CORONAVIRUS
OVERCOMING THE DIFFICULTIES

SPECIAL RULES FOR PHARMA SECTOR IN RUSSIA DURING THE COVID-19 EMERGENCY

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The COVID-19 pandemic raises new challenges for the healthcare and pharmaceutical industries and special rules were adopted at various levels of legislation in this connection, which should be borne in mind by market players. The new rules raise monitoring and prevention tools, seek to facilitate the distribution of medicines, introduce certain price controls, provides for certain import duty and VAT exemptions, provides for tougher sanction for specific criminal and administrative offences, and relax a number of administrative and, to a limited extent, safety requirements.

We provide below a high level summary of the main news provisions in chronological order.

1. The Russian Government included coronavirus 2019-nCoV in the **list of diseases dangerous for the public** on **31 January 2020** (**Resolution of the Russian Government no. 66 dated 31 January 2020**). In accordance with the Law "On protection of health of Russian citizens" (no. 323-FZ dated 21 November 2011) healthcare organizations must specifically monitor the health of patients with diseases dangerous for the public. The official classification of COVID-19 as a disease dangerous for the public was used as legal basis for introducing specific regulations applicable in the current pandemic situation as explained below.

2. On **17 March 2020** the President of Russian Federation issued **Order no. 187 legalizing on-line retail sales of pharmaceuticals**, provided on-line sales meet the following conditions:

   - on-line retail sales are permitted only for over-the-counter (OTC) pharmaceuticals;
   - only licensed pharmacies are allowed to sell OTC drugs on-line;
   - licensed pharmacies shall obtain a special authorization for on-line sales from the Federal Service for Supervision in Healthcare (Roszdravnadzor).

   Detailed rules on on-line retail sales of OTC drugs, including the procedure of issuance of special authorizations, additional requirements for pharmacies, procedures of on-line sales and deliveries, will be issued by the Russian Government. However, as of today, no governmental regulatory acts were issued and, in their absence, on-line sales of drugs are not feasible in practice.

Based on Order no. 187, relevant provisions on on-line retail sales of OTC pharmaceuticals were introduced by **amendments** to **Law "On circulation of pharmaceutical products"** (no. 61-FZ dated 12 April 2010) and **Law "On information, information technology and protection of information"** (no.149-FZ dated 27 July 2006). However, the amendments still do not provide the detailed procedures that are necessary for the actual launch of on-line sales of OTC pharmaceuticals.

3. Distinct **amendments** to the **Law "On circulation of pharmaceutical products" (no. 61-FZ dated 12 April 2010)** and the **Law "On protection of health of Russian citizens" (no. 323-FZ dated 21 November 2011)** were adopted on **26 March 2020** supplying the Russian Government with broad powers to **control and fix the prices of pharmaceutical products** (other than those included in the special list of vital and essential pharmaceuticals, which are already under an administrated price regime) **and medical goods in case of emergency or risk of dissemination of public dangerous diseases, or 30 % increase of retail prices during a 30 days period.**

   Based on the new provisions the Russian Government can set maximum sales prices for drug producers as well as wholesale and retail margins, which will remain in force for 90 days.

4. The **Eurasian Economic Union** (EAEU) Commission's Council issued on **16 March 2020** a **Decision no. 21** aimed at preventing the spread of COVID-19 within the EAEU, which has direct effect for all member States starting from **03 April 2020**.

   The EAEU Decision **exempts from import duties certain goods imported** into the member States **for the purpose of prevention of and fight against the COVID-19** pandemic, including, among others

   - goods used for manufacturing of pharmaceuticals;
   - goods used for manufacturing of antiseptics;
   - vaccines, reagents and goods for diagnosis;
   - goods used for manufacturing protecting gloves, spectacles, masks and other personal protection and protective clothing;
   - medical syringes, injectors and systems for blood taking and transfusion;
   - other equipment for medical purposes;
   - thermal bags, freezers and special containers.

   The import declaration for such goods should be registered by 30 September 2020, and the intended use should be further confirmed by a document to be issued by the State healthcare authority concerned. The Decision also provided for derogations from other customs procedures.

