

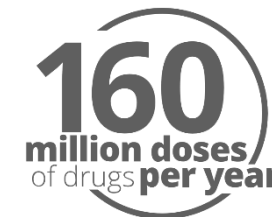


full-cycle  
biotechnological  
company

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

- Product portfolio includes original pharmaceutical products, contract medicines and food supplements.
- R&D center, patents for molecules and technologies in Russia and abroad.
- Biotechnological manufacturing in accordance with the EAEU and EU GMP standards.
- One of the largest exporters of influenza vaccines and original pharmaceutical products.
- Partner of international Big Pharma companies.

The company's investment strategy is aimed at investigation, production development and import substitution of medicines and vaccines used in the treatment of socially significant conditions, such as oncological, autoimmune, infectious and orphan diseases.



# HISTORY OF DEVELOPMENT

1996 -  
2004

- **Company foundation**
- Registration of **Polyoxidonium**® medicine and **Grippol**® vaccine
- Opening of the production facilities for manufacture of APIs, finished dosage forms
- Establishing partnership with **Solvay Pharma** (currently, **Abbott**)

2014 -  
2016

- Pneumococcal vaccine supplies **Prevenar**® 13 for Russian National Immunization Schedule
- Market launch of **Imoferaza**® cosmetic cream
- Establishing cooperation with **Boehringer Ingelheim** on localization of innovative thrombolytics **Metalyse**® and **Actilyse**®
- Joining **the Interros Group**

2005 -  
2009

- Market launch of **Longidaza**® drug product
- Opening of a modern **manufacturing complex** in Moscow Region. The first syringe line for vaccine production in Russia
- Market launch of the first Russian influenza vaccine **Grippol**® plus in pre-filled syringes
- Development and manufacture of vaccines against pandemic strain of influenza: > **15 million doses**

2017 -  
2019

- Market launch of **Grippol**® Quadrivalent, Russian first quadrivalent inactivated subunit adjuvanted influenza vaccine
- Expanding the portfolio with a new product — **Velson**® (INN: Melatonin)
- Registration of a new dosage form — **Polyoxidonium**® solution
- **Commissioning of the 3rd manufacturing line** for the APIs and finished dosage forms
- Successful completion of the post-authorization safety study (PASS) of Polyoxidonium® **in the EU**

2010 -  
2013

- **Opening of the 2nd line** for manufacturing vials and ampoules
- Start of a localization project of the **13-valent conjugate pneumococcal vaccine** manufacturing (in cooperation with **Pfizer**)
- Obtaining **EU GMP** certificates, start of **Polyoxidonium export** to the EU
- Start of export supplies of **Grippol**® plus vaccine

2020 -  
2022

- Market launch of new products: **Uronext**®, **VitaFerr**®, **Gialera**®, **ARTNEO**®
- Obtaining USA, Indian, South Korean and EU patents for **Longidaza**®
- Production expansion: **opening of the 4th line** of production for manufacturing of injectable dosage forms, start of construction of new biotechnological complex
- The beginning of cooperation with ISU ABXIS (South Korea) to **localize production** of medicine for orphan therapy – **Fabry disease**
- **Change** in the shareholder composition – Interros Group left the membership of the company.
- Large-scale **clinical trials program** of Polyoxidonium® and Longidaza® in the prevention and treatment of COVID-19
- Project for the development and manufacture of the **vaccine** against COVID-19 — **Convidecia** — in cooperation with **CanSino Biologics Inc.**

# DIFFERENTIATED PRODUCT PORTFOLIO

- Original pharmaceutical products and vaccines**  
 Polyoxidonium<sup>®</sup>, Longidaza<sup>®</sup>,  
 Grippol<sup>®</sup> Plus, Grippol<sup>®</sup> Quadrivalent
- Contract medicines and vaccines**  
 Prevenar<sup>®</sup> 13, Metalyse<sup>®</sup>, Actilyse<sup>®</sup>, Fabagal<sup>®</sup>
- Generics**  
 Velson<sup>®</sup>, Demefecil
- Food supplements**  
 ARTNEO<sup>®</sup>, VitaFerr<sup>®</sup>, Uronext<sup>®</sup>, Gialera<sup>®</sup>,  
 Sundevit<sup>®</sup>, Omegika<sup>®</sup>
- Cosmetic cream**  
 Imoferaza<sup>®</sup>



## ORIGINAL PRODUCTS

### VACCINES



#### Grippol® plus

Influenza vaccine [inactivated] + azoximer bromide

Trivalent inactivated subunit adjuvanted influenza vaccine.

#### Grippol® Quadrivalent

Influenza vaccine [inactivated]+ azoximer bromide

The first Russian quadrivalent inactivated subunit adjuvanted influenza vaccine.



### COSMETIC CREAM

#### Imoferaza®

Cosmetic cream for specialized care of scars, adhesions, which includes immobilized hyaluronidase.



