

IMPORT SUBSTITUTION IN THE PHARMACEUTICAL AND MEDICAL INDUSTRIES IN RUSSIA: LEGISLATIVE DEVELOPMENTS AND INITIATIVES



Import substitution (a significant increase of the share of medicines and medical devices of Russian origin) in the pharmaceutical and medical industries is envisaged by:

- the Strategy of Pharmaceutical Industry Development in the Russian Federation for the period up to 2020 approved by the Order of the Ministry of Industry and Trade of the Russian Federation (Minpromtorg) No. 965 dated 23 October 2009, under which localization of manufacturing and development of medicines in Russia is the first of three main stages;
- the Federal Target Program 'Development of the Pharmaceutical and Medical Industry of the Russian Federation for the period up to 2020 and further' ('Pharma 2020') approved by the Resolution of the Government of the Russian Federation No. 91 dated 17 February 2011, and by the State Program of the Russian Federation 'Development of Pharmaceutical and Medical Industry' for 2013 - 2020 approved by the Resolution of the Government of the Russian Federation, No. 305 dated 15 April 2014, providing that by 2018 the share of domestic medicines under the nomenclature of the list of strategically important medicines and the list of vital and essential medicines shall be 90%, the share of domestic medical devices within the priority areas of healthcare - 22%.

The main directions of legal regulation of import substitution in Russia include:

- creation of incentives for localization of production facilities by foreign manufacturers in the Russian Federation, including granting of subsidies for organisation of clinical trials and manufacturing of medicines and medical devices;
- restriction of the procurement of foreign goods for state and municipal needs.

The recent changes in laws and legislative initiatives in these areas are considered below in more detail.

Subsidies to the Russian manufacturers of medicines and medical devices and(or) pharmaceutical substances

On 1 October 2015, the Government of the Russian Federation adopted a number of resolutions to approve the procedures and conditions for granting subsidies from the federal budget to Russian organisations for partial compensation of costs:

1. related to the clinical trials of medicines: for the purchase of raw materials and consumables for producing samples of the developed medicine, for the purchase of comparator medicine, for the third-party services on laboratory, clinical and diagnostic trials and searches, processing of resulting findings, transport of clinical samples, as well as for premiums on insurance of life and health of patients participating in clinical trials of the medicine (Resolution No. 1045);
2. incurred in the implementation of projects for the production of medicines and(or) pharmaceutical substances under the list of vital and essential medicines (Resolution No. 1047). Subsidies are granted in respect of payments (except for initial payment) under equipment leases, for the third -party services on commissioning of equipment for the production of pharmaceutical substances, for the purchase of consumables, reagents for the production technology development, including the run of pre-production batches (validation series) of pharmaceutical substances, as well as for payment for other third-party services associated with the project;
3. incurred in the course of conducting clinical trials of medical devices included in the list of medical devices implanted into the human body when providing medical assistance under the program of state guarantees of free medical aid to citizens (Resolution No. 1046). The subsidies may be granted to Russian organisations possessing valid permits to conduct clinical trials of medical devices included in the list of medical devices implanted into the human body when providing medical assistance under the program of state guarantees of free medical care to citizens approved by the Government of the Russian Federation;
4. related to the organisation of high-tech manufacturing of medical devices in such areas as: medical devices implanted in the human body; disposable medical devices; consumables for medical devices;

technical means of rehabilitation related to medical devices for handicapped persons and persons with disabilities; installations for high efficiency ion beam radiation therapy; medical devices for personal remote monitoring of patients; medical devices for ophthalmology (Resolution No. 1048). The subsidies are granted to Russian organisations with total revenue from the sale of medical devices of own production during 2012 - 2015 years in the amount not less than 100 million roubles and possessing at least one valid registration certificate for the medical devices manufactured thereby.

The subsidies are provided upon an application based on the agreement entered into between Minpromtorg and a Russian organisation.