5. **Federal Law no. 89** dated and in force from **01 April 2020**, implemented **administrative fines for the sale of substandard, counterfeit or unregistered pharmaceutical products** or nutritional supplements **using mass media or telecommunication networks**, including the **Internet** (paragraph Art. 6.33 (3) of the Code of Administrative Offenses of Russia). This amendment includes mass media and telecommunication networks within the scope of existing administrative offences and sets higher amounts of fines for new administrative offence.

Offender	Fine amount for general offence (Art. 6.33 (1))	Fine amount for offence using mass media or Internet (Art. 6.33 (3))
Individual person	70,000 – 100,000 Rubles	75,000 – 200,000 Rubles
Individual entrepreneur	100,000 – 600,000 Rubles or administrative suspension of activity for up to 90 days	150,000 – 600,000 Rubles or administrative suspension of activity for up to 90 days
Public Official	100,000 – 600,000 Rubles	150,000 – 600,000 Rubles
Legal entity	1,000,000 – 5,000,000 Rubles or administrative suspension of activity for up to 90 days	2,000,000 – 6,000,000 Rubles or administrative suspension of activity for up to 90 days

In turn, **Federal Law no. 95** , also dated and in force from **01 April 2020**, added a new element to the criminal offence foreseen by Article 238.1 of the Criminal Code, consisting of large scale production, import or sale of substandard, counterfeit or unregistered pharmaceutical products or nutritional supplements using mass media or telecommunication networks, including the Internet, which may be sanctioned with up to 6 years' imprisonment and a fine up to 2,5 mln. Rubles. Similar to administrative offences, the sanction for the same criminal offence committed without the use of mass media or the Internet is lower – up to 5 years' imprisonment and up to 2 mln. Rubles fine.

6. Further to **EAEU Decision no.21**, the Russian Government adopted **Resolution no. 419** dated **02 April 2020**. This instrument rests on the EAEU Decision and identifies the State authorities competent for providing documents confirming the intended purpose of imported goods (prevention of and fight against the COVID-19 pandemic), and furthermore **exempts such goods from VAT**, both when imported into Russia and sold within Russia.

   The list of goods exempted from VAT was widened by the Resolution, including COVID-19 tests, protective gloves, spectacles, protective masks, protective clothing, electronic thermometers, protective breathing equipment, air filtration equipment, artificial lung ventilation apparatuses and other certain products used during treatment of COVID-19.

7. On **03 April 2020** the Russian Government issued Special rules (**Resolution of the Russian Government no.441**) for the circulation of medical drugs used in case of emergency, for treatment of diseased dangerous for the public and the effects of hazardous factors. These Special rules are applicable in situations of actual emergency, spread of dangerous diseases and health hazards, or risk of thereof, and provides for **lower requirements for obtaining marketing authorization for pharmaceuticals** intended for such uses, by:

   a. Reducing the criteria to asses risk/effect balancing, when the manufacturing of packaging site of a registered medicine is changed;

   b. Replacing actual laboratory experiments with the laboratory tests envisaged by Article 52.1. of Federal Law no. 61-FZ dated 21.04.2010 "On turnover of pharmaceutical products" before placing the pharmaceutical on the market;

   c. Providing the documentation required in accordance with the Law "On turnover of pharmaceutical products" during the emergency period in electronic form only.

   These simplified rules relate to the second stage of the procedure for obtaining marketing authorization, which follows the passing of Good Manufacturing Practice inspections and clinical trials.

8. Starting from **06 April 2020** and till **01 January 2021** a special procedure of registration is applied to the releasing of lots of medical products for use in military activities, emergency, prevention and treatment of diseases dangerous to the public and diseases caused by health

hazards. **Resolution no. 430** of the Russian Government dated **03 April 2020** provides that **ordinary technical tests, toxicological tests and clinical trials for medical products are not mandatory in cases of emergency or threat thereof**. The certificate of registration of lots released on the basis of this Resolution will be valid till **01 January 2021**.

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