

2019



**Petrovax**

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# Petrovax

A Russian full-cycle biopharmaceutical company with a 20-year record of success on the pharma market

An **Interros Group** company



### R&D Center

> 20 worldwide patents



Pharmaceutical exports to the EAEU, EU, and Iran.

The company is among the **Top-5** immunobiological manufacturers in Russia

A **partner** of leading global pharmaceutical companies



A **full-cycle** biopharmaceutical company  
GMP and ISO-compliant **manufacturing facilities**



Original product and generic portfolio

**600** highly skilled employees



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## Polyoxidonium®

(Azoximer bromide)

A multi-purpose pharmaceutical product with immunomodulating, detoxifying, and antioxidative properties.

The product is indicated for the treatment and prevention of respiratory infections as well as for the treatment efficacy improvement in gynecology and urology.



## PRODUCT PORTFOLIO

## Longidaze®

(Bovhyarulonidase azoximer)

An advanced combined-effect enzyme for the treatment of connective tissue hyperplasia conditions



## Imoferaza®

A specialized external scar revision cream for the care of scars and cicatricial tissue; it contains immobilized hyaluronidase, an unique enzyme.



## Velson®

(melatonin)

A state-of-the-art medication for sleep normalization and human biorhythms. Velson® regulates the sleep-wake cycles, provides for quicker falling asleep, jet lag and weather changes adaption in meteopathic individuals. It is good for the emotional personality sphere (mood) and intellectual and mnestic functions of the brain (intelligence, memory).



## Grippol® plus

(Influenza vaccine [inactivated] + Azoximer bromide)

A Russian trivalent inactivated influenza 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). It is preservative-free, and supplied in pre-filled syringes.



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A vaccine for prevention of pneumococcal infections caused by *Streptococcus pneumoniae*, serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, such as sepsis, bacteremia, meningitis, pneumonia, and acute otitis media.

Indicated for subjects aged 2+ months without further age restrictions.

The finished dosage form is manufactured as a full-cycle process by Petrovax in cooperation with Pfizer.

## Prevenar® 13

(13-valent polysaccharide adsorbed pneumococcal vaccine)



## INTERNATIONAL PROJECTS LOCALIZED PHARMACEUTICALS

An innovative thrombolytic agent for the treatment of myocardial infarction. The only recommended single-injection, bolus-dose (for 5-10 seconds) thrombolytic agent in the world to be used in the emergency care setting in patients with acute myocardial infarction to provide medical aid within the shortest time possible.

Currently, tenecteplase is one of the most thoroughly studied thrombolytics worldwide.

Manufacturer: Petrovax in cooperation with Boehringer Ingelheim.



## Actilyse® (Alteplase)



## Metalyse® (Tenecteplase)



A biotechnology thrombolytic agent to treat both myocardial infarction and ischemic stroke (which is major advantage and a unique evidence-based indication).

Alteplase is the only thrombolytic medication indicated in patients with ischemic stroke within 4.5 hours following the onset of the symptoms.

Manufacturer: Petrovax in cooperation with Boehringer Ingelheim.

## R&D

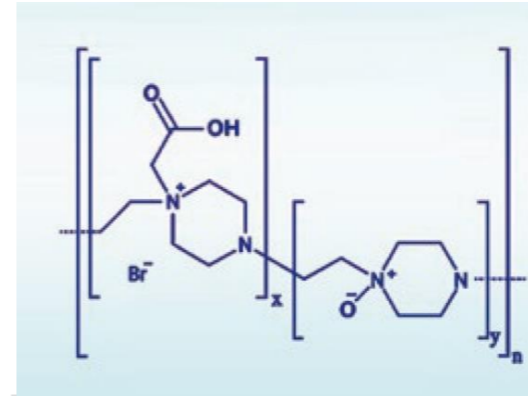
Petrovax's development concept is based on branded products. The R&D and Implementation Department structure provides for the molecule inception and the product lifecycle support from the idea to practical implementation. Ad hoc research involves leading local and foreign industry-specific scientific institutions.