The Resolutions establish the following general rules for granting subsidies:

- a. an organisation applying for a subsidy must be registered in the Russian Federation and possess a license for manufacturing of medicines for medical use (according to the Resolutions No. 1045 and No. 1047) or medical devices (according to the Resolution No. 1048), respectively;
- b. the business plan must stipulate the release into circulation of a pharmaceutical substance or medical device manufactured under the project not later than within 3 years after entering into the agreement for granting of the subsidy;
- c. subsidies are granted in respect of the costs of Russian organisations actually incurred on or after 1 January 2015, confirmed by documents, related to the project and provided for by the business plan;
- d. subsidies will cover no more than 50% of the total costs and no more than 200 million roubles (5 million - in case of clinical trials of implantable medical devices) per a legal entity.

'Third Weird': Restrictions in Public and Municipal Procurement

Article 14 of the Federal Law No. 44-FZ 'On the Contract System in the Area of Procurement of Goods, Works and Services for Public and Municipal Needs' (Law No. 44-FZ) provides for the right of the Government of the Russian Federation to impose a ban on the admission of goods originating from foreign countries and to restrict the admission of such goods for the purposes of the relevant procurement.

Based on the above provisions of the Law No. 44-FZ, the Government of the Russian Federation adopted the Resolution No. 102 dated 5 February 2015 which provides for the obligation of a customer in the course of procurement of medical devices included in the list approved by this resolution for public and municipal needs to reject all tender bids for the supply of medical devices originating from foreign countries, except for Armenia, Belarus and Kazakhstan, provided that there are at least two bids that simultaneously meet the following requirements:

- contain offers of the supply of the medical device(s) included in the list and originating from Russia, Armenia, Belarus or Kazakhstan;
- do not contain offers for the supply of the same type of medical device of the same manufacturer.

By the end of this year, the Government of the Russian Federation is to adopt another Resolution (a so -called 'Third Weird') providing that from 1 January 2016 in the course of procurement of a medicine for public and municipal needs by way of a tender or auction, the restrictions on admission of the bids for the supply of the following medicines will apply:

- originating from foreign countries (except for Armenia, Belarus and Kazakhstan);
- in respect of which in the territory of Russia and(or) Armenia, Belarus, Kazakhstan only the stages 'primary packaging' and(or) 'secondary packaging' of technological process are effected,

in the event there are two or more bids filed by different manufacturers for the supply of medicines originating from Russia and(or) Armenia, Belarus, Kazakhstan, and in the territory of the relevant country the technological process stage 'production of the finished dosage form' is performed.

The procedure for confirmation of the technological process stages of manufacturing of medicines, including the stages of production of active pharmaceutical ingredients, should be approved by Minpromtorg by 1 January 2016.

The respective draft regulatory act provides that medicines, serums and vaccines will be deemed the goods of the Russian origin based on the criteria of 'the technological process stages performed in the Russian Federation' as well as the criteria of their state registration in Russia.

The stages will be divided into 'production of the finished dosage form' and 'packaging'. From 1 January 2016 the goods manufactured in Russia are to include only medicines with respect to which both these stages are performed in the Russian Federation.

In addition, the Ministry of Economic Development of the Russian Federation and Minpromtorg shall by 1 January 2016 adopt the regulatory act establishing the differentiated scale of preferences depending on the technological process stage of manufacturing of a medicine for the purposes of determining a contract price in the course of state and municipal procurement.

According to the Head of the Department of Development of Pharmaceutical and Medical Industry of Minpromtorg, the medicines not covered by the 'Third Weird' Resolution will be subject to the 15% preference related to the contract price under the Order of the Russian Ministry of Economic Development 'On Conditions for the Admission of Goods Originating from Foreign Countries, for the Purposes of the Procurement of Goods, Works and Services for Public and Municipal Needs' No. 155 dated 25 March 2014.

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GRATA Law Firm provides for a broad range of services to pharmaceutical and medical industries, including:

- advising and legal support in participating in public procurement and localisation of manufacturing facilities in the territory of the Eurasian Economic Union countries (the EEU);
- representing interests in the course of public discussions of the draft laws and regulatory acts, including the acts of the Eurasian Economic Commission;
- advising on the requirements and restriction regarding the import and circulation of medicines and medical devices in the EEU.

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