### DRUG PRODUCTS

#### Polyoxidonium®

azoximer bromide

Original product with complex effect: immunocorrector, detoxifier, antioxidant, for treatment and prevention of infectious diseases.



#### Longidaza®

bovhyaluronidase azoximer

Original enzyme medicine for combined therapy of connective tissue hyperplasia diseases (fibrosis).



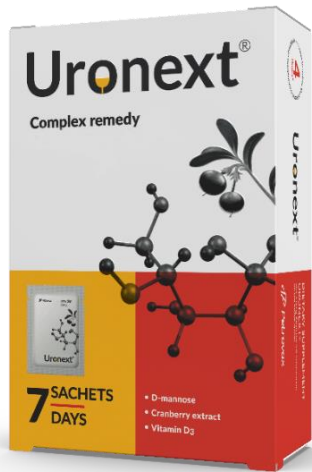
#### Demefecil®

dimethinden+phenylephrine

A combined antiallergic agent with a vasoconstrictive effect for the treatment of acute, vasomotor, chronic and allergic rhinitis, acute and chronic sinusitis, acute otitis media (as an auxiliary treatment method) in adults and children from 1 year.



## OTC MEDICATIONS & FOOD SUPPLEMENTS



### Uronext®

Complex remedy for urinary tract infections.

Active ingredients: D-mannose, Cran-Max (patented cranberry fruit concentrate), vitamin D3.



### ARTNEO®

Complex with a special, native collagen type II with a radically new mechanism of action for the protection of joints and spine.

Active ingredients: native (undenatured) type II collagen, boswellic acids, MSM, vitamin C and vitamin D3.



### Gialera®

A combination of sodium alginate and hyaluronic acid, providing a comprehensive approach for heartburn.



### Velson®

Melatonin

A modern drug for sleep and circadian rhythms' normalization. Velson® regulates sleep-wake cycles, adaptation to jet lag and to weather changes conditions.

### Sundevit®

Specially selected dosage of Vitamin D3 2000 IU in combination with Vitamin K2 in a soft gel capsule for strong immunity, muscle, bone and joint support



### VitaFerr®

The latest generation of iron fortified with vitamins and folates for better absorption. The optimal choice for replenishing iron levels. Suitable for pregnant women.

Active ingredients: iron bisglycinate, vitamin C; Vitamin B6; Vitamin B12; calcium L-methylfolate.

### Omegika®

Special combination of crystal clear concentrate of omega-3 acids in combination with vitamin K2 for health and beauty support.



## LOCALIZED DRUGS (CMO)

### Prevenar® 13

Pneumococcal polysaccharide conjugate adsorbed vaccine, thirteen valent

Vaccine for the prevention of pneumococcal infections caused by the bacterium *Streptococcus pneumoniae*, 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 for all ages over 2 months.

Manufactured by Petrovax as a full-cycle manufacturing of the finished dosage form in cooperation with Pfizer.



### Fabagal®

Agalsidase beta

Fabagal is used for long-term enzyme replacement therapy for the Fabry disease, a rare genetic disorder that damages kidneys, causes neuropathic pain in the extremities, congestive heart failure, heart attack and stroke. Is used to treat adults and children from 8 years old.

Petrovax collaborates with ISU Abxis from South Korea to localize the full-cycle manufacture of Fabagal.



### Actilyse®

alteplase

A biopharmaceutical thrombolytic which is used for acute myocardial infarction, ischemic stroke and pulmonary embolism treatment.

Produced by Petrovax Pharm in cooperation with Boehringer Ingelheim.



### Metalyse®

tenecteplase

Innovative thrombolytic for the treatment of acute myocardial infarction. This thrombolytic is recommended for worldwide use with a single bolus injection (in 5-10 seconds), which allows immediate medical care to be provided to patients with acute myocardial infarction at the earliest possible time as part of emergency medical care. Currently, tenecteplase is one of the most extensively studied thrombolytic medicines.

Produced by Petrovax Pharm in cooperation with Boehringer Ingelheim.



Petrovax is the holder of patents for molecules and pharmaceutical manufacturing technologies in Russia and abroad. The company's investment program ensures the financing of advanced R&D projects.

R&D center and vivarium for preclinical studies allow to carry out a full cycle of development and implementation of medicinal products.

- Search for innovative molecules and conducting preclinical studies
- In-depth study of the mechanism of action in terms of the pathogenesis of a corresponding disease
- Proof of the safety and efficacy of drugs in preclinical studies
- Development of quality control methods and manufacturing technologies
- Conducting of clinical studies in accordance with GCP standards
- Introduction of innovative technologies, development and optimization of manufacturing processes

## International clinical studies

2020

International Multicenter Clinical Study of the efficacy and safety of the Convidecia COVID-19 vaccine in cooperation with CanSino Biologics with participation of 40,000 volunteers

2020

International Multicenter Phase 3 Clinical Study of efficacy and safety of the Polyoxidonium® in Complex Therapy of Patients with COVID-19



R&D center



Petrovax is a full-cycle biotechnological company

The manufacturing processes include the synthesis of APIs, the production of sterile and non-sterile medicines, including immunological and biopharmaceutical drugs in various dosage forms. The production operates in accordance with the EAEU and EU GMP standards.

