# Why Russian Pharmaceutical Market is Attractive for Foreign Generics, ARS PharmRussia Explains

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Overseas generic pharmaceutical industry from ICH region (US, Japan, EU) and 'pharmerging' countries have good opportunities to gain profits in Russia despite the strong governmental support of local drug manufacturers.

How can producers from ICH countries benefit?

It is expected that the rules of the Eurasian Union (EAEU) on medicines' registration, examination and bioequivalence investigation will actually work in 2018. They will be very close to the EU guidelines. The legislation will allow to register a medicine based on own clinical research data obtained in ICH countries before 2016; a reference product may originate from ICH countries, not compulsory from Russia; bio-waivers will be applicable for BCS class I and III drugs in immediate-release oral solid dosage forms; etc.

Considering the above, it becomes feasible to combine one bioequivalence study for EU and EAEU drug marketing authorization applications through placing this at a Russian clinical pharmacology unit and using bioanalytical pharmacokinetics laboratory and taking a reference drug from EU.

What about advantages for generics makers from developing countries?

Currently, Indian companies mainly benefit from their presence in the Russian market. In 2017, they sponsored 31 of 222 local bioequivalence clinical studies approved by the Russian Ministry of Health; 151 trials were initiated by local companies, 25 projects - by EU developers, and none - by producers from China or Brazil.

At the same time, Russia is among top generic drug markets in the world. In 2017, the share of generics was 64% in monetary and 88% in natural terms; GI, CNS, and CV products were in the lead in sales.

From other side, today Russian finished drug makers are highly dependent on foreign APIs, mostly coming from China, India, and France. To stimulate localization of APIs production in Russia, the state plans to provide preferences to domestic producers of the full cycle.

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Nevertheless, presently 90% of Russian drugs are made from imported substances. Therefore, the finished drugs market remains competitive and lucrative for foreign players.

Moreover, in Russia, there are about three dozen state and private bioequivalence research units actively competing with each other, differing in cost, experience, and CRO's clinical monitoring required. In 2017, the average workload was eight bioequivalence projects per unit per year, ranging from one to 28 studies per center annually. Hence, underutilized capacities are still significant.

*Relevant links:*
www.pharmrussia.com
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