RUSSIAN PHARMACEUTICAL MARKET: THE 2018 YEAR RESULTS

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VEGAS LEX

Content

In this overview, we summarize the results of regulatory developments on the Russian pharmaceutical market in 2018 and analyse possible impact on the industry.

The basic changes in state regulation of the pharmaceutical industry in 2018 relate to pricing and registration of medicines listed on the Vital and Essential Drugs List (hereinafter — the EDL). The work on implementation of mandatory drug labelling also continues.

It is important to mention the measures focused on development of contract manufacturing of drugs in Russia. Furthermore, Russian legislation is being gradually harmonized with the legislation of the Eurasian Economic Union (EEU). However, issues related to parallel imports and compulsory licensing still remain outstanding.

The new registration rules of the maximum manufacturer's selling price of an EDL medicine as well as methodology for calculating such prices have been introduced

Maximum manufacturer's selling prices (hereinafter — the MSP) are subject to state control only if they apply to medicines included in the EDL, annually approved by the Russian Government. Over the period of 2017 to 2018, the Ministry of Healthcare of the Russian Federation (hereinafter — the MoH) has been dealing with development of new pricing rules that are divided in two documents:

- the Rules for Registration of the Maximum Manufacturer's Selling Prices for EDL Medicines (hereinafter — the Price Registration Rules)
- the Methodology for Calculation of the Maximum Manufacturer's Selling Prices for EDL Medicines upon State Registration and Re-Registration (hereinafter — the Pricing Methodology)[1].

The documents initially drafted by the MoH have been criticized consistently by both pharmaceutical industry representatives and key governmental stakeholders — the Federal Antimonopoly Service (hereinafter — the FAS Russia) and the Ministry of Industry and Trade of the Russian Federation (hereinafter — the MoIT). However, after numerous discussions, the approved documents still contain disputable provisions.

The Price Registration Rules preserve the possibility for manufacturers to increase the MSP, however such re-registration is allowed only once a year. To increase the MSP the applicant shall submit supporting documents to the FAS Russia for economic analysis[2]. At the same time, there are no limitations on a number of re-registrations to revise the MSP downwards[3].

The Pricing Methodology has introduced the following new developments:

- the maximum level of profitability of EEU manufacturers shall not exceed 30% upon re-registration of the MSP[4];
- the "basket" of reference countries was renewed and now includes Hungary, Belgium, Greece, Spain, the Netherlands, Poland, Romania, Slovakia, Turkey, France, the Czech Republic and the country of a foreign drug manufacturer[5].

The MSP for a foreign medicine offered for state registration shall not exceed the minimum selling price for the same medicine in reference countries. Moreover, if a drug price reduces in one of the reference coun-

1 Both the documents approved by the Russian Government Decree dated 8 October 2018 No.1207.
2 Clause 35 of the Price Registration Rules.
3 Clause 30 of the Price Registration Rules.
4 Clause 23 of the Pricing Methodology.
5 Annex No.2 to the Pricing Methodology.

tries, the manufacturer is obliged to reduce the registered MSP in Russia. To comply with the new requirements the drug manufacturers need to monitor the world prices regularly.

In furtherance of the policy of drug price reduction, on 16 January 2019 the Russian State Duma approved in the first reading the draft federal law obliging manufacturers to revise all previously registered MSP for EDL medicines according to the new Pricing Methodology[6]. The deadline for submitting amendments to the draft law is 14 February 2019.

Market experts suggest that manufacturers may have to increase prices for non-EDL drugs to reimburse the expenses incurred upon reduction of prices for EDL drugs according to the new rules.

Furthermore, as noted by pharmaceutical industry representatives, due to the Russian pharmaceutical market specifics foreign manufacturers already incur expenses, which do not exist in other countries, for example, expenses for re-conducting of clinical trials[7]. However, the new Pricing Methodology ignores this factor, and its application will entail additional expenses for manufacturers.

Thus, along with reduction of prices for EDL medicines, one cannot rule out the possibility of both the increase in prices for other drugs and withdrawal of certain drugs from the Russian market due to unprofitability of sales under the new rules.