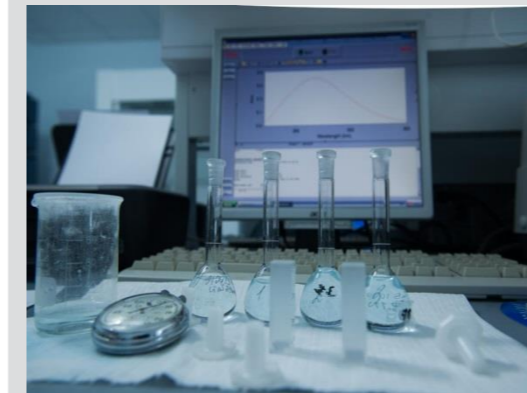
### In-house vivarium

Petrovax has an in-house certified state-of-the-art vivarium with four types of laboratory animals used for clinical trials of own pharmaceutical products and providing CRO services. Specific temperature/humidity parameters and light conditions are maintained in the animals' rooms to provide for keeping SPF mice and rats as well as common breeds of rabbits and Guinea pigs.

Preclinical data from in-house studies make the foundation for marketing authorization applications for the products developed by Petrovax. The company's R&D units have been issued ISO:9001 quality certificates.



An advanced search for promising candidate molecules with further preclinical evaluation of safety and potency. Mechanism-of-action studies in the disease pathogenesis setting for the products under development.



Preclinical safety and efficacy studies for medicinal products-to-be. The development of quality control techniques and production process.



Planning and management of GCP-compliant authorization clinical trials. Implementation of innovative technologies; optimization of state-of-the-art processes; production scale-up.

# Production



**Petrovax** is a full-cycle pharmaceutical company. Manufacturing facilities are fully compliant with the applicable Russian and international GMP standards and ISO 9001:2015 (cleanliness class zoning, raw and other material, personnel, intermediate and finished product flows).



The company's state-of-the-art pharmaceutical manufacturing and warehousing complex was put in operation in Moscow Region in 2008 and is among Russia's most advanced high-tech biopharmaceutical facilities. Petrovax is the first Russian immunobiological manufacturer to be issued international GMP certificates by the state regulatory authorities of the EU (Slovakia) and Iran.



The company manufactures active pharmaceutical ingredients (APIs) and liquid, semi-solid, and solid dosage forms in pre-filled syringes, ampoules, vials. Its production capacities provide for releasing over 160 million shots of immunobiologicals a year.



**1<sup>st</sup> production line:** pre-filled syringe products  
**2<sup>nd</sup> production line:** injectables in ampoules and vials  
**3<sup>rd</sup> production line:** APIs, semi-solid, and solid dosage forms

# Quality



Petrovax has an effective quality management system (QMS) in place, with an ISO 9001:2015 certificate issued.

Importantly, QMS covers not only the production unit but also all other units, including the R&D unit and the company's office.



- The QMS high-level performance is annually certified through a comprehensive audit by ISO certification authorities.
- The document workflow system provides for keeping track of all actions by the employees engaged in product manufacturing and quality control, both in real time and historically.



- The company cooperates with approved raw and other material suppliers only.
- The company has an automated training system in place: WebTutor, an education and professional development web portal, provides each employee with an individual QMS training and testing plan.



A pharmacovigilance system is in place at the company that is run in compliance with the applicable international and Russian regulatory guidelines. To provide for product safety control, the company's pharmacovigilance responsible persons continuously monitor the relevant product efficacy and adverse event data.

## Geography

Petrovax's strategic goals include the expansion of export potential and geographic footprint in respect of sales.

The company operates in all Russian regions and exports its pharmaceutical products to 12 countries.

Prospective export areas: the South-Eastern Europe, Egypt and other MENA countries.



