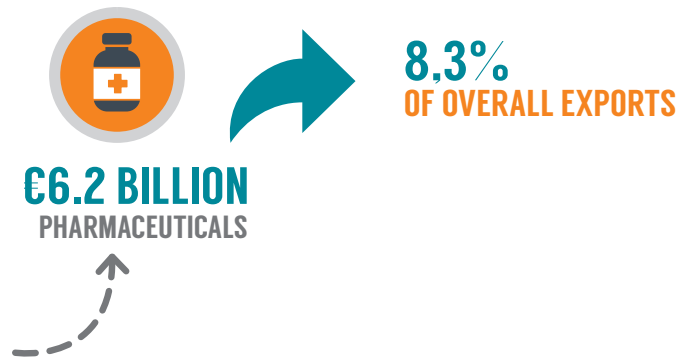


## EFPIA Key priorities in Russia

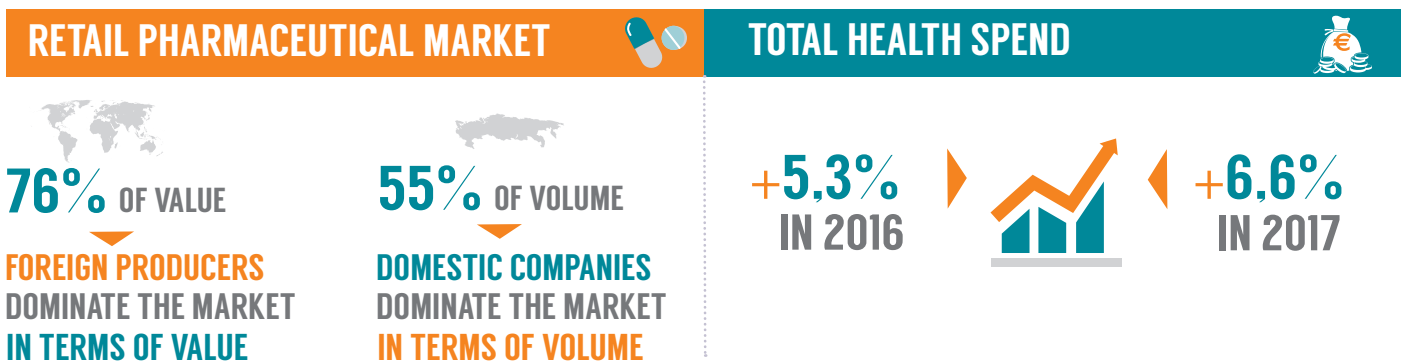


Russia remains the fifth largest export market for European pharmaceuticals (following US, Switzerland, Japan and China), covering a total of 4.3% of total EU pharmaceutical exports<sup>1</sup>. In 2015, EU exports to Russia amounted to €73.9 billion, and pharmaceuticals made up 8.3% of these exports, representing €6.2 billion. However, the economic slowdown coupled with strong protectionist government policies have significantly worsened the outlook for the industry and the ability to effectively access the Russian market. In the past years, exports fell significantly, and in 2015, the growth rate plummeted to -28.4%, including a -20.3% growth rate for innovative pharmaceuticals, compared to 2014 figures<sup>2</sup>.

**RUSSIA IS THE 5<sup>TH</sup> LARGEST EXPORT MARKET FOR EUROPEAN PHARMACEUTICALS**



Taking into account foreign exchange effects, the pharmaceutical industry has also been strongly affected by the broader economic effects of low oil prices, high interest rates, and strong consumer price inflation. Weak GDP growth will slow down further improvements in access for patients (including to innovation) due to significant funding constraints and budget cuts, where public healthcare expenditure is expected to stay at a similar level (total health spend in Russia is forecast to grow at a rate of 5.3% in 2016 and 6.6% in 2017<sup>3</sup>). Domestic producers have traditionally concentrated on the production of generics. Foreign producers have a strong presence in the retail pharmaceutical market in terms of value (76%), while domestic companies dominate the market in terms of volume (55%), notably supported by government localisation policies<sup>4</sup>.



The investment climate and market access continues to be challenging for the innovative pharmaceutical industry, as the Russian Government continues to focus on a protectionist agenda, with increased localisation efforts such as discriminatory tendering procedures and proposed compulsory licenses, in order to support domestic manufacturing.

<sup>1</sup> Eurostat, Comtext database, April 2016.

<sup>2</sup> [http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc\\_113440.pdf](http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_113440.pdf)

<sup>3</sup> IHS Life Sciences Healthcare Forecasts and MARS Q4 updates, October 2016

<sup>4</sup> IHS Country and Industry Forecast 2015



## REGULATORY ISSUES

### Good Manufacturing Practice (GMP)

Since January 2016, Russia requires local GMP certificates for foreign producers as part of the drug registration application. Due to the timelines for the certification procedure<sup>6</sup> and capacity constraints, this effectively hinders access to the market of foreign producers, whereas the same requirements do not apply for local producers. As a consequence, there have been no new drug registration applications filled by foreign companies in Russia in 2016. A set of proposed amendments have been put forward by the government, with industry participation, where foreign manufacturers can apply for registration of new products without a valid Russian GMP Certificate, which is pending outcomes of discussion in the Duma.

### Eurasian Economic Union (EAEU) Common Pharmaceutical Market

On 16 November 2016, EAEU Member States signed the entry into force of the common pharmaceutical market. This is a welcome development as the regulations are aligned with EU and ICH standards and EFPIA, in coordination with our local association AIPM, has been actively supporting the regulators throughout this process. However, it is unclear how the regulations of the common market will be enforced, and EFPIA considers it important to closely monitor and effectively support the proper implementation of the common marketplace.



## PROCUREMENT

In November 2016, a draft resolution presented a three-tier preference procurement system, which effectively hinders access of foreign producers to state procurement of medicines. It stipulates priority in tender access for a product that has a full cycle local manufacturing process (including the active pharmaceutical ingredient) currently in Russia but going to be extended to the Member States of the Eurasian Economic Union (EAEU). If no such product exists, the tenders will be based on current regulations, i.e. a 15% price preference to local products and the “three is a crowd rule”<sup>5</sup>.



## INTELLECTUAL PROPERTY

### Regulatory data protection (RDP)

In October 2016, the Russian Ministry of Health published amendments to Federal Law Nr 61, which contain elements that are contrary to Russia’s WTO commitment to provide an effective RDP period of six years. These would allow (pre)-clinical data available in the public domain to be relied upon by a generic company for state registration of its products before the expiry of the originator’s RDP term and without any longer requiring the written consent or the right-owner. Such an approach is of significant concern as it would go against the very principle of RDP and contribute to further weakening the RDP regime in Russia.

### Compulsory Licensing (CL)

In November 2016, the Government presented a draft law on CLs that provides for amendments to the Russian Civil Code whereby the Government may authorise the use of a patented product without the consent of the right-holder for the purposes of protecting national security and health. Specifically, it is justified by the need to reduce the economic dependence of Russia upon foreign manufacturers in light of growing prices and currency fluctuations. This clearly amounts to protectionism and discriminates against foreign manufacturers on grounds that are not compatible with the principles of the WTO TRIPS Agreement. In addition, the procedure and criteria for granting CLs are unclear and prone to abuse.

<sup>5</sup> The foreign product will not be allowed to participate in tenders in case two or more local products have submitted a bid

<sup>6</sup> Long period for GMP certificate issue procedure – 230 working days