1. GENERAL BACKGROUND

→ Despite major economic challenges, Russia has a large pharmaceutical market offering various opportunities to market players (manufacturers of pharmaceutical and medical products, companies specialized in the R&D, etc.).

→ The pharmaceutical sector is one of the priorities for the Russian government.

Source: Pharmvestnik, January 2017, Interview with Mrs. Olga Kolotilova, Head of the department for development of pharmaceutical and medical industry at the Ministry of Industry and Trade (the “Minpromtorg”) (http://www.pharmvestnik.ru/pubs/lenta/interjvju/soxranajte-spokojstvie-872.html#.WH4qreO9qUk)
1. GENERAL BACKGROUND

Main goals of the Russian authorities are among others defined by the Federal program for development of pharmaceutical and medical industry for the period until 2020 and subsequently - approved by Regulation of the Russian Government No.91 dated 17 February 2011 (as amended).

These goals are in particular as follows:

+ To increase the share of medicines and medical products manufactured locally, in particular medicines included into the most important and essential drugs list ("EDL");
+ To improve the quality and quantity of local medicines and medical products;
+ To develop local research and release of innovative products;
+ To develop exports of medicines and medical products.
2. GENERAL LEGAL FRAMEWORK*

→ National legislation and regulations / Regulations at the level of the Eurasian Economic Union (the “EEU”).

→ Main specific national laws:
  + Federal Law No.61-FZ dated 12 April 2010 “On circulation of medicines” (as amended);
  + Federal Law No.323-FZ dated 21 November 2011 “On the principles of protection of health of the population in the Russian Federation”, which regulates among others the circulation of medical products/devices (as amended);

→ Main general national laws:
  + The Civil Code (as amended);
  + Federal Law No.99-FZ dated 4 May 2011 “On licensing of certain types of activity“ (as amended);
  + Federal Law No.44-FZ dated 5 April 2013 “On the contract system in procurement of products, works and services for state and municipal needs” (as amended);
  + Federal Law No.135-FZ dated 26 July 2006 “On protection of competition” (as amended);

* Tax and customs aspects are not covered in this presentation. There are also specific laws regarding the circulation of particular products such as psychotropic and narcotic substances, biomedical cell products, etc.
3. MAIN LEGAL TRENDS AND CHALLENGES

3.1. Main trends

➔ **Legal framework is in continuous improvement** → Frequent amendments and adoption of new laws and regulations. For example:

+ Introduction of new legal definitions and concepts such as “interchangeable medicines”, “orphan medicines”, “biologic medicines”, etc.;
+ Reforming of the conditions for conduct of clinical trials et ethical expertise;
+ Accelerated registration procedure for orphan drugs and certain generics;
+ Starting from 1 January 2017, circulation of biomedical cell products including their development, trials, registration, etc. is regulated by Federal Law No.180-FZ dated 23 June 2016 “On biomedical cell products”.
3. MAIN LEGAL TRENDS AND CHALLENGES

3.1. Main trends

WTO and other international rules are taken into consideration → Legal rules related to IP were for example significantly amended:

+ Russia acceded to the WTO in 2012, and its internal legislation shall conform to the TRIPS - Agreement on Trade-Related Aspects of Intellectual Property Rights, administered by the WTO and setting down minimum standards for intellectual property regulation.

+ Part 4 of the Civil Code, which regulates IP (including scientific works, trademarks, software, database, know-how, utility models, inventions) had undergone substantial changes, which entered into force on 1 October 2014.

+ A 6 year data exclusivity was introduced in Russian pharmaceutical legislation.
3. MAIN LEGAL TRENDS AND CHALLENGES

3.1. Main trends

Elaboration of modernized local standards to improve quality:

+ Good Manufacturing Practice (GMP) → Order of the Minpromtorg No.916 dated 14 June 2013 (as amended on 18 December 2015);

+ Good Laboratory Practice (GLP) standards → Order of the Ministry of Health (the “Minzdrav”) No.199h dated 1 April 2016;

+ Good Clinical Practice (GCP) → Order of the Minzdrav No.200h dated 8 September 2016;

+ Good Storage and Transportation Practice (GSP) → Order of the Minzdrav No.646h dated 31 August 2016 (will come into effect on 1 March 2017);

+ Good Pharmacy Practice (GPP) Order of the Minzdrav No.647h dated 31 August 2016 (will come into effect on 1 March 2017).
2. MAIN LEGAL TRENDS AND CHALLENGES

3.1. Main trends

→ Reinforcement of quality requirements and controls:

+ Necessity for local manufacturers to obtain a Russian GMP certificate.


+ Necessity for foreign manufacturers to obtain a Russian GMP certificate to register new medicines or any variations to existing registered medicines.

+ Draft amendments to existing rules were proposed by the Minpromtorg and the Association of International Pharmaceutical Manufacturers (the “AIPM”) to relax this obligation (Source: http://regulation.gov.ru/projects#npa=59225).