**> 30** Russia's largest cities

**> 10** Export countries



**Belarus:** in 2015, the first in the Russian history manufacturing localization project was implemented that involved the Russian branded Grippol® plus influenza vaccine to be produced in Belarus under the agreement with the Belorussian Ministry of Health and the Republican Unitary Enterprise 'Belmedpreparaty'.



**Iran:** a strategic cooperation aimed to localize production of Grippol® plus influenza vaccine in Iran as well as transfer the relevant 4-valent polymer subunit influenza vaccine production technologies.



# International Projects

## Petrovax

Petrovax collaborates with leading Russian and international research institutes and pharmaceutical companies to develop new products and transfer full-cycle pharmaceutical manufacturing technologies.



**Abbott**

### A biotechnological project unique to the Russian scientific and production areas

- GMP-compliant facility construction.
- Personnel training and implementation of GMP-compliant sterile vaccine manufacturing standards.
- Production of the first Russian Grippol® plus mercury preservative-free vaccine in pre-filled syringes. Since 2009, the vaccine has been procured for the National Immunization Schedule.
- More than 120 million people were immunized with Grippol® plus over the entire successful vaccination period, including under the Russian National Immunization Schedule as well as in the EAEU and Iran .



### Localization of immunobiological products in Russia with a transfer of innovative full-cycle production technologies

- Localization of Prevenar® 13, a 13-valent conjugate pneumococcal vaccine, in Russia including a full-cycle production, control and quality assurance technology in compliance with the applicable international GMP standards.
- Since 2014, the pneumococcal vaccine has been supplied under the Russian National Immunization Schedule. In 6 years, 22 million vaccine shots were supplied .
- Production potential for foreign markets.



### Localization of full-cycle production of cardiac pharmaceuticals

- Petrovax is the second site in the world manufacturing Boehringer Ingelheim's innovative thrombolytic agents.
- The production capacities provide for fully meeting the relevant patient demand in Russia.
- 2017: first commercial batches produced.
- 2019: a full-cycle manufacturing process to be implemented.

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## Company's growth dynamics: 2013 → 2018



In 2013–2018, an average growth rate in terms of annual revenues was 25%. Exports accounted for 12% of the company's total sales as of 2018.



### International partnerships

Successful implementation of a joint project with Pfizer and a start of a new project with Boehringer Ingelheim.



### Production upgrade

Start and completion of the 3rd production line construction. GMP certificates issued by the Russian Federation, EU, Iran, Belarus. The 'Labelling' project.



**Export footprint expansion** to the EAEU, EU, and Iran. Transfer of Grippol® Plus production technologies to Belarus.



**R&D.** Market launch of Imoferaza® skin cream and the first in Russia 4-valent influenza vaccine Grippol® Quadrivalent.



### An updated marketing strategy

Launch of a media campaign and online promotion.



### An efficient regional team

More than 70 employees in 30 cities.  
CRM implementation.



### Business solution automation

Process optimization and management performance boost.



In 2012, Pfizer and Petrovax's pneumococcal vaccine localization project won the All-Russian Contest «**Platinum Ounce - 2011**» in the category "Project of the year".



Petrovax won the All-Russian Contest of the **Russian Union of Industrialists and Entrepreneurs (RUIE) 'Russian Business Leaders: Performance and Commitment' 2017'** in the category 'For the Dynamic Development of Business'



In 2018, Petrovax won the **National Import Substitution Award 'PRIORITY-2018'** for Grippol® Quadrivalent vaccine



In 2019, Petrovax won **the Award «Russian Business Guide. People of the year»** in the category «Pharmaceutics» for the contribution to the Russian economy development and dynamic business activities.



**Polyoxidonium®** won the Russian Pharma Awards in the category 'The Medication of Choice for ARVI and influenza prevention in children' in 2016–2018 and the SmartPharma® Awards in 2018

**Longidaze®** won the Russian Pharma Awards in the category 'The Medication of Choice for pathogenetic treatment of chronic prostatitis and relapse prevention' in 2018



**Thank you for  
your attention!**

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