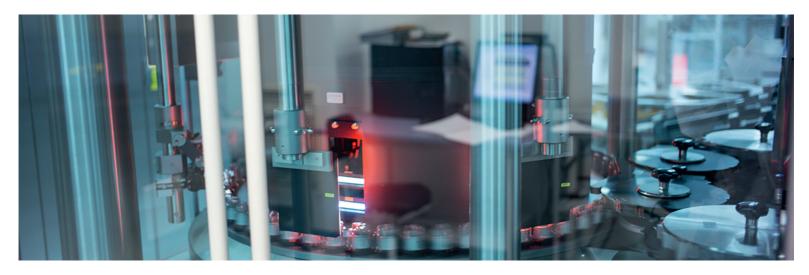




# CONTENTS



Company Profile	2
Strategy	3
History	4
Original Product Portfolio	6
R&D	10
Manufacturing	12
QMS	13
Strategic Alliances	14
Geographic	15
Social Responsibility	16

## COMPANY PROFILE



VEARS OF INNOVATION IN THE PHARMACEUTICAL MARKET

Petrovax Pharm is the leading Russian R&D and manufacturing company focusing on innovative pharmaceutical products and vaccines. The company was founded in 1996 by Prof. Arkady Nekrasov and a group of Russian chemists, biologists and biotechnologists.

- A powerful and promising portfolio of original and innovative pharmaceutical products widely used in the most relevant areas of medicine, such as infectious diseases, preventive vaccination, immunology, urology, gynaecology and reproductive health.
- An advanced R&D platform. Petrovax Pharm holds over 20 patents for new molecules, inventions of pharmaceutical products and manufacturing technologies.
- Hi-tech pharmaceutical manufacturing facilities compliant with the Russian and international GMP standards.
- Pharmaceutical products export to the CIS, EU and Iran. The Russian vaccine localization in Belarus and Iran.
- 650 highly skilled employees.

# STRATEGY



NPO Petrovax Pharm is a full-cycle biopharmaceutical company with an in-house R&D Center, strategic development, API and finished dosage form manufacture, quality control, administrative, marketing and sales units.

#### MISSION

#### STRATEGIC PRINCIPLES

- Development and supply of innovative pharmaceutical products to improve human health and quality of life.
- Commitment to innovative technologies and R&D.
- Building an advanced original product portfolio.
- R&D and manufacturing-related cooperation with pharmaceutical market leaders.
- Manufacturing in compliance with the Russian and international GMP standards.
- Building and development of an expert team.
- Business growth through geographical expansion.

# COMPANY HISTORY



#### 1996-2004

- Petrovax Pharm is founded.
- Polyoxidonium<sup>®</sup> and Grippol<sup>®</sup> are registered.
- Prof. Arkady Nekrasov and his team are awarded the Russian Federation State Prize for Polyoxidonium<sup>®</sup> and Grippol<sup>®</sup> development and implementation in the country's healthcare system.
- A facility is launched to manufacture APIs, semi-solid and solid dosage forms (tablets) and injectables.
- Partnership with Solvay Pharma (currently, Abbott).



#### 2005-2009

- Longidaze<sup>®</sup> is launched to the market.
- A state-of-the-art GMP-compliant manufacturing and warehousing complex is put in operation in Pokrov (Podolsk District, Moscow Region).
- Launch of a unique pre-filled syringe line.
- Grippol<sup>®</sup> Plus a preservative-free innovative influenza vaccine is launched to the market.
- Development and manufacturing of the A/H1N1 pandemic influenza vaccines MonoGrippol Neo, MonoGrippol Plus, and MonoGrippol.





### 2010-2013

- Grippol<sup>®</sup> Plus vaccine manufacturing for the National Immunization Schedule.
- Partnership with Pfizer to localize production of a 13-valent pneumococcal conjugate vaccine (including vaccine manufacturing and registration). This project received a Russian Platinum Ounce award.
- Polyoxidonium<sup>®</sup>Vet Solution is registered for veterinary use.
- EU GMP audit successful completion.
- NPO Petrovax Pharm controlling interest is acquired by Interros Group owner and founder Vladimir Potanin's company.



### 2014-2016

- Agreements are signed on Grippol Plus flu vaccine manufacturinglocalization in the Republic of Belarus and Iran.
- Imoferaza<sup>®</sup>, an innovative special care cosmetic cream for post-trauma, post-surgical and post-acne scars is launched to the market.
- The WHO approves bovhyaluronidase azoximer as the INN for Longidaze<sup>®</sup>.
- The Russian Ministry of Health licenses Petrovax Pharm to manufacture Grippol<sup>®</sup> Plus, a Russian influenza vaccine, using flu antigens produced by St. Petersburg Research Institute for Vaccines and Sera of Russia's Federal Medical and Biological Agency.
- Partnership with Boehringer Ingelheim to localize a full-cycle manufacturing of the most advanced cardiovascular pharmaceutical products.