The procedure for state registration of medicines has been changed

On 15 June 2018, the new procedure for state registration of drugs including those manufactured outside Russia took effect[8].

The new procedure corresponds to the state policy for promotion of contract manufacturing expansion in the Russian Federation. The basic development is to enable the registration of drugs having the same International Non-proprietary Name (hereinafter — the INN) but different trade names, which have been manufactured on the same manufacturing site.

According to Alexander Petrov, a member of the Russian State Duma's Committee for Public Health, it is intended that this novelty will enable Russian pharmaceutical manufacturers to produce, besides its products, the drugs of other manufacturers, which will develop contract manufacturing in Russia[9].

Further, according to the new procedure, if a foreign manufacturer does not have a report of its compliance with requirements of the rules of good manufacturing practice (hereinafter — the GMP), it is sufficient to provide a copy of the MoIT resolution on conducting inspection. Thus, the registration process may commence even before the inspection of the manufacturer is completed. Given that the inspection may take 160 days from the date the decision on its conducting is made[10], the reform will help to speed up the launch of foreign drugs to the Russian market.

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6 See at: http://sozd.parliament.gov.ru/bill/592388-7.

7 See at: https://www.rbc.ru/society/04/12/2018/5bfd22f79a79475874adb308?fbclid=IwAR2nyRq8KjdgOi9QiXjRTDlR0WHLYL7Ae4PWVUIPYjAJOxYR5LwhgS2Ru4E.

8 Federal Law dated 4 June 2018 No.140-FZ "On amendments to the Federal Law "On Drug Circulation".

9 See at: https://www.pnp.ru/economics/petrov-zakon-o-gosregistracii-lekarstv-stimuliruet-ikh-kontraktnoe-proizvodstvo.html.

10 Rules for organizing and conducting the inspections of drug manufacturers for compliance with requirements of the rules of good manufacturing practice, as well as issuance of conclusions of compliance of drug manufacturers with the specified requirements, approved by Russian Government Decree dated 3 December 2015 No.1314.

In addition, it is envisaged that the MoH shall suspend sales and use of a drug in case the MoH receives information on the manufacturer's non-compliance with GMP and/or violation of licensing requirements. Inter alia, such a decision shall be made in the following cases:

- the formula / technology of the drug production differs from the one specified in registration dossier;
- the drug is manufactured on the site not specified in registration dossier;
- the manufacturer has no documents confirming the quality conformance of the drug to the requirements established upon its registration[11].

We assume that it will be possible to analyse the first results of the new procedure for drug registration, estimate its efficiency and impact on the level of contract manufacturing in Russia by the end of 2019.

The procedures for mandatory certification and declaration of conformance with regard to medicines have been abolished

Since May 2017, the MoIT has been initiating the exclusion of pharmaceutical drugs from a list of products subject to certification and declaration. On 20 November 2018, the Russian State Duma approved in the third reading a federal law[12] amending both the Federal Law dated 27 December 2002 No.184-FZ "On Technical Regulation", and the Law on Drug Circulation[13].

The new rules for introduction of pharmaceuticals into circulation are focused on bringing the Russian legislation into line with the EEU legislation. According to the Resolution of the Customs Union Commission dated 7 April 2011 No. 620, pharmaceuticals shall not be regarded as products subject to mandatory certification of conformance.

Additionally, the change of the procedure for introduction of drugs into circulation is caused by inefficiency of the previous procedure. According to Dmitry Kostennikov, Deputy Minister of Health, the system was unduly expensive and failed to ensure the proper control over the quality of pharmaceuticals[14].

According to amendments to the Law on Drug Circulation, the drug manufactured in Russia (other than immunobiological drug) may be introduced into circulation on the ground of the manufacturer's document certifying the quality, as well as certification of conformance of a drug to the requirements established upon its state registration by the authorized person of manufacturer[15].

As regards drugs imported into Russia (other than immunobiological drugs), the appropriate documents are the manufacturer's certificate confirming the quality of a drug and its conformance to regulatory requirements, as well as certification of conformance to the requirements established upon its state registration by representative of the importing organization[16].

