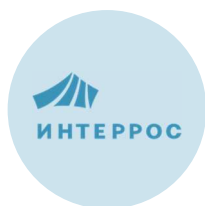




[www.petrovax.com](http://www.petrovax.com)

## Petrovax is a Russian full-cycle biopharmaceutical company with 25 years of successful experience

- R&D center  
> 20 world patents
- Manufacturing in accordance with GMP and ISO standards
- Part of the Interros Group
- The company is among the Top 5 immunobiological pharmaceutical manufacturers in Russia
- Portfolio of original and generic pharmaceutical and nutraceutical products
- Export of products to EAEU, EU countries and Iran
- Partner of international Big Pharma companies
- > 600 qualified employees



## Our mission

Innovative products for treatment, prevention and well being

## OUR VALUES



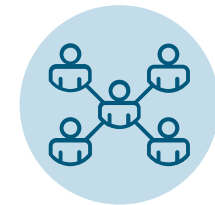
OPENNES



CAN-DO SPIRIT



OWNERSHIP



TEAMWORK

## PRODUCT PORTFOLIO



### Grippol® plus

influenza vaccine  
[inactivated] + azoximer bromide

Russian influenza trivalent inactivated polymer-subunit vaccine, preservative-free in pre-filled syringes.



### Grippol® Quadrivalent

influenza vaccine  
[inactivated] + azoximer bromide

The first Russian quadrivalent inactivated subunit influenza vaccine to protect against 4 flu virus strains, i.e., 2 virus A strains (A/H1N1 + A/H3N2), and 2 lineages of influenza B virus (B/Yamagata + B/Victoria). Preservative-free pre-filled syringes.



### Polyoxidonium®

Azoximer bromide

An original product of complex action: immunomodulator, detoxifier, antioxidant. It is used for treatment of infectious diseases of bacterial, viral, or fungal origin, and is widely used in therapeutics, pediatrics, gynecology, and urology. Dosage forms: lyophilizate, solution, tablets and suppositories.



### Imoferaza®

Cream for specialized treatment of scars. Based on immobilized hyaluronidase enzyme.



### Longidaze®

Hyaluronidase azoximer

An advanced combined-effect enzyme for treatment of connective tissue hyperplasia conditions. Dosage forms: lyophilizate and suppositories.



### Velson®

Melatonin

A modern medication for sleep normalization and human biorhythms stabilization. Velson® regulates the sleep-wake cycle, promotes faster falling asleep, adaptation to jet lag and weather sensitivity. Dosage form: film-coated tablets.



### Uronext®

Complex product for urinary tract infections\*. Formula with D-mannose, Cran-Max (patented cranberry fruit concentrate) and Vitamin D3. Dosage form: powder sachet.



### VitaFerr®

Complex product for prevention of iron deficiency among women. Contains: iron, vitamins C, B6, B12 and a highly bioavailable folate. Dosage form: capsules.

# PRODUCT PORTFOLIO

## Localized production



### Prevenar® 13

Pneumococcal polysaccharide conjugate adsorbed vaccine, thirteen-valent

Vaccine for prevention of pneumococcal infections caused by the bacterium Streptococcus pneumoniae of serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, such as sepsis, bacteremia, meningitis, pneumonia and acute otitis media. Recommended from 2 months without age restrictions onwards.

Manufactured by Petrovax in cooperation with Pfizer.



### Actilyse®

Alteplase

A biotechnological thrombolytic drug used for myocardial infarction, and also ischemic stroke (this is the main unique advantage, clinically proven). Alteplase is the only thrombolytic agent indicated for treatment of patients with ischemic stroke within 4.5 hours of symptom onset. Manufactured by Petrovax in cooperation with Boehringer Ingelheim.



### Metalyse®

Tenecteplase

An innovative thrombolytic agent for treatment of myocardial infarction. It is the only thrombolytic agent worldwide recommended for usage with a single bolus injection (in 5-10 seconds), making it possible to immediately provide medical care to patients with acute myocardial infarction at the earliest possible time an emergency medical care situation. Currently, tenecteplase is one of the most studied thrombolytic agents. Manufactured by Petrovax in cooperation with Boehringer Ingelheim.