# ORIGINAL PRODUCT PORTFOLIO

### PHARMACEUTICALS



#### Polyoxidonium<sup>®</sup> (azoximer bromide)

Polyoxidonium<sup>®</sup> is a cutting edge multi-purpose pharmaceutical product with immunomodulating, detoxifying and antioxidative properties. Polyoxidonium<sup>®</sup> is indicated for the treatment of infectious bacterial, viral or fungal diseases etiology, both acute and chronic; it is widely used in surgery, general medicine, urology, gynaecology and paediatrics. Efficacious for influenza and ARVI prevention. Dosage forms: vials, tablets, and suppositories.

#### Longidaze<sup>®</sup> (bovhyaluronidase azoximer)

Longidaze<sup>®</sup> is an advanced extended release enzyme used in a combined therapy of diseases associated with connective tissue hyperplasia (adhesions, scars and fibrous processes). It is used in gynaecology, urology, dermatovenerology, pulmonology, orthopaedics, surgery, aesthetic medicine and otolaryngology. Dosage forms: suppositories and vials.



#### VACCINES

**Grippol family** are the latest-generation inactivated adjuvanted subunit influenza vaccines with proven high efficacy and excellent tolerability. Over the time span of their application, a total of more than 300 million people have been successfully vaccinated.



#### Grippol<sup>®</sup> (influenza vaccine [inactivated] + azoximer bromide)

Grippol<sup>®</sup> has been used for mass immunization in Russia for over 20 years. Since 2006, this vaccine has been successfully used under the National Immunization Schedule.

#### Grippol<sup>®</sup> Plus (influenza vaccine [inactivated] + azoximer bromide)

Grippol<sup>®</sup> Plus is the Russian first preservative-free influenza vaccine produced in disposable syringes. It is widely used to vaccinate representatives of various social categories, including the high-risk groups as follows: children from six months of age, pregnant women, elderly, and patients with chronic somatic diseases, allergic disorders, and immunodeficiency. Since 2009, it has been used under the National Immunization Schedule for preventive immunization of pregnant women and children.

# ORIGINAL PRODUCT PORTFOLIO

### VACCINES

#### **BEAUTY PRODUCTS**





#### Prevenar<sup>®</sup> 13 (13-valent pneumococcal polysaccharide adsorbed vaccine)

Prevenar<sup>®</sup> 13 is used 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, bacteraemia, meningitis, pneumonia, and acute otitis media.

Prevenar<sup>®</sup> 13 is recommended for all age groups starting from 2 months. NPO Petrovax Pharm performs Prevenar<sup>®</sup> 13 full-cycle manufacturing as a finished dosage form jointly with Pfizer.

### Imoferaza®

Imoferaza<sup>®</sup> is a state-of-the-art external scar revision product. It is indicated specifically to treat problem and scarred skin areas resulting from cosmetic procedures, injuries, burns, acne (post-ac-ne), and surgery. Imoferaza<sup>®</sup> may also be applied to reduce the likelihood of unaesthetic scars on damaged skin.



#### **VETERINARY PRODUCTS**





#### **Azoxivet**®

Azoxivet is a high-molecular multi-purpose immunomodulator developed to treat and prevent acute and chronic infectious diseases, deal with intoxications of various origins, and increase resistance to adverse environmental factors.

Dosage forms: 3 and 6 mg ampoules for small pets, and 24 mg and 240 mg ampoules for bigger farm animals.

### **Vetolaza**<sup>®</sup>

Vetolaza<sup>®</sup> is a hyaluronidase (proteolytic enzyme) conjugate with a high molecular weight carrier serving to prolong the primary effect; it is intended for a combined therapy of acute and chronic endometritis to stimulate cattle fertility.

Dosage form: lyophilizate for solution for injection, 20 mg (3 000 IU).

Currently, the pharmaceutical product undergoes registration; its market launch is scheduled for 2017.

### R&D



over 20 PATENTS NPO Petrovax Pharm focuses exclusively on manufacturing original pharmaceuticals. The company operates an in-house state-of-the-art R&D center and is committed to developing new products through investment in R&D projects.

Petrovax Pharm holds over 20 patents for new molecules, inventions of pharmaceutical products and manufacturing technologies.

The R&D function is structured in such a way as to ensure full control at the molecular synthesis stage and throughout the product life cycle from inception to marketing authorization. The company conducts core research enjoying support by the leading Russian and international R&D institutions.

Innovative search for potential candidate molecules with subsequent safety and specific activity evaluation in preclinical trials.

Development mechanism of action study in disease pathogenesis.

Development safety and efficacy profiling in preclinical trials.





### OVER 10 INNOVATIVE PRODUCTS IN THE PIPELINE

Currently, the company has more than 10 innovative products at various development stages.

In the coming years, NPO Petrovax Pharm plans to launch a new multi-purpose polymer pharmaceutical product to treat intoxications of various origins, and three prolonged action biopharmaceuticals with improved pharmacological properties based on recombinant therapeutic proteins for treating hepatitis B and C, anaemia in cancer, chronic renal failure, and rheumatoid arthritis patients.

An adjuvanted quadrivalent influenza vaccine against four influenza strains with the highest safety profile will be commercially available in 2018.

Development of quality and process control methods.

Planning and conduct of pivotal clinical trials.

Implementation of manufacturing processes, upgrade and improvement of established processes, and production scaleup.

