



PHARMACTA  
NON-COMMERCIAL PARTNERSHIP  
QUALITY AND STANDARDS

# PharmActa. Quality and Standards.

---

Moscow, 2016

# General Information



PHARMACTA  
NON-COMMERCIAL PARTNERSHIP  
QUALITY AND STANDARDS

- PharmActa is non-commercial partnership and was founded in 2011.
- Based on scientific evidence, PharmActa supports the harmonization of Russian regulations of medicines with EU/US standards.
- Our knowledge builds on over 30 years of scientific research in the field.
- Half of the Top 20 pharma companies are supporting the partnership.
- Experience in BRIC markets.
- Collaborations with regulators in EU e.g. Germany and EAEU, e.g. Russia.
- Cooperation with leading academic institutions in EAEU and EU.

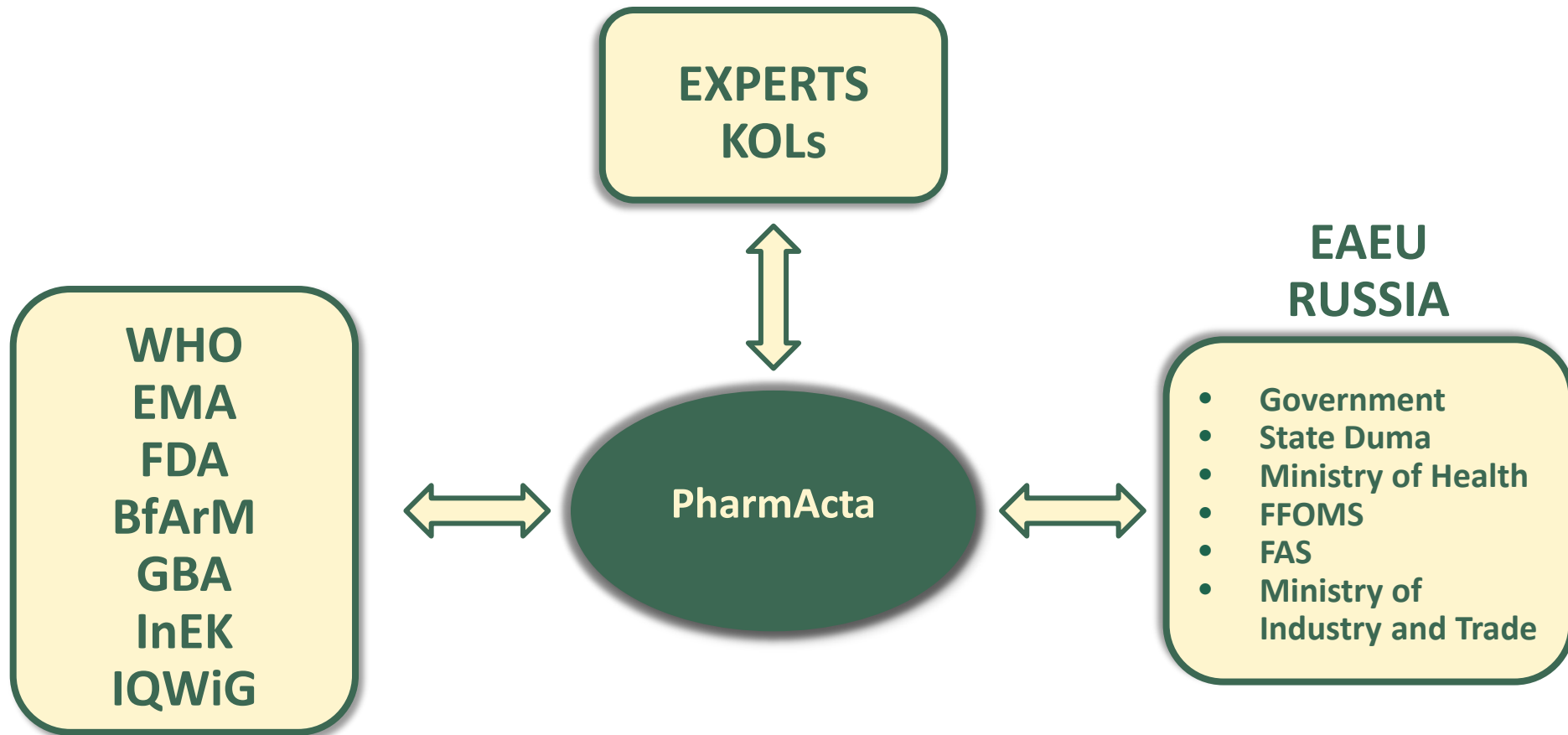
# Mission



- Support the development of the drug market in Russia and EAEU.
- Harmonization of the Russian/EAEU regulation of medicines and Optimization of the Russian health system with international standards, incl. approval process, pricing, interchangeability, quality control, clinical trials, reimbursement/budget, DRG-formation, etc.
- Represent the interests of its members at the government level.

