THE LIFE SCIENCES LAW REVIEW

TENTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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Editor
Richard Kingham

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CONTENTS

PREFACE

The tenth edition of *The Life Sciences Law Review* covers a total of 30 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year, like its predecessor, was dominated by the covid-19 pandemic. Manufacturers of healthcare products continued to expedite the development and testing of drugs, biologics, diagnostics and personal protective equipment. Vaccines, many making use of novel technologies, have moved from the laboratory to the clinic and then to patients in record times; a matter of months rather than years or decades. Regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency. Manufacturers and international organisations have worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. In the wake of the pandemic, it is to be hoped that governments learn from the lessons of covid-19, placing systems and structures in place for the next pandemic or other health emergency and expediting the development and approval of new healthcare products to deal with endemic health issues such as cancer, coronary heart disease and genetic disorders.

In times like these, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
February 2022

Chapter 19

RUSSIA

Evgeny Alexandrov and Ilya Goryachev[1]

I INTRODUCTION

The Russian life sciences framework is primarily shaped by the Federal Law of 12 April 2010 No. 61-FZ on turnover of medicines (the Pharmaceutical Law) and the Federal Law of 21 November 2011 No. 323-FZ on the principles of healthcare of citizens in the Russian Federation (the Healthcare Law). The Ministry of Healthcare of the Russian Federation (MoH) is the primary regulatory body and its subsidiary, the Federal Service for Surveillance in Healthcare (Roszdravnadzor), is the enforcement authority.

From 1 January 2021, the relations on registration of medicines are governed by the Eurasian legislation, namely under the Eurasian Economic Commission Council Decision of 3 November 2016 'On rules of registration and examination of drugs for medical use' (the Eurasian Rules).

More detailed aspects of life sciences regulation are provided in the by-laws of the government and the MoH (including the good practices).

Aspects of the life sciences industry related to intellectual propery (IP) are codified in the Russian Civil Code.

General issues on state procurement contracts are subject to regulation by the Civil Code, while the detailed regulation on state tenders and procurement contracts (including aspects related to the supply of pharmaceuticals) are provided for in the Federal Law of 5 April 2013 No. 44-FZ on the contractual system for the supply of goods, work and services for meeting state and municipal needs.

Advertising and competition issues are governed by the Federal Law of 13 March 2006 No. 38-FZ on advertising (the Advertising Law) and the Federal Law of 26 July 2006 No. 135-FZ on the protection of competition (the Competition Law), of which the Federal Antimonopoly Service is the regulator.

The Federal Law of 29 July 2017 on amending certain legislative acts of the Russian Federation on issues of applying information technologies in healthcare systems (the Telemedicine Law) entered into effect, thus providing legislative framework on use of digital technologies in medical aid industry.

1 Evgeny Alexandrov is a partner and Ilya Goryachev is a senior lawyer at Gorodissky & Partners Law Firm.

II THE REGULATORY REGIME

i Classification

The Pharmaceutical Law defines medicines as substances or their combinations that have the following classification features:

a capable of contact with the human or animal body, or penetrating into the organs and tissues of the human or animal body;

b applied for the prevention, diagnosis (except for substances that do not make contact with the human or animal body) and treatment of disease, rehabilitation, or preservation, prevention or interruption of pregnancy; and

c obtained from the blood, blood plasma, organs or tissues of a human being or animal, from plants, minerals using synthetic methods or using biological techniques.[2]

Medicines fall into two categories:

a pharmaceutical substances – active ingredients of biological, biotechnological, mineral or chemical origin, with pharmaceutical activity, intended for the manufacturing and production of pharmaceutical medicines and determining their effectiveness; or

b pharmaceutical medicines – pharmaceutical products in dosage form, used for the prevention, diagnosis or treatment of disease, rehabilitation, or preservation, prevention or interruption of pregnancy.

Further classifications defined by the Pharmaceutical Law are: (1) referential (original), generic, biosimilar and interchangeable medicines; (2) biological, immunobiological, biotechnological, gene therapy medicines; (3) botanical and homeopathic medicines, narcotic and psychoactive medicines, radiopharmaceutical drugs; and (4) adulterated and counterfeit medicines.