# MANUFACTURING





NPO Petrovax Pharm is a full-cycle pharmaceutical company with the manufacturing unit fully compliant with the Russian and international GMP standards and ISO 9001:2008 (cleanliness class zoning, raw and other material flow, personnel, intermediate and finished products). The company operates its own warehouse to ensure appropriate storage conditions for the pharmaceuticals produced.

It manufactures APIs and liquid, semi-solid, and solid dosage forms in disposable syringes, ampoules, vials and plastic containers. Its production capacity is over 160 m doses of immunobiologicals per year.

The company's hi-tech pharmaceutical manufacturing and warehousing complex put in operation in the Moscow region in 2008 is among Russia's most sophisticated biopharmaceutical enterprises. Petrovax Pharm is the only immunobiological manufacturer in Russia holding international GMP certificates issued by the government regulatory authorities of Ukraine, the EU (Slovakia) and Iran.









Petrovax Pharm has an effective **quality management system (QMS)** in place officially certified to the ISO 9001:2008 standard.

Aside from the manufacturing unit, it covers all of the company's supporting functions, including the R&D and back office.

- The QMS high-level performance is annually certified through comprehensive audits carried out by an ISO certification authority.
- The document management system provides for keeping track of all actions by the manufacturing and quality control personnel, both in real time and historically.
- Petrovax Pharm cooperates with the approved raw material suppliers only.
- The company has an automated QMS training program in place based on the WebTutor, an education and professional development portal providing each employee with individual QMS training and testing plans.

Petrovax Pharm also runs a **pharmacovigilance system** set up in compliance with the international standards and the Russian regulatory requirements. The company's pharmacovigilance experts perform ongoing monitoring of pharmaceutical product efficacy and adverse effect data of to ensure a proper safe drug use control.

# STRATEGIC ALLIANCES

Petrovax Pharm partners with the major Russian and international R&D institutions and pharmaceutical companies to develop new products and transfer full-cycle manufacturing technologies.

### PARTNERSHIPS IN RUSSIA

- Petrovax Pharm's R&D activities have been based at the Institute of Immunology – State Research Center of Russia's Federal Medical and Biological Agency (FMBA), the company's trusted partner ever since.
- For over 20 years, Petrovax Pharm has partnered with the Research Institute of Influenza, the Scientific Children's Health Center of the Russian Academy of Medical Sciences, and the Research Institute for Pediatric Infections of Russia's FMBA in the innovative influenza vaccine research.
- Petrovax Pharm and St. Petersburg Research Institute for Vaccines and Sera of Russia's FMBA developed and implemented a highly purified influenza antigen manufacturing technology without mercury preservative. Due to this project, since 2016, all Grippol<sup>®</sup> Plus ingredients have been manufactured in Russia.

#### **INTERNATIONAL PROJECTS**

- In 2008, Petrovax Pharm, jointly with Abbott (former Solvay Pharma), successfully completed the construction of a modern pharmaceutical facility to develop and manufacture immunobiological pharmaceutical products.
- In 2015, the company delivered a localization project jointly with Pfizer to implement a full-cycle manufacturing, quality control, and quality assurance technology for a 13-valent pneumococcal conjugate vaccine.
- In 2016, Petrovax Pharm established a partnership with Boehringer Ingelheim to localize full-cycle manufacturing of the most advanced cardiovascular pharmaceutical products.







\bbott

### GEOGRAPHIC





**Belarus:** In 2015, Petrovax Pharm completed the first-ever manufacturing localization project for Grippol<sup>®</sup> Plus, a Russian original influenza vaccine, in Belarus as part of its agreement with the Ministry of Health of the Republic of Belarus and Republican unitary enterprise Belmedpreparaty.



Iran: Petrovax Pharm has established strategic cooperation with Iranian partners to localize Grippol® Plus (a Russian influenza vaccine) manufacturing in Iran and transfer technologies for manufacturing a quadrivalent polymer subunit influenza vaccine.

# SOCIAL RESPONSIBILITY



### 6 KEY FOCUS AREAS

- Professional conduct, business and management ethics. High standards of both internal and external relations.
- Major contribution to the Russian pharmaceutical industry development. Petrovax Pharm is a member of the Union of Professional Pharmaceutical Organizations and the Association of Russian Pharmaceutical Manufacturers.
- Comprehensive staff training and professional development programs. Petrovax Pharm's employees are given an opportunity to improve their professional skills through internal and external training programs. The company strictly adheres to the HSE principles and regulations and implements social programs for its employees.









- Charity. Ever since its incorporation, Petrovax Pharm has been actively engaged in supporting nonprofit organizations, veterans, healthcare, and educational institutions.
- Education and awareness raising. Petrovax Pharm supports educational projects for students and physicians as well as initiatives to promote influenza vaccination among the general public and healthcare professionals.
- Environmental protection. The company's facilities operate in full compliance with the international environmental and pharmaceutical product manufacturing and quality control standards, including GMP and ISO 9001.



22 Krasnaya Presnya St., Moscow, 123022, Russia Tel./Fax: +7 (495) 730-75-45/60 E-mail: info@petrovax.ru www.petrovax.ru