- **Analyze** the regulatory environment of the Russian/EAEU drug market.
- Work out **recommendations** for the development of the Russian/EAEU drug market.
- Involve specialists (KOLs) to validate our recommendations, present drafts of **guidelines and changes in the law** to the government.
- Support the **improvement of Russian/EAEU regulation** impacting drug **quality**.

# Collaboration scheme

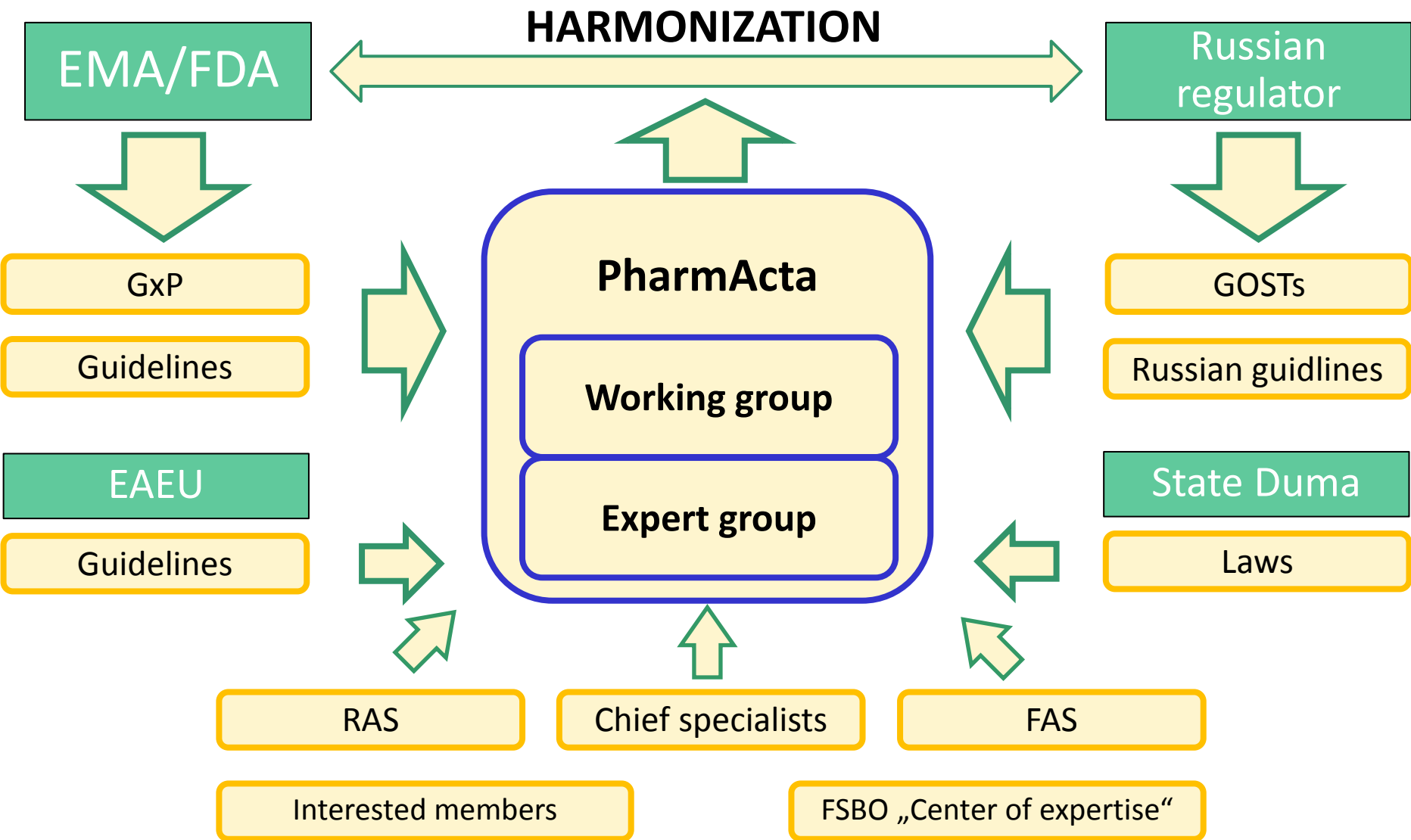


# Activity plan 2016

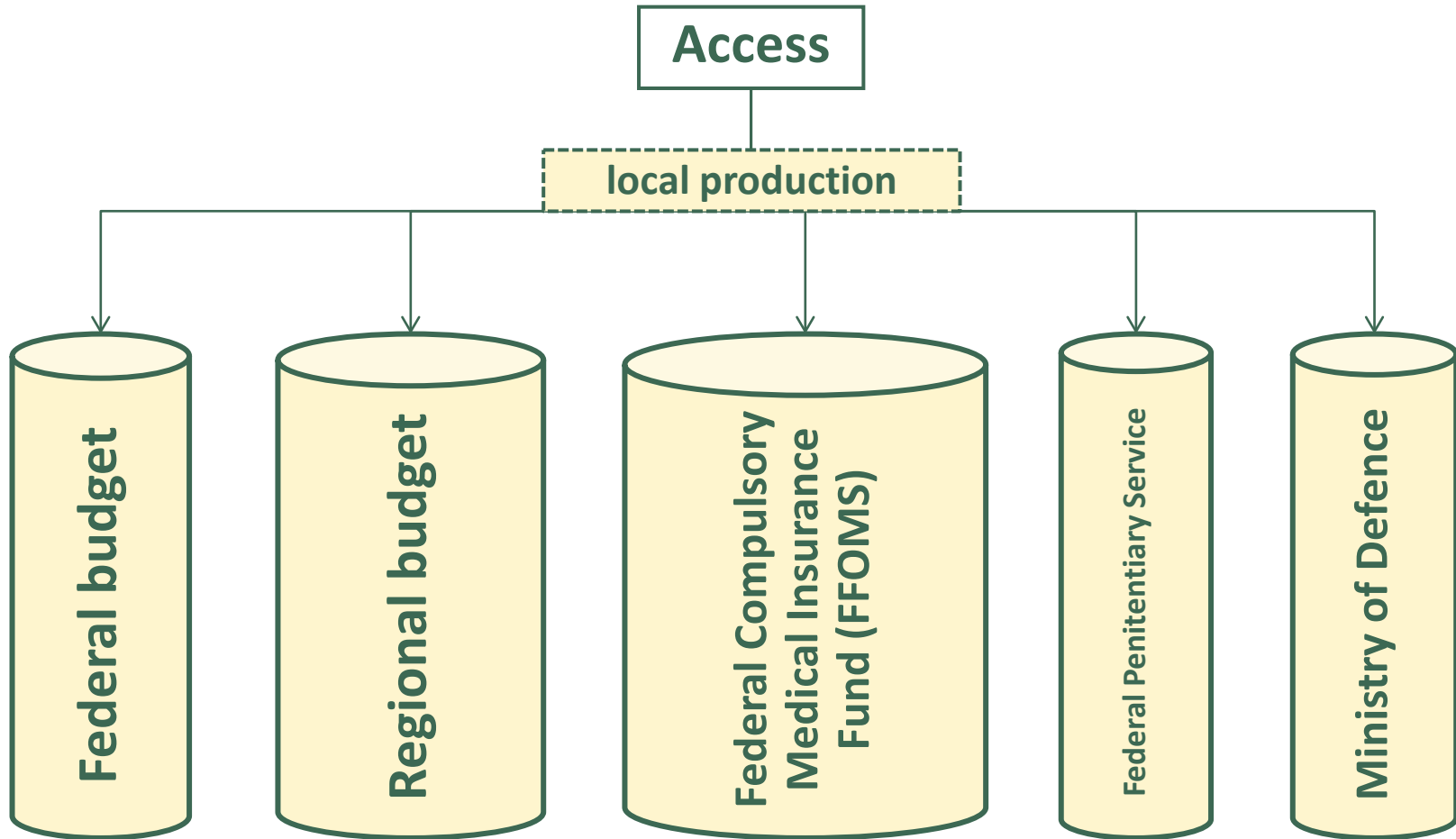


- Support of import substitution.
- DRG. Development. Recalculation of coefficients. Formation of new (sub)groups. Support of the developments of the working group at HIF.
- Pricing: innovative medicines and Gx. New methodology. Improvements.
- EDL. Formation. Support.
- Prevention, diagnosis and treatment of HIV/Hep C in the Russian Federation. Improvements. Increasing of drug access. Compulsory/voluntary licensing.
- INN of biosimilars. Development of the recommendations.
- Support of the development of guidelines in EAEU.
- Improvement of the patent system/law. Amendments to the Civil Code to reduce the consequences of patenting additional or new uses and therapies of a known drug, as well as the consequences of ill-founded patents.

# How we work (example)



# Support in access





# Cooperation (Russia)



PHARMACTA  
NON-COMMERCIAL PARTNERSHIP  
QUALITY AND STANDARDS



State Duma



ФАС России

The Federal Antimonopoly  
Service



Ministry of Health



Federal Service for Supervision of  
Consumer Rights Protection and  
Human Welfare



Federal Compulsory  
Medical Insurance  
Fund (FFOMS)



Federal State Budgetary  
Organization "Scientific center  
of expertise of medicines"



Federal AIDS Center



Lomonosov  
Moscow State  
University



*Russian Academy of Sciences*



Interregional public organization  
"Association of Clinical Pharmacology"



PharmActa. Quality and Standards

125190, Moscow

Leningradsky prospekt d. 80 korp. 17

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

contact@pharmacta.com