## MANUFACTURING



The pharmaceutical manufacturing and warehouse complex was opened in the Moscow region in 2008.

Manufacturing capacity – **160 mln doses** of drugs per year

Line 1 — manufacturing medicines in pre-filled syringes

Line 2 — manufacturing medicines for injection, including lyophilizates

Line 3 — synthesis of APIs, manufacturing of soft and solid dosage forms

Line 4 — manufacturing of injectable dosage form

**15**  
years  
of Petrovax  
manufacturing  
complex

# QUALITY

The company has implemented and effectively operates a GMP certified pharmaceutical quality system (PQS), confirmed by international partners audits.

Petrovax has been certified EU GMP (Slovakia) since 2012.

- The Company cooperates only with approved suppliers of raw and other materials
- Quality control of manufactured pharmaceutical products and vaccines is guaranteed at all stages of production, from the sampling of raw materials to the control of finished products. More than a hundred people work in the quality service
- The pharmacovigilance system functions in accordance with international standards and Russian regulatory requirements to ensure medicine product safety surveillance



# INTERNATIONAL PARTNERSHIP / CMO

Petrovax cooperates with leading international pharmaceutical companies on the transfer of innovative technologies for the production of medicines

## Abbott

2008

**A unique biopharmaceutical project in the scientific and industrial spheres**

In cooperation with Abbott, a biopharmaceutical project to build a modern pharmaceutical complex for the development and production of immunobiological drugs in the Moscow region has been successfully implemented. In 2008, for the first time in Russia<sup>1</sup>, the release of influenza vaccine Grippol® Plus in disposable syringes without the preservative thiomersal was launched. It is one of the most exported influenza vaccines in Russia and is part of the state immunization programs of several countries.

## Boehringer Ingelheim

2017

**Localization of biopharmaceutical drugs for the treatment of cardiovascular diseases**

Throughout cooperation with the international company Boehringer Ingelheim, the local production of Actilyse® and Metalyse® drugs for the treatment of cardiovascular diseases were introduced to the acute phase of heart attacks and ischemic strokes treatment. The use of these drugs today is the "gold standard" of thrombolytic therapy. Petrovax is the second site in the world to produce innovative Boehringer Ingelheim thrombolytics.

## Pfizer

2014

**The first implemented project on import substitution of high-tech vaccines in Russia**

In partnership with Pfizer, a project was implemented for the first time to introduce the technology for the full cycle of production of finished dosage forms, control and quality assurance of the 13-valent pneumococcal conjugate vaccine Prevenar® 13 in Russia. Since 2014, more than 35 million doses of the vaccine have been delivered to the Russian market, significant results in reducing mortality caused by pneumonia among children of the first year of life have been achieved — 56%\* reduction noted.

## ISU Abxis

2022

**Technology transfer of the full cycle production of the drugs for the treatment of orphan disease, including substance synthesis**

In cooperation with the South Korean company ISU Abxis, a project on localization of full-cycle production of agalsidase beta (Fabagal medicine) for the Fabry disease treatment is being implemented. Fabry is an orphan disease, which belongs to the group of lysosomal storage diseases and in the absence of timely diagnosis and therapy it leads to early disability and premature death of patients. As a result of the project, Petrovax will synthesize the substance and produce the finished dosage form.

\*<https://rosstat.gov.ru/compendium/document/13269>

# Project on orphan diseases



## Fabagal (INN agalsidase beta) for the treatment of **Fabry disease**

Manufactured by ISU Abxis, approved and used in the Korean market since 2014.

### Project parameters



Agalsidase beta

Investments – **2 billion rubles**

The strategic goal of Petrovax is to **provide 100% of patients** with Fabry disease with a Russian-made enzyme replacement drug.



**10** countries  
of export

**Petrovax has been successfully operating in foreign pharmaceutical markets for more than 20 years:**

- one of the largest Russian exporter of influenza vaccines and original pharmaceutical products
- the products are presented in 10 countries, including the EU
- EU GMP since 2012

## EXPORT POTENTIAL

**Petrovax has significant competitive advantages:**

- original portfolio of innovative products
- high-tech manufacturing according to international GMP standards
- R&D investment program and experience in implementing of international projects

Increasing the export potential and expanding the sales geography are the strategic goals of Petrovax.

Petrovax is the winner in the categories "**Exporter of the Year**" and "**Partnership of the Year**" of the Russian Pharma Inspiration Awards-2021.

Our mission

Innovative products for health and better quality of life



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Corporate values

 Petrovax



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