Clinical Trials in Russia & EAEU’s Regulatory Update

Declining healthcare spending combined with increased pressure on the HC system budget is creating an incentive for patients to consent to new treatments and fostering a positive environment for the development of the CT sector. There are a multitude of factors that influence companies’ decisions to open clinical operations in Russia for all types of clinical trials: the patient pool, relevant investigators’ expertise and cost-efficiency, to name just a few. This article analyses the key factors that are shaping the Russian and CIS market for clinical trials in the short term, and discusses the regulatory initiatives that are coming into force to facilitate its further development, in particular the introduction of the regulatory framework affecting the clinical trials sector within the Eurasian Economic Union (EAEU).

Having a projected value of 21 billion dollars in 2019, the Russian and CIS pharmaceutical markets remain attractive for the international pharmaceutical industry. There are many unmet medical needs in the region, particularly in the treatment of non-communicable diseases and lifestyle disorders, such as cardiovascular diseases, diabetes and cancer.

The Healthcare, Pharmaceutical and Clinical Trial Environment in Russia
With the increasing price pressure on international pharma, and with promotion of cheaper generic alternatives in the region, it remains unclear how the current deteriorating economic situation in Russia and the CIS will affect patients’ access to innovation. Russia does not have a well-defined reimbursement system and there is no clarity as to what path the reimbursement in Russia will take in the near future – either opting to concentrate on socially unprotected categories, patients with treatable conditions, severe stages of diseases or the working population. An additional challenge in bringing innovative drugs to market lies with the current procedure for registration of pharmaceutical products that may appear daunting and lengthy to the companies that do not have substantial local knowledge of the political, cultural and regulatory differences. However, the slowing of HC spending and increasing pressure on the HC system budget create an incentive for patients to consent to new treatments and create a positive environment for the CT sector development.

How is Russia Positioned in the Clinical Trial Landscape?
Growth in the number of clinical trials conducted in the country has increased considerably over the past five years, with an average of close to 100 new trials being conducted every year. The number of trials outsourced to CROs is also growing, offering pharma an opportunity to benefit from local resources and specialised expertise.

The EUEA region is positively ranked in terms of cost-saving opportunities, and in 2016 clinical trials in Russia alone were sponsored by companies from 39 countries.

How is it Possible to Increase the Competitiveness of Russia and the CIS?
Stability and predictability in the regulatory process could be a game-changer: improving opportunity for direct discussions with authorities on dossier submission, greater transparency, simplifying the process and reducing the time needed for clinical trial applications were mentioned by the industry players as key improvements that would be welcomed by the market players. Krishnan Ramanathan at Novartis commented that the “Greater focus on pediatric critical trials and granting priority for early stage studies (Phase II Vs. Phase III) will help to address unmet needs.” He also...
added that “such improvements as increasing digitisation and availability of electronic medical records can lead to accurate planning and patient selection. Creation of local registries and epidemiology data for better surveillance of different diseases could help demonstrate health-economic benefit in addition to clinical-benefit.”

**Figure 3. The clinical trials map of the world (Source: QuintilesIMS)**

**Clinical Trials – New Legislation**

One of the most noteworthy changes that the market expects is a long list of regulations of the Eurasian Economic Union that will enter into force in the next 1-10 years, including those related to clinical trials and aiming at further harmonising procedures of registration and control in circulation of medicines in Russia and the EU/US.

**The Introduction of the Regulatory Framework Affecting the Clinical Trials Sector within the Eurasian Economic Union (EAEU)**

The Eurasian Economic Union includes the Russian Federation, the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan and the Kyrgyz Republic. The creation of a single market will have an enormous impact on the development of the pharmaceutical industry as a whole and will particularly affect the clinical trials sector.

The legal framework for the medicines and medical product circulation in the EAEU is in the final stage of development. A number of documents have been shaped by the Department for Technical Regulation and Accreditation, Eurasian Economic Commission in the past couple of years.

During the Clinical trials in Russia Forum organised by the Adam Smith Conferences in November 2016, Moscow, Dmitry Rozhdestvensky, Deputy Head of the Department for the Coordination of Formation of the Common Market for Drugs and Medical Devices, Department for Technical Regulation and Accreditation, Eurasian Economic Commission, explained the guiding principles of the new legislation. He announced mid-2017 as a release date for the much-anticipated uniform procedure of clinical trials in the EAEU, as well as the document containing requirements for the inspection of clinical trials.

The new regulation incorporates the best European practices and is aimed at ensuring unity of the mandatory requirements for the quality, effectiveness and safety of drugs which are circulated in the territory of the EAEU. At present, those documents are displayed at the Eurasian Economic Commission’s website and are open for public discussion.

**What to Expect from the New Regulatory Framework in the EAEU**

All new drugs will be analysed based on the new standards that are in line with the Guideline for Good Clinical Practice (GCP), while genetic parameters will be in line with those outlined in the Good Laboratory Practice (GLP). As for previously approved generic drugs, they will have to undergo a procedure of “bringing the dossier into compliance” (in order to ensure that the dossier is in line with the new Union’s requirements). Mr Rozhdestvensky announced that producers will have a lead time of up until the end of 2025 to ensure that the volume of the investigation (data used) is compliant with the new Union’s standards. Industry players are encouraged to look for the supporting data across the published scientific research papers.

Time lead for the approval of the clinical investigation is still considered rather long, compared to EU countries, which has an immediate impact on commercial motivation. While 30 days for designing a protocol is considered sufficient for the experts to raise any issues, it is unlikely that this period will be shortened by the regulator.

Addressing the audience’s questions regarding the prospects of implementing seamless Phase II/III designs, Dmitry Goryachev, Head of Expertise and Control of Ready Medicaments, FSBI “Scientific Centre for Expert Evaluation of Medicinal Products” of the Ministry of Health of the Russian Federation, reassured the industry that if properly applied, there is no regulatory objection in principle to a seamless Phase II/III design forming one part of a confirmatory evidence base. At the same time, in order to merge Phases II and III, regulators will require strong scientific proof and statistical data, outlining the grounds. He also mentioned the necessity of the submission of the intermediate data analysis, in order to share the scientific and statistical evidence with the regulator.

With year-on-year growth in the number of approved clinical trials, fast patient recruitment rates, experienced investigators and further development and increased transparency of the legislative framework regulating the Eurasian Economic Union, EAEU countries are staying
in the spotlight for sponsors and CROs alike. Increasing digitalisation and further use of innovative technologies, as well as creation of the unified electronic medical records, would further facilitate development of clinical trials and would approve availability of the innovative medicines to the patients.

References
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4. QuintilesIMS report, November 2016

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