Contributed by: CMS Russia, Vsevolod Tyupa, Counsel, Head of Life Sciences & Healthcare

Reflections on the cancellation of local clinical trials and other important legislative developments for pharmaceutical companies

The legislator and the expert community in Russia have reverted to the discussion of the recognition of the results of clinical trials conducted outside the Russian Federation. Currently, the registration of a drug in the country requires so-called "local" clinical trials, i.e. trials conducted in Russia by medical institutions accredited by the Russian Ministry of Health. This takes a significant amount of time (up to one and a half to two years) during which the drug is not available to a wide range of patients. An exception to this rule is made only for so-called "orphan" drugs. These are drugs intended for the treatment of especially rare diseases (the incidence rate should not exceed 10 cases per 100,000 people; the list of such diseases is approved by the Russian Government).

Taking such a decision and amending the legislation accordingly would definitely be a step forward for the Russian pharmaceutical industry. The recognition, at least partially, of the results of clinical trials conducted in developed countries outside of Russia is long overdue.

Many experts believe that it is excessive to conduct another trial in Russia as the drug has already been tested in the European Union, the USA and other developed countries. These countries (for example, Germany, the UK, France and Japan) enjoy advanced medicine and the highest standards of clinical trials. Therefore, one more trial in Russia will not bring any significant added value. Also, for the benefit of patients, it would be more reasonable to recognise the results of foreign trials in order to register a drug in Russia, thereby making it possible to launch the drug more quickly on the Russian market.

That said, one should also agree with the fact that not all the results of foreign clinical trials can be recognised in Russia. Many of these results may be irrelevant to our country. By way of example, one can refer to the inadequate quality of trials (given the low level of medicine in the country of the trial), or the significant difference between the biological and anatomical characteristics of the trial patients and those of Russian residents (e.g. different ethnic origins). Obviously, the results of a clinical trial conducted in Congo or Guatemala would be of little use in Russia because of the different pharmacodynamic effect of the trial drug on the body of a patient belonging to a different ethnic group, and significantly differing genetic and physiological features and the lack of confidence that the trial was conducted in compliance with all international standards.

Therefore, when deciding whether to recognise the results of foreign clinical trials, the following key factors should be taken into account:

- a clinical trial has been conducted in a country that complies with international standards on clinical trials and at a duly licensed and accredited healthcare facility;

- the results of a clinical trial are applicable to Russia taking into account ethnic, genetic and physiological features of the patient census in the clinical trial country.

Also, the existing mechanism for recognising clinical trials of "orphan drugs" could be applied for other medicines. Currently, in order to have "orphan" drugs registered in Russia, reports on clinical trials conducted abroad can be submitted provided that the conditions of the trials meet the requirements of good clinical and laboratory practices in Russia, and that the trial reports have been translated into Russian.

Interestingly, under Article 3(5) of the Federal Law "On Circulation of Medicines", foreign clinical trials can in theory be recognised "based on a reciprocity principle" and "in accordance with international treaties of the Russian Federation". In other words, Russia can enter into an international treaty with another country to recognise the results of clinical trials on a reciprocal basis. However, in practice this rule has been in a "sleeping mode", and no such treaties between Russia and other countries have ever been signed.

Apart from possible changes relating to clinical trials, the Russian pharmaceutical market will, in the near future, see a number of other legislative developments. The most notable of them are the introduction of a new system of medicine quality assurance, that will become effective from 29 November 2019, and a new marking system in 2020.

Instead of the requirement to file a declaration of conformity, which has been in place for many years, pharmaceutical companies will soon be required to submit two documents to the Russian Federal Service for the Supervision of Public Health and Social Development (Roszdravnadzor), namely a certificate of analysis for the medicine and a confirmation that the medicine is in conformity with the registration dossier. In addition, drug manufacturers will be required to file with Roszdravnadzor the protocols of studies of the first three series (batches) of a first-time produced or imported medicine which studies must be conducted by a Russian laboratory subordinate to the Ministry of Health or Roszdravnadzor. Thus, the legislator intends to introduce a stricter and more efficient model of quality assurance than the previous one.

The new marking system that will start to apply next year will allow monitoring medicines on route from the manufacturer to the consumer and confirm their authenticity. This is intended to allow for the swift and efficient identification of poor-quality and counterfeit medicines and thus create serious obstacles for illicit dealers distributing such medicines.