Medical devices have the following classification features:

a they are instruments, apparatus, tools, equipment, materials and other products, applied for medical purposes, separately or in combination, as well as with other accessories, that are necessary for application, including special software;

b they are intended by the manufacturer for prevention, diagnosis, treatment and medical rehabilitation, health monitoring, medical research, recovery, substitution, change of anatomical structure or physiological functions of the body, or prevention or interruption of pregnancy; and

c their function is achieved not by pharmacological, immunobiological, genetic or metabolic influence.[3]

The new Federal Law No. 180-FZ on biomedical cell products (adopted on 23 June 2016) has been in effect since 1 January 2017. This law regulates development, trials and other aspects of commercialisation of biomedical cell products for treating diseases, as well as citing various types of such products and the biological material necessary for the production of such products.

Occasionally, problems arise because of the distinction between medicines or medical devices and food products (including biological food additives) and cosmetics. In the event

2 Article 2 of the Pharmaceutical Law.

3 Article 38 of the Healthcare Law.

of a dispute, it should be borne in mind that all these products have different regulatory regimes, and it is necessary that they be governed by the criteria stipulated in the related legislation. Apart from the specific regulatory issues, there may be different consequences in terms of import duties (e.g., some products may attract a higher rate of state customs duty), advertising requirements and terms of sale. Judicial practice has seen the customs authority, for example, refusing to classify silicone gel as a medical device (classified by the company as a type of bandage), claiming that the gel was cosmetic and therefore subject to the increased rate of import duty; however, in subsequent litigation, the company managed to prove that this gel was, in fact, a medical device, used during the treatment of burns and scars in specialised institutions, which was also confirmed by the related marketing authorisation (MA) from the competent state authority, and by expert opinions. Cosmetic products, pursuant to the effective legislation, are used for rendering a more pleasant appearance to the skin. In this case, the courts agreed with the applicant and revoked the customs authority's classification decision.[4]

ii Non-clinical studies

Pre-clinical trials are held for the use of chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental research on the substance, drug and physical effect, means, methods and technologies of preventive measures, diagnostics and treatment by applying scientific methods of evaluation for the purpose of researching a specific effect or proof of safety for health.

Pre-clinical trials are governed by good laboratory practice,[5] the specific focus of which is, among other things, requirements for research laboratories and related documents.

Use of the information in the results of pre-clinical trials for commercial purposes is not allowed within the first six years without the consent of the owner of the information. However, in the case of generic medicines, the applicant is allowed to use a review of scientific publications on the results of pre-clinical trials of the original product.[6]

iii Clinical trials

A clinical trial is defined as the study of diagnostic, therapeutic, prophylactic and pharmacological features of the drug during its use on human beings and animals, including the processes of absorption, distribution, excretion and changes by scientific methods to obtain evidence for the safety, quality and efficacy of the drug, data on adverse reactions in the human or animal body and the effect of its interactions with other drugs and food or feed.[7] The Pharmaceutical Law also encompasses multi-institutional, international multi-institutional and post-registration clinical trials.

Clinical trials are undertaken upon filing an application for drug registration and approval from the quality and ethics committee.[8] Compliance with the rules of clinical practice under the Eurasian legislation is obligatory.[9]

4 *Meda Pharmaceuticals Switzerland GmbH v. the Russian Federal Customs Service* (Resolution of the Federal Commercial Court of the Moscow Region of 22 February 2013, Case No. 40-72336/12-145-16).

5 Eurasian Economic Commission Council Decision of 03.11.2006 No. 81.

6 Section 10, Article 18 of the Pharmaceutical Law.

7 Section 41, Article 4 of the Pharmaceutical Law.

8 Article 39 of the Pharmaceutical Law.

9 Eurasian Economic Commission Council Decision of 03.11.2006 No. 79.

Use of the information in the results of pre-clinical trials for commercial purposes is not allowed within the first six years without the consent of the owner of the information.