## R&D

Petrovax is historically based on original products development. Our company structure allows a full cycle of activities from early R&D to market entry and medical practice. Highly specialized research is carried out with involvement of leading local and foreign specialized scientific institutions.

## In-house vivarium

Petrovax has its own certified modern vivarium with 4 types of laboratory animals, in which the company conducts preclinical studies of its own drugs and offers services to partner organizations. The premises maintain all necessary parameters to allow keeping mice and rats of SPF status, as well as conventional rabbits and guinea pigs. R&D has successfully passed **ISO:9001** quality system audit.

- An innovative search for promising candidate molecules, followed by safety and specific activity assessment in preclinical studies.
- Mechanisms of action study for developed drugs in the disease pathogenesis.
- Determination of the safety and efficacy profile for future drugs in preclinical studies.
- Development of quality control methods and manufacturing technology.
- Planning and conducting clinical registration studies in accordance with **GCP standards**.
- Implementation of innovative technologies, modernization and processes optimization, production scaling.





## Production facility

A full-cycle pharmaceutical company. Complies with Russian and international standards GMP, ISO 9001:2015 (zoning by clean room grades, direction of movement of materials, personnel, intermediates and finished products).



A constantly upgraded pharmaceutical production and warehouse complex in Moscow region started its operations in 2008 and it is one of the most advanced biopharmaceutical enterprises in Russia. Petrovax is the first Russian manufacturer of immunobiological products to pass international **GMP certification** from the state regulatory authorities of the EU (Slovakia) and Iran.



APIs, finished drug forms in disposable syringes, ampoules, vials, soft and solid dosage forms are produced on our manufacturing sites. Petrovax capacity is more than **160 million** dosages of immunobiologicals per year.

**Line 1** – drug products in pre-filled syringes.  
**Line 2** – injectables in ampoules and vials.  
**Line 3** – manufacturing of APIs, soft and solid pharmaceutical forms.  
**Line 4 (2021)** — manufacture of injectables.

## Quality

Petrovax implemented and operates a QMS, complying with **ISO 9001:2015**.

More so QMS is implemented not only in production department, but also in other business units, including R&D and back office.



- High level of QMS functioning is annually confirmed on large-scale ISO certification audit.
- The arrangement of document flow allows both real-time and retrospective tracing of activities results for all employees involved in product manufacturing and QC.
- The cooperation is performed only with approved suppliers of materials.
- An automated training system has been implemented – WebTutor training and development portal, where each employee has an individual training and testing plan in accordance with QMS.
- The company has a pharmacovigilance system, operating in accordance with international standards and requirements of regulatory authorities of Russian Federation.
- Responsible employees constantly monitor information on adverse reactions and efficacy to ensure drug use control safety.



## Export profile

Petrovax strategically develops its export potential and overseas sales.

Our products are supplied to **12 countries** of the world.



**>10** Countries of export presence

**>30** Largest cities of Russian Federation

## International collaborations

Petrovax cooperates with leading Russian and international research institutes and pharmaceutical companies in order to create new products, transfer technologies for a full-cycle of drug manufacture.



### Localization of immunobiological drugs with innovative technologies transfer in Russian Federation

- Production localization, control and quality assurance of 13-valent conjugated pneumococcal vaccine **Prevenar® 13** in accordance with international GMP.
- More than **30 mln.** doses were supplied to the local market, starting **from 2014**.
- Manufacture potential for overseas markets.



### A unique biotechnological project for the market of Russian Federation

- Construction of a GMP compliant production facility
- Staff training and introduction of GMP standards for sterile vaccine production.
- Release of the **Grippol® plus** - first Russian vaccine in disposable syringes without mercury preservatives.
- More than 120 million people have been vaccinated during the years of successful use of the **Grippol® plus** vaccine, including the vaccination within the scope of the National Vaccination Schedule of the Russian Federation, as well as in the EAEU countries and Iran.