For the first three batches of the drug manufactured in Russia for the first time or imported into Russia for the first time it is obligatory to provide to the Federal Service

[11] Article 65(3) of the Law on Drug Circulation.

[12] Federal Law dated 28 November 2018 No.449-FZ.

[13] Federal Law dated 12 April 2010 No.61-FZ "On Drug Circulation" (the Law on Drug Circulation)

[14] Shorthand notes of the State Duma's proceedings dated 29 March 2018 No. 106 are available at http://api.duma.gov.ru/api/transcript/374838-7.

[15] Part 1 of Article 52.1 of the Law on Drug Circulation, as amended by Federal Law dated 28 November 2018 No.449-FZ.

[16] Part 2 of Article 52.1 of the Law on Drug Circulation, as amended by Federal Law dated 28 November 2018 No.449-FZ.

for Supervision in Healthcare (hereinafter — the Roszdravnadzor) a protocol of test for conformance of the batch to the quality parameters provided for by regulatory documents.

The regime for immunobiological drugs has certain specifics and provides for obtainment of a permit from Roszdravnadzor. The ground for permit issuance shall be the report of conformance of the medicine batch to requirements established upon its state registration issued by the federal state-financed institution subordinate to Roszdravnadzor.

It should also be noted that in case drug manufacturers and organizations importing drugs intend to cease or suspend imports, they must notify Roszdravnadzor on this fact at least 1 year before the intended suspension or cessation. Despite the fact that procedures related to cancellation of mandatory certification and declaration of conformance will become effective on 29 November 2019, the rule on the prior notice about imports suspension or cessation came into effect on 28 November 2018.

The work on implementation of mandatory drug labelling continues

In February 2017, a two-year pilot project for monitoring of drug circulation was launched[17]. The experiment is conducted on a voluntary basis and is focused on creation of an information system for drug monitoring using labelling and identification of drug packages. The manufacturers generally support implementation of a drug labelling system and ready to bear associated costs in order to track the production flows.

However, on 28 April 2018, the Russian Government published the Resolution No.791-r determining basic principles and an organizational model of the labelling system using the means of identification in Russia. According to this resolution, a check code must be generated using cryptographic technologies.

The pharmaceutical community is negative about change of labelling parameters because the new requirement to place a cryptography on drug packages will cause additional expenses. Firstly, manufacturers will have to acquire new equipment. Secondly, according to manufacturers, it will reduce the rate of packages production with simultaneous increase in the quantity of defect production[18].

Furthermore, the Association of Russian Pharmaceutical Manufacturers notes that, currently, there is no technological solution that could ensure the readability of a crypto code placed by manufacturer throughout the manufacturer-to-final consumer chain[19].

Cost of labelling

The operator of products labelling system in Russia, i.e. the Advanced Technology Development Centre (hereinafter — the ATDC), informed that the labelling service will cost 50 kopecks excluding VAT for each product unit[20]. According to the FAS Russia, these costs of drug manufacturers should not entail an increase in prices for EDL drugs. At the same time, the pharmaceutical community representatives do not rule out the possibility that manufacturers will reimburse expenses by increasing prices for other drugs[21].

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[17] Pursuant to the Russian Government Decree dated 24 January 2017 No.62 "On conducting of experiment in the check (identification) mark labelling and monitoring over circulation of certain types of medicines" (as amended on 28 August 2018).

[18] See at: http://www.aipm.org/news/2018/12/18/news_312.html.

[19] See at: ibid.

[20] See at: https://crpt.ru/rashody-na-sozdanie-sistemy-markirovki-tovarov-v-rf-prevysjat-200-mlrd-rublej/.

[21] See at: https://www.rbc.ru/society/08/11/2018/5be2f9f29a79471323bd63d9?from=main.

Time limits

Currently the drug labelling proceeds within the pilot project, which will last until 31 December 2019. The mandatory labelling for all drugs will be implemented since 1 January 2020.