For generic drugs, full-scale clinical trials may not be undertaken – in this case the applicant is allowed to submit bioequivalence trial results.

The management of a clinical trial may be exercised by the sponsor itself, educational facilities or research institutions, but clinical trials as such should be undertaken in accredited institutions. Relations between the clinical trial authorisation (CTA) holder and the accredited medical institution are regulated by a private contract between them. This contract should contain certain essential features: the terms of the trial; an indication of the total costs, including remunerations to the researcher (co-researcher); and a description of the form of report for submission to the MoH.

The chief officer of the medical institution appoints the researcher (co-researcher), who selects patients for the clinical trials. Patients should participate in the trials voluntarily.

The Pharmaceutical Law provides the outline of the requirements that are set out for patients.[10] Requirements are also set out regarding the information that should be included on the written consent form completed by the patient, namely:

a details of the drug, its safety and risks;
b the terms of participation;
c what the patient should do in the event of side effects;
d insurance conditions; and
e confidentiality guarantees.

Informed consent is obligatory, which is confirmed by the patient's signature (or the signature of his or her duly authorised representative) on an information list for the patient. Patients have the right to terminate their participation in a trial at any time.

Minors may act as patients only with the written consent of their parents and on condition that the trial is specifically focused on the aspects of using the drug on minors.

People with mental afflictions may participate in clinical trials for drugs intended for the treatment of mental afflictions on the condition that their representatives give their written consent.

Certain sections of the population cannot participate in clinical trials, such as:

a law enforcement officers;
b military officers (except for trials of drugs developed specifically for use in warfare, emergency situations or other similar circumstances);
c pregnant women as well as breastfeeding women (except for trials of drugs intended only for such women in compliance with risks-mitigating requirements);
d orphaned children; and
e imprisoned people.

The CTA holder is obliged to insure the patients against death (cover of 2 million roubles) or disability (cover ranges from 300,000 to 1.5 million roubles, depending on the degree of impairment to health) as result of the clinical trial. A patient cannot participate in a trial should the CTA holder fail to obtain insurance for that person.[11]

10 Article 43 of the Pharmaceutical Law.
11 Article 44 of the Pharmaceutical Law.

Clinical trials results must be recorded and safety reporting is obligatory. Should the trial be terminated, the CTA holder must inform the MoH of the reasons for the termination.

iv Named-patient and compassionate use procedures

In Russia, the general rule is that an MA is required for administering medicine, although the following exceptions exist when an MA is not required:

a drugs produced by pharmacies according to the prescriptions and requirements of medicinal institutions;
b drugs purchased by individuals abroad and intended for personal use;
c drugs imported to Russia for providing medical help owing to the life-saving necessity of the patient based on the regulator's decision;
d drugs imported to Russia based on the regulator's permission for holding clinical trials or for holding examinations for state registration;
e pharmaceutical substances;
f radiopharmaceutical drugs produced directly by medical institutions as per the established regulations; or
g drugs manufactured for export.[12]

v Pre-market clearance

Marketing of a drug is allowed only once the MA is approved (except for those circumstances described in Section II.iv). The stages of the pre-marketing procedure are as follows:

a Development stage: the search for new pharmaceutically active ingredients, their subsequent examination, pre-clinical trials and development of manufacturing technologies. It is not possible to determine the specific timing of this stage, as it depends on the activity of the sponsor.
b State registration: the application for CTAs (if necessary) and examination of the quality, efficacy and safety of the drug. The general timing for original drugs is approximately 160 business days (excluding the time for clinical trials) and 80 days for medicines under the fast-track examination procedure. The following stages may be discerned:
    - the applicant files an application with the MoH and the registration dossier is prepared;
    - the registration dossier is reviewed by the specialised institution by the MoH, considering whether the CTA may be issued – an ethics committee also participates at this point;
    - based on the results of this examination and ethics committee review, a decision on the issuance of the CTA by the MoH;
    - the CTA holder launches clinical trials (by entering into an agreement with the accredited medical institution, arranging insurance for the patients, etc.);
    - the results of the clinical trials are submitted to the MoH;
    - the examination of the drug's quality, efficacy and safety, as well as a risk-benefit analysis is undertaken by the specialised institution approved by the MoH; and
    - based on the results of the examination, the MoH issues the MA, requests a re-examination or refuses to issue the MA.