+ Russian authorities plan to test new marking rules for some medicines in order to allow a control of the movement of each unit from the manufacturer to the patient (source: http://government.ru/media/files/TZp2xmnNFAedJuSAhkEDjv5tAifTOAa4.pdf).
3. MAIN LEGAL TRENDS AND CHALLENGES

3.1. Main trends

→ Localization of R&D and production are encouraged:

+ Starting from 1 January 2017, local production of the finished dosage form required to be considered as a Russian manufacturer → Regulation of the Russian Government No.719 dated 17 July 2015 (as amended);

+ Access to state and municipal procurement restricted for certain foreign medicines and medical products:

  + Certain types of medical products/devices, which do not originate from the EEU, are banned from state and municipal procurement in Russia → Resolution of the Russian Government No.102 dated 5 February 2015 (as recently amended);

  + Foreign medicines included into the EDL, which do not originate from the EEU, are under certain conditions banned from state and municipal procurement in Russia → Resolution of the Russian Government No.1289 dated 30 November 2015;

  + A system of 15% price preference for local medicines was introduced → Order of the Ministry of Economic Development No.155 dated 25 March 2014.

+ Creation of special investment contracts.

+ Tax incentives for local R&D and production (e.g. Skolkovo, regional tax incentives for investments projects, etc.).

+ State subsidies may be granted for development of substances, new medicines and clinical trials (Source:http://www.pharmvestnik.ru/pubs/lenta/interjvju/soxranajte-spokojshtvie-872.html#.WH4qreO9qUk).
3. MAIN LEGAL TRENDS AND CHALLENGES

3.2. Some significant challenges

→ Definition of an acceptable balance between the goals of the Russian authorities and the risk of disappearance of certain foreign medicines from the Russian market.

→ Parallel imports and compulsory licensing, which are considered by Russian authorities in order to reduce price for certain foreign medicines and facilitate the access of Russian population to these foreign medicines.

→ Functioning of the single pharmaceutical market within the EEU.
4.1. Legal developments at the level of the EEU

→ A single pharmaceutical market between Russia, Kazakhstan, Belorussia and Armenia may start to function shortly pursuant to the Agreement on the EEU dated 29 May 2014 and the Agreement on common principles and rules for the circulation of medicines within the EEU dated 23 December 2014.

→ It was initially expected to be launched on 1 January 2016.

→ However, a set of key regulations required for the functioning of this single market was adopted by the EEU Commission on 3 November 2016 only. Some of these regulations:

  + Regulations on the creation of an expert committee for the purpose of the harmonization of the legislation of member states;
  + Rules governing the procedure for determination of generic medicines to reference medicines;
  + Rules governing the cooperation of member states for identification of counterfeit and poor-qualified medicines;
  + Rules on registration and expert examination of medicines (until 31 December 2020 registration may be conducted either in accordance with national legislation or rules of the EEU);
  + Good Pharmacovigilance Practice; Good Clinical and Laboratory practices in order to ensure recognition of the results of trials in each member state.

+ Additional set of regulatory acts may be adopted this year (Source: http://www.eurasiancommission.org/ru/nae/news/Pages/14-12-2016-12.aspx).
4. RECENT LEGAL DEVELOPMENTS

4.2. Localization and Special investments contracts

**Localization schemes:**

- **Localization may be carried out through a contractual scheme** with a third-party local manufacturer → it may entail the conclusion of supply and license agreements in relation to bulk products or “tooling/contractual manufacturing” agreements.

- Other option: localization through its own production site in Russia.

- Special investments contracts are a new legal instrument created in accordance with Federal Law No.488-FZ dated 31 December 2014 “On industrial policy of the Russian Federation” that may be of interest to investors contemplating a localization project.

**Special investments contracts:**

- Regime and template of special investments contracts defined by Regulation of the Russian Government No.708 dated 16 July 2015 (as amended).
4.2. Localization and Special investments contracts

What is it?

- It is a contract between the investor and state (federal or regional) or municipal authority;
- Duration: no longer than 10 years;
- Subject: (i) creation or modernization of an industrial plant; (ii) introduction of best available technologies; or (iii) development of a production, which has no analogues in Russia;
- Minimum investment amount: RUB 750,000,000 for a special investment contract at Federal level;
- Advantages: tax incentives, guarantees against adverse legal changes, etc.;
- The list of incentives established by applicable legislation is to be proposed by the investor;
- Duration of the procedure for conclusion of a special investment contract: 90-100 working days;
- Special investment contracts at Federal level are signed by the Minpromtorg;
- They are elaborated with the assistance of the Industrial Development Fund (http://idfrf.org/).
4. RECENT LEGAL DEVELOPMENTS

4.3. Growing role of Federal Anti-Monopoly Service (the “FAS”)

→ Control over state and municipal procurement.

→ Frequent investigations against pharmaceutical companies and distributors (abuse of dominant position, restriction of competition, cartels, etc.).

→ Control over medicines’ advertising.

→ Functions related to the regulation of prices on medicines included in the EDL further to the abolition of the Federal Tariff Service in July 2015.

→ Development of clarifications and recommendations → e.g.:
  
  + Recommendations of the FAS published on 30 June 2015 in relation to the development and implementation of commercial policy by entities in a dominant position on the pharmaceutical market and the market of medical products/devices;

  + Code of Good Practice in the Pharmaceutical Industry dated 19 April 2016 elaborated by the Association of European Businesses (the “AEB”) and the FAS – this Code is aimed at self-regulating certain areas of activity of medicines’ manufacturers.

→ Significant role in the “law making” process.
5. SUMMARY

International practice and legislation of Western jurisdiction are more and more taken into consideration by Russian authorities → some similar aspects:

+ Possible double protection of IP rights with patents and data exclusivity;
+ Significant recent reinforcement of quality requirements;
+ Importance of anti-monopoly compliance;
+ Existence of elaborated pharmacovigilance rules;
+ Existence of ethical requirements, including limitations applicable to the relations between pharmaceutical and medical employees.
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