### Localization of manufacturing of products for cardiovascular diseases treatment

- Petrovax is the second site in the world producing innovative Boehringer Ingelheim thrombolytics.
- The capacities of the manufacturing complex will be able to fully satisfy the needs of Russian patients for these drugs.
- 2017 – release of the first commercial batch.
- 2019 – full cycle of finished drug form manufacturing

## Petrovax in COVID-19

The global academic community considers immunotherapy and preventive vaccination to be one of the promising strategies against COVID-19.

### Prevention

International multicenter clinical trial of **Ad5-nCoV** vaccine against COVID-19

Open-label study of **Polyoxidonium** in health care personnel operating in the red zones

### Treatment

International multicenter clinical trial of **Polyoxidonium** in patients with COVID-19 as per WHO protocol

Observational study of **Polyoxidonium** in COVID-19 patients

### Rehabilitation

Immunorehabilitation of patients recovering from COVID-19 with **Polyoxidonium**

Open label observational study of **Longidaze** in patients recovering from COVID-19 (pulmonary fibrosis)

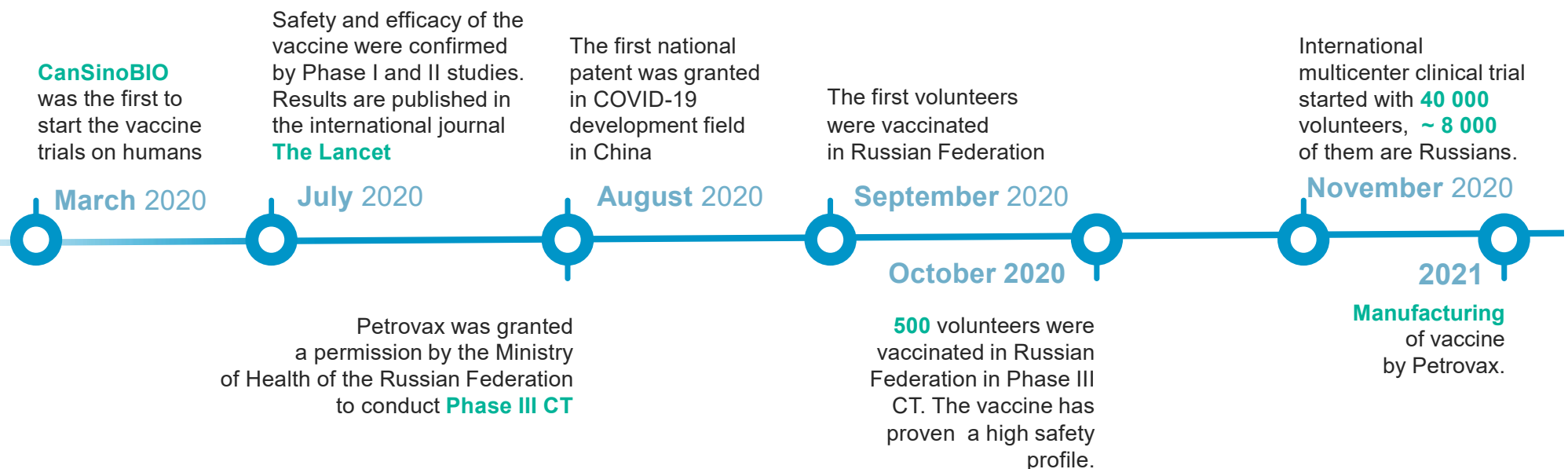
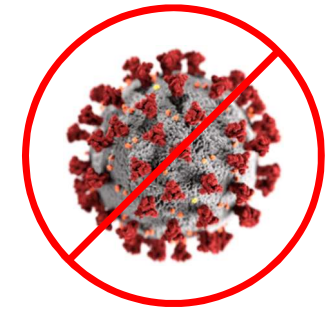


<https://medicine.wustl.edu/news/boosting-immune-system-a-potential-treatment-strategy-for-covid-19/>



<https://vakcina.ru/files/tmpfiles/upload-documents/COVID-19/osnovy-immunoreabilitacii-covid19-kostinov.pdf>

## Development and manufacturing of a candidate **AD5-NCOV** vaccine against COVID-19 with a Chinese partner





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