12 Article 13 of the Pharmaceutical Law.

Similar stages exist for the registration of medical devices, depending on their class.[13]

Special procedures

An expedited (fast-track) procedure is applicable to the following types of drugs:

a orphan medicines;
b the first three medicinal products for registration in Russia as generic products; and
c medicines for use exclusively by minors.

The fast-track procedure does not apply to:

a biosimilar medicines;
b original medicines (except for orphan medicines);
c generic medicines, except for:
  - the first three medicinal products for registration in Russia as generic products; and
  - medicines for use exclusively by minors;
d new combinations of previously registered medicines; and
e medicines, registered previously, but manufactured in other pharmaceutical dosage forms in accordance with the list of pharmaceutical dosage forms and in the new dosage.

For generic drugs, reference to a review of scientific publications on the results of pre-clinical trials of the original product (instead of pre-clinical trials of a generic drug) and bioequivalence trials (instead of clinical trials) is allowed.[14]

All the aforementioned tests (quality, safety, etc.) are undertaken during the expedited procedure, except for clinical trials, and the requirements during the examinations are the same as in the general procedure.

Special fast-track procedures are also available for medicines for use under the circumstances relating to emergencies and for the organisation of medical care to persons affected by emergency situations, prevention of emergency situations, prevention and treatment of diseases that pose a danger to others, diseases and lesions resulting from exposure to adverse chemical, biological and radiation factors.[15]

Fees

The specific fees depend on the type of the CTA or on the medicine at issue. Starting from 2022, as a result of the operation of the medicines market under the Eurasian rules, the amount of the fee changed; for instance, the amount of the fee for confirming the registration of the medicine will be 172,000 roubles and amending the registration dossier with changes requiring tests will be 490,000 roubles.[16]

For medical devices, the fees for examination, depending on the class, may range from 45,000 to 115,000 roubles. The fee to issue an MA is 11,000 roubles starting from 2022.[17]

13 Regulation of the Russian Government of 27 December 2012, No. 1416.
14 Articles 18 and 26 of the Pharmaceutical Law.
15 Resolution of the Russian Government of 3 April 2020, No. 441.
16 Federal Law of 29 November 2021 No. 382-FZ.
17 Article 333.32.2 of the Russian Tax Code.

vi Regulatory incentives

Patent protection

Pharmaceutical products may be protected by a substance patent, a process patent or a use patent.[18] Patent protection is effective for 20 years starting from the priority date. Regular renewals are required to keep the patent in force.

The patentee has the exclusive right to import the patented product into Russia, manufacture, use, offer for sale, sell or otherwise commercialise the product; this matches with the patentee's right to forbid other persons from infringing that exclusive right.

The list of activities that fall under the scope of a patent is non-exhaustive. The following types of activities are specifically mentioned:

a importation into Russia, manufacturing, working, offering for sale, sale or other commercialisation or storage of the product according to the purpose for which the subject of the patent is used;

b the same actions in (*a*) in respect of a product, manufactured directly from the patented process;

c the same actions in (*b*) in respect of:
- a device, if such a device automatically functions using the patented process; and
- a product working in accordance with the purposes indicated in the manufacturer's claims; and

d implementation of a process in which the invention is used, including by means of using the process.

Research on a product or process in which the patent is used, or experimentation on it, is not a patent infringement, but if the defendant's activities extend beyond the scope of research or experimentation (e.g., the defendant starts commercialisation), its activities may be considered an infringement.