As to orphan drugs, according to the Russian Government Decree dated 14 December 2018 No.1557 the labelling will become mandatory from 1 October 2019. The Russian Government established the period for registering drugs in a drug flow monitoring system, i.e. from the 1st to the 8th of July 2019 (or within 7 days from the date on which the need of drug circulation entities to carry out the activity related to circulation of such drugs arises).

Thus, vigorous activity for launching a drug circulation monitoring system is carried out by both regulatory agency and market participants. It is obvious that implementation of mandatory labelling will have a positive impact on the quality of medicines in circulation and will enable to promptly control the counterfeit products.

However, we assume that the monitoring system requires improvement and its implementation will be possible only if there is a balance between the interests of manufacturers and final consumers.

Compulsory licensing

In June 2018, the Arbitrazh Court of Moscow in case No. A40-71471/2017 rendered a precedent award and granted a simple (non-exclusive) compulsory licence for a medicine for its use within the Russian Federation[22]. The licence to use the invention owned by the Celgene (USA) was issued in favour of Nativa (Russia).

The pharmaceutical industry expressed its concern over possible consequences of this case. The expansion of such practices may prevent from development of innovations in pharmaceutical industry since manufacturers will have no interest in development of new drugs, which requires significant investments.

In the meantime, on 27 December 2018, the Court for Intellectual Property Rights reversed the decisions taken in this case by lower courts, and approved a settlement agreement between the parties. According to this agreement, Nativa waived its claims with regard to the Celgene's invention.

The case may have a significant impact on the law application practice in 2019. In particular, the Arbitrazh Court of Moscow currently considers another case No. A40-245729/2018 initiated by Nativa[23]. This time Nativa requests for a compulsory licence over the patent of the anti-cancer drug "Nilotinib" owned by Novartis (Switzerland).

In parallel, Russian stakeholders take measures to modify existing legislation — the public discussion of the draft law amending the Russian Civil Code was held in November 2018. This draft law entitles the Russian Government to issue a compulsory licence to use the invention related to pharmaceuticals for the purposes of exporting relevant medicines.

The Ministry of Economic Development of the Russian Federation provided a positive opinion on this draft law, and the draft law must be submitted to the Russian Government for consideration shortly[24]. We note that earlier the FAS Russia has repeatedly proposed amendments to the Russian Civil Code regarding compulsory licensing, however, the initiatives were not implemented.

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[22] See at: http://kad.arbitr.ru/Card/322413fa-38a7-4085-9cc7-3c8ff9fd7d92.

[23] See. http://kad.arbitr.ru/Card/195417c9-d893-46d0-9f18-a05c96083957.

[24] See. https://regulation.gov.ru/projects#npa=83577.

Despite the fact that amendments proposed by the Ministry of Economic Development and the FAS Russia have not reached the stage of adoption, pharmaceutical companies are concerned about unpredictability of policies in the defence of patents and constantly emerging new initiatives.

The draft law protecting intellectual property rights upon drug registration has been prepared

Currently, the MoH carries out state registration of medicines without checking the documents for compliance with third parties intellectual property rights. Therefore, circulation of medicines containing results of intellectual activities of third parties without their consent used to be a common situation. Unfortunately, current judicial procedures for protecting the intellectual property rights of patent holders are inefficient in such situations.

Following the EEU Rules for Drug Registration and Examination[25], the MoH has prepared the draft law amending the Law on Drug Circulation[26]. The draft law obliges manufacturers to provide the following information when submitting an application for state registration of a medicine:

- information on availability of the legally effective patent within the Russian Federation;
- information on registration of a trademark;
- confirmation that the drug registration does not violate intellectual property rights of a third party.

With regard to medicines already registered within the Russian Federation, the applicant must provide a licensing agreement. In addition, the draft law obliges the existing holders of registration certificates to provide information on availability of intellectual rights to the registered drug to the authorised state agency before 1 January 2020.

Changes to the drug registration procedure may decrease a number of disputes concerning the protection of intellectual rights to medicines.

[25] Approved by the Decision of the Council of the Eurasian Economic Commission dated 3 November 2016 No.78

[26] See. https://regulation.gov.ru/projects/List/AdvancedSearch#npa=85240.

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