The Challenges and Opportunities of a Foreign Drug Registration in Russia, ARS PharmRussia Reveals

By Ekaterina Mochalova, Director of Business Development at ARS PharmRussia

15-Jan-2018

Few foreign biotechnology & pharmaceutical companies know about real chances to win state tenders in Russia. Overcoming local challenges, they gain great opportunities in drug development.

What an overseas maker needs to prepare

When applying for registration of medicines manufactured abroad, a potential marketing authorization holder (MAH) is obliged to provide a Russian GMP. Moreover, a typical dossier must include local clinical research data. The lack of clear dossier documentation requirements for certain groups of drugs and the situational approach at the expertise stage create additional obstacles.

The protectionist state policy supports domestic biopharmaceutical industries and encourages localization of production in the country; for instance, today it is impossible to win a public procurement tender by a foreign company when there are two or more Russian participants. Government regulation of pricing of medicines from the Vital and Essential Drugs List (VEDL) is often unfavorable for foreign businesses with considerably higher R&D expenditure.

It is also required to adjust a normative document (quality control indicators and methods) in accordance with the National Pharmacopeia and to translate into Russian and print out a large amount of documents of a drug dossier no matter what the volume is. Absence of actual legislation resources in English causes another problem.

Opportunities in drug development

Engaging Russia in multinational late-stage clinical research gives access to high quality data, significantly lower labor cost and fast patient recruitment, as well as enables a foreign drug developer to avoid additional local ‘registration’ Phase III studies. Withal, local clinical trials are not required for the medicines approved more than twenty years ago, orphan drugs studied abroad, and generics in the form of water solutions, powders, lyophilizates, and gases; extra optimization scenarios are provided by the Eurasian Union (EEU) legislation.

ARS LLC, Testovskaya St. 10
MIBC “Moscow-City”, Northern Tower
Moscow, 123112, Russia
Phone: +7 (495) 374 62 84
Fax:+ 7 (499) 638 23 00
E-mail: info@pharmrussia.com
http://www.pharmrussia.com

Currently expensive and important medicines are purchased by the state; almost half of the drugs from the state registry refer to VEDL; around 47% of INNs from the List are still either not covered by the Russian manufactures or produced only by one local company.

CTD format implemented and the possibility for a foreign entity to act as a MAH simplify drug registration process and reduce business risks for the industry from abroad. Furthermore, until 2021, a Russian GMP will be acceptable for drug registration within the EEU procedures.

Relevant links:
www.pharmrussia.com
www.eurasiancommission.org/ru/nae/news/Pages/20-09-2017-V.aspx
www.grls.rosminzdrav.ru

Source: https://www.prnewswire.com/news-releases/the-challenges-and-opportunities-of-a-foreign-drug-registration-in-russia-ars-pharmrussia-reveals-300581980.html