In judicial practice, there are examples where courts ruled that submission of a drug for an MA before the expiry of a patent does not as such constitute infringement of a patent, but further commercialisation of a drug before the patent expires is viewed as an infringement.[19] Nevertheless, if the generic MA or maximum sale price registration is filed some time prior to expiry of the patent, the patentee may argue that there is a threat of patent infringement, and an example of this has been seen in judicial practice, where the court recognised the activities of early filing of an MA and subsequent maximum sale price registration as constituting a threat of infringement.[20]

If the court adjudicates that the commercialisation of a specific drug is a breach of the patent legislation, the MoH is obliged to revoke the MA.[21]

18 Article 1350 of the Russian Civil Code; Federal Law of 29 November 2021 No. 382-FZ.

19 Resolution of the Presidium of the Supreme Commercial Court of the Russian Federation of 16 June 2009, No. 2578/09, Case No. A40-65668/08-27-569.

20 Resolution of the Intellectual Rights Court of 24 April 2018, No. C01-206/2018 on Case No. A41-85807/2016.

21 Article 32 of the Pharmaceutical Law.

The Eurasian Rules require the applicant in the MA registration procedures to provide a confirmation of non-infringement of intellectual rights as a result of the medicine registration as well as to indicate whether their patent is effective in the territory of the Eurasian Union Member States and, if applicable, to provide a copy of the patent or licence agreement.[22]

Extension of patent protection

Extension of a pharmaceutical patent is possible for no more than five years if more than five years elapse between the filing date and the date when the MA is issued.[23]

Data exclusivity

It is not permitted to use (without consent), for commercial purposes, the information in the results of pre-clinical trials and clinical trials, submitted by an applicant for the original product within six years of the registration of the original medicine in Russia.

It is permitted to file for the MA four years after registration of the original product (three years for biosimilars).[24] Non-compliance with the term results in the MoH dismissing a generic drug application.[25]

vii Post-approval controls

The MoH and Roszdravnadzor are competent for monitoring the safety of drugs.[26] There are specific rules on monitoring safety, as well as guidelines introduced by the Roszdravnadzor with regard to in-house monitoring of drug safety.[27]

As part of pharmacovigilance, the MA holder and other entities involved in product commercialisation are obliged to report any side effects not listed in the instructions for use of the drug, serious adverse reactions, unexpected adverse reactions in the application of drugs, and the peculiarities of drug interactions with other drugs that have been identified in clinical trials. The MoH is entitled to suspend commercialisation of a product in the event of any such report.

Furthermore, as of 1 January 2016, the MA holder is obliged to report regularly to the regulator with the results of pharmacovigilance.[28]

The MA may be revoked in the following cases:

a if, as result of state safety monitoring, it is evident that a risk to health exists;

b a voluntary revocation application is filed;

c if an MA was issued for five years, but upon expiry of that term no confirmation of state registration exists;

d in the event that the registration dossier needs to be amended, but the MA holder fails to respond to the related request within 30 days;

e if an MA is issued for a trade name that has already been registered for another drug with a different combination of active ingredients;

f if one and the same drug has been registered under various trade names;

22 Section 3.1 Annex 2 to the Eurasian Rules.

23 Article 1363 of the Russian Civil Code.

24 Article 18 of the Pharmaceutical Law.

25 Resolution of the 9th Commercial Appeal Court of 16 June 2017 on Case No. A40-657/17.

26 Articles 5, 9 and 64 of the Pharmaceutical Law.

27 Order of the Roszdravnadzor of 15 February 2017 No. 1071.

28 Article 18 of the Pharmaceutical Law.

g if a court renders a decision on infringement of IP rights during commercialisation;
h if the drug is not commercialised within three years;
i when there has been a failure to comply with pharmacovigilance obligations; or
j if there has been a refusal to amend an instruction for use if the risk of taking the drug exceeds the effect of using the drug.[29]

Any amendments or changes regarding the MA holder should be notified to and approved by the MoH.

viii Manufacturing controls

The manufacturing of a drug is allowed once the appropriate licence is obtained by the manufacturer in Russia; licence control is exercised regularly.[30]

The manufacturing procedure should comply with the rules of good manufacturing practice approved by the Ministry of Industry and Commerce,[31] which set out specific technical requirements depending on the type of pharmaceutical product.

The manufacturer is obliged to develop internal regulations that include a list of the pharmaceutical substances and auxiliary ingredients, the data on the equipment used in manufacturing and a description of the technological process and control methods for each stage of manufacturing, as well as to appoint a responsible authorised person (meeting qualification requirements) that confirm compliance of the manufactured medicines with the MA and good manufacturing practice.

ix Advertising and promotion

Advertising and promotion of drugs (and the following points (*c*) to (*j*) also relating to medical equipment) is subject to general advertising and competition rules (such as restrictions on unfair advertising and unfair completion, including incorrect comparisons)[32] and specific restrictions and prohibitions,[33] under which it should not:

a be addressed to minors;
b cite specific cases of cure or improvement of health (not applied to advertising intended only for medical professionals in specialist publications or events);
c use expressions of gratitude by specific individuals (not applied to advertising intended only for medical professionals in specialist publications or events);
d invoke the results of obligatory clinical trials or examinations as evidence of any advantages of the drug;
e contain the assertion that consumers have certain diseases or health problems;
f give the impression that a healthy person should use the drug (not applied to advertising of preventive drugs);
g give the impression that by using the drug, it is not necessary to consult a doctor;
h guarantee favourable effects of the drug, its safety and effectiveness, and the absence of side effects;

29 Article 32 of the Pharmaceutical Law.
30 Article 45 of the Pharmaceutical Law.
31 Order of the Russian Ministry of Industry and Commerce of 14 June 2013, No. 916.
32 Article 5 of the Advertising Law; Chapter 2.1 of the Competition Law.
33 Article 24 of the Advertising Law.

i imply that the drug is a biologically active additive or food supplement or any other product that is not a medicine; and

j imply that safety or effectiveness of the drug is explained by its natural origin.

The description of the features and characteristics of the drug should not go beyond the scope of the instructions for use. A special notice is also required that instructs the user to read the instructions for use and of the need to consult a doctor (except for advertising aimed at medical professionals).

The advertising of prescription medicines or medical devices for use where special knowledge is required is allowed only if the advertising is aimed at professionals (i.e., only at the related conferences or in specialist publications). Promotional events at which drug samples that contain narcotic and psychotropic ingredients are distributed are forbidden.

Special rules on promotional communications between representatives of pharmaceutical companies and hospital or pharmacy employees are also established to prevent conflicts of interest (such as a restriction on the distribution of promotional merchandise among doctors).[34]

Recent years have seen the increasing role of self-regulation between advertisers in the life sciences industry. Namely, in 2018 the Recommendations on advertising on over-the-counter drugs have been signed by representatives of the industry under approval from the Federal Antimonopoly Service.[35] The Recommendations clarify certain problematic issues on over-the-counter drugs' advertising and consolidate the previous enforcement experience.

x Distributors and wholesalers

The initial distribution of drugs and medical devices is exercised by the holders of the MA and the related licences (to manufacture drugs and medical devices). Wholesale and retail sales of drugs are subject to licensing (sales of medical devices are not licensed).[36]

In the sale of drugs, it is possible to apply for both wholesale and retail licences.

As part of the government incentive to have an increased level of localised manufacturing, restrictions on state procurement of foreign pharmaceuticals were imposed at the end of 2015.[37]

Furthermore, the wholesale and retail of medicines are subject to good distribution practices and good pharmacy practices, and compliance with these practices is subject to state control.[38]

xi Classification of products

A distinction is made between drugs that may not be sold to end consumers without a prescription from a doctor (prescription drugs) and drugs that may be sold over the counter. The MoH regulates the procedure of doctors issuing prescriptions.[39] There is also a limit

34 Articles 74 and 75 of the Healthcare Law.

35 The Recommendations may be found at https://fas.gov.ru/news/26296.

36 Article 12 of the Federal Law of 4 May 2011, No. 99-FZ on licensing of certain activities.

37 Resolution No. 1289 of the Russian Government of 30 November 2015.

38 Article 5 of the Pharmaceutical Law.

39 Order of the Russian MoH of 14 January 2019, No. 4n.

on the total number of medicines that may be covered by one prescription.[40] Classification of a drug as a prescription drug affects its advertising in that it is only allowed if aimed at professionals.

xii Imports and exports

The import of drugs into Russia is regulated in detail by the government[41] within the framework provided by the Pharmaceutical Law.[42]

The precondition of importation is that there should be a certificate from the manufacturer confirming the compliance of the drugs being imported with the requirements of the pharmacopoeia monograph or – in its absence – with the regulatory documents.

There are specific categories of entities that may import drugs (such as sponsors, wholesale companies and medical institutions). Importation for personal needs by individuals is also allowed.

As a general rule, there should be a Russian MA for imported drugs, but exceptions are made for clinical trials and their import by individuals for personal use, or cases when there is a decision by the regulator to allow use of a specific medicine for a specific individual. A permit to import, issued by the MoH, is generally required.

The export of drugs from Russia may be exercised without restriction, although a special procedure is provided for drugs being exported for use in humanitarian aid or emergency situations.[43]

xiii Controlled substances

Narcotics and psychotropic drugs are subject to detailed control over commercialisation (manufacturing and storage) and use. Every aspect of their commercialisation is subject to specific requirements as set out in the Pharmaceutical Law. The list of substances to which this applies is provided by the government.[44]

xiv Enforcement

While the MoH is the main regulatory authority, enforcement is mainly undertaken by Roszdravnadzor. Monitoring is exercised and compliance with licence requirements is observed. Penalties may range from administrative fines to criminal punishments. Revocation or suspension of product commercialisation may also take place as a sanction.

III PRICING AND REIMBURSEMENT

State regulation of prices for essential drugs is undertaken by the government[45] and the list of drugs is approved annually. The prices for these listed drugs are subject to state registration.[46]

40 Regulation of the Russian MoH of 12 February 2007, No. 110.
41 Regulation of the Russian Government of 29 September 2010, No. 771.
42 Article 47 of the Pharmaceutical Law.
43 Article 47 of the Pharmaceutical Law.
44 Regulation of the Russian Government of 30 June 1998, No. 681.
45 Article 60 of the Pharmaceutical Law.
46 Articles 61 and 62 of the Pharmaceutical Law.

The executive authorities of the constituent parts of the Russian Federation are entitled to regulate flat wholesale and retail benefits with regard to the actual prices for end users.[47]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Decisions made by the regulatory authorities may be challenged in the commercial courts, and these cases are heard by judges specialising in administrative cases. The procedure is general, as it is used for other cases when state authority decisions are challenged; the time limit for filing an action is three months after the decision was issued.[48]

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

The following restrictions and prohibitions are imposed on prescribers in their relations with medical representatives:

a gifts and money cannot be received from manufacturers, MA holders and other entities participating in the commercialisation drugs (except for remunerations as result of clinical trials or scientific and educational activities);

b no undertakings to provide recommendations should be made;

c samples of products cannot be accepted for patients' use (except for use in clinical trials);

d it is forbidden to provide incorrect or misleading information concerning alternatives to prescribed drugs;

e it is forbidden to entertain medical and pharmaceutical representatives (except in connection with clinical trials or except for conferences undertaken by the administration of the hospital); and

f doctors should not write prescriptions for drugs for patients on the advertising materials of specific drugs or on printed materials bearing the trade names of specific drugs.[49]

With regard to payers, the main aspects are in the field of advertising and prohibition of passing-off, as well as the requirement for package marking.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

In the event that damage results from the use of drugs, the manufacturer is liable should either of two conditions be present: (1) the drug was used according to its purpose as provided in the instructions for use and the damage was caused because the drug was substandard; or (2) the damage was caused when the instructions for use contained incorrect information.

Wholesalers and retailers may be also held liable if damage resulted from a breach of the requirements for sale.[50]

In addition, commercialisation of substandard (off-grade), falsified or counterfeit medicines may give rise to criminal liability.[51]

47 Article 63 of the Pharmaceutical Law.

48 Chapter 24 of the Russian Commercial Procedure Code.

49 Article 74 of the Healthcare Law.

50 Article 69 of the Pharmaceutical Law.

51 Article 238.1 of the Russian Criminal Code.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Patent-related agreements are exempted from antitrust control,[52] but this does not preclude risk estimation in the event of the patent-related agreements containing provisions going beyond the scope of the patent transaction.

Further, a patentee holding the dominant position who unduly refuses to enter into a supply agreement with another company, invoking its exclusive right to a patent or a trademark used with regard to the drug, risks facing liability.[53]

ii Transactional issues

Corporate transactions, including mergers and acquisitions and strategic partnerships, are subject to general antitrust control based on the economic criteria.[54]

VIII CURRENT DEVELOPMENTS

The covid-19 situation continues to influence regulations of drugs turnover; for instance, resulting in further development of online sales of medicines as well as introducing changes in specialised procedures for medicine registrations.

From a regulatory standpoint, the introduction of the Eurasian rules for medicines since January 2021 is one of the most important events. The obligation of the MA applicants to provide information on non-infringement of IP rights under the Eurasian Rules is seen as an important development aimed at reducing IP infringements.

Over recent years, among the legislative trends have been laws that amend the quality control system in drugs manufacturing. That said, on 29 November 2019 new legislative amendments came into force providing more detailed regulation over entry of medicines into circulation. Amendments have also been introduced with regard to the administrative procedures dealing with maximum sale price registrations applied to essential and indispensable drugs.

Practical developments on the launch of telemedicine services took place in 2019, including the launch of national online (electronic) prescriptions for drugs.

Among other current developments are preparations for the launch of mandatory marking of medicine packaging, starting from 1 July 2020, to monitor the life cycle of medicines on the market (the related test launch of obligatory marking of medicines already took place in 2018).

Discussions are continuing regarding initiatives aimed at introducing antitrust control over certain aspects of using IP rights. The Federal Antimonopoly Service has continued to pay close attention to the advertising of pharmaceuticals. Additionally, among potential trends may be the paying of closer attention to contol over naming of food additives in case of their similarity with medicines. That is combined with increasing trends on self-regulation in advertising, supported by the federal anti-trust authority, which may also affect consideration of life sciences advertising breaches to the extent of establishing more in-depth industry rules.

52 Section 4, Articles 10 and 11 of the Competition Law.

53 Resolution of the 9th Commercial Appellate Court of 6 October 2014 No. 09AP-34696/2014; Case No. A40-42997/2014.

54 Chapter 8 of the Competition Law.

Appendix 1

ABOUT THE AUTHORS

EVGENY ALEXANDROV

Gorodissky & Partners Law Firm

Evgeny Alexandrov graduated from the Russian State Academy of Intellectual Property (Moscow) as a lawyer, and in 2005 received his PhD degree in law. He joined Gorodissky & Partners in 2005.

He advises clients on intellectual property (IP) issues, including copyright, and associated rights, patent, trademark and other IP-related matters. He is one of the most experienced litigators in the firm and represents clients before the commercial courts and courts of general jurisdiction, as well as before administrative and law enforcement bodies.

Mr Alexandrov often participates in IP conferences as a speaker on IP issues and regularly publishes articles in Russian and foreign magazines and internet portals. He is a member of AIPPI and INTA, and speaks English.

ILYA GORYACHEV

Gorodissky & Partners Law Firm

Ilya Goryachev graduated from Moscow State Linguistic University in 2012 as an international lawyer and joined Gorodissky & Partners in 2013.

He focuses on providing legal support on intellectual property (IP) and general commercial matters, including trademarks, patents and copyright enforcement; unfair competition; domain disputes; licensing, assignments, franchising and other IP-related transactions; advertising and marketing regulations; launching joint ventures; IP issues in M&A transactions; IP due diligence; personal data protection; and industry-related regulatory affairs, including advising life science companies.

Mr Goryachev is the author of several articles on IP and commercial law matters. He speaks English and French.

GORODISSKY & PARTNERS LAW FIRM

B Spasskaya Str, 25, bldg 3
129090 Moscow
Russia
Tel: +7 495 937 6116
Fax: +7 495 937 6104
alexandrove@gorodissky.ru
goryachevi@gorodissky.ru
www.gorodissky.com

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