SPIC in Pharmaceutical Sphere of the Russian Federation

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1991 - 2009 - No special requirements in Russia to the place and stages of pharmaceutical manufacturing. Import and package of the medicine products prevailed: no much investments, no transfer of patents to Russia.


December 2015 – The Regulation of the Russian Government “Odd man out” – preferences for the local pharmaceutical products while public bids for the governmental needs. The packaging stage is recognized as local production.

January 01, 2017 – MADE IN RUSSIA (finished pharma product and packaging)
The volume of the foreign investments to the Russian pharma industry exceeded 2 bln EURO.

There were put into operation new 25 pharmaceutical sites (Novartis, AstraZeneca, Teva, etc.)

There were concluded many contract manufacturing agreements (Pfizer, Eli Lilly and Company, Boehringer Ingelheim, Ipsen, Teva etc.)

Major foreign investments to the Russian pharmaceutical sites (Sanofi, in 2014 Abbot has become a major shareholder of the company VeroPharm and made investments exceeded 300 mln USD)

Cooperation agreement (partnership) between Russian and foreign pharma companies (July 2016 – NovaMedica and Pfizer)

2016 - near 10 SPICs are in process of the approval by the state authorities
Subject matter of SpIC

Essence of the special investment contract (SpIC) is as follows:

1. Put into operation or industry modernization and (or) development of pharmaceutical productions of industrial output by the Investor in Russia

2. Guarantees of stability of tax and regulatory conditions to the investor from the Russian Federation or its subject as well as accomplishment of measures of stimulation of investor’s activities

3. The milestones of the contract executions are not so rigid nowadays as the obligations of the investor under the standard localization agreements. Draft bill – annual and final covenants of production

Subject matter of SpIC:

1. Put into operation or industry modernization and (or) development of pharmaceutical production in the Russian Federation (the requirement of the Law on industrial policy)

2. Introduction of the pharma production which doesn't have analogs in the Russian Federation

3. The best available technology adoption

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Parties to SpIC are:

1. Investor
   - Investor may involve the other person (so-called involved person) for realization of the investment project within SpIC.
   - No prohibition for the foreign company (*non-offshore company – draft bill*)

2. The Russian Federation and the subject of the Russian Federation and/or the municipal authority OR the subject of the Russian Federation and/or the municipal authority

   The state authorities and Investor are not co-investors - public authorities provided the measures of stimulation
Business plan of the Investor shall meet the tasks and (or) promote achievement of targeted indicators and indicators of the Russian Federation state programs in pharmaceutical industry (Pharma-2020)

The documents supported the absence of the analog pharma products in Russia

The volume of investment shall be at least 750 million rubles (11 mln EURO/10 mln GBP) or 3 billion rubles (44 mln EURO/39 mln GBP) for the obtaining “exclusive state supplier” status

SpIC term shall not be more than 10 years
Unconditional guarantees for the investor and/or the involved persons during SpIC’s term:

- Regulatory acts (and amendments) establishing prohibitions, restrictions on SpIC’s conditions, as well as the mandatory requirements to production or process of production of industrial output accepted after the SpIC conclusions of SPIK shall not apply

- The cumulative tax burden of the income of the investor and/or the involved persons in comparison with those being in force at the time of the SpIC conclusion shall not increase

- Other measures of stimulation could be provided by the public authorities

- Exclusive supplier status could be obtained by the Investor for the pharmaceutical production manufactured under SpIC and supplied for public needs at regulated prices
September 1, 2016 - the public customer can determine a pharma supplier as an exclusive supplier of goods for the public needs if its production is manufactured under SpIC and:

1. The volume of investment on the project made during the term of SpIC exceeds 3 billion rubles (44 mln EURO/39 mln GBP)

2. Production of the pharma products in the territory of the Russian Federation will be performed by the Russian legal entity

3. Country of consignment of the finished pharma products is the Russian Federation

4. Delivery of the pharma production for the state and municipal needs doesn't exceed 30% of annual production

5. Responsibility for limiting excess of amount of products in the form of a penalty in the amount of 50% of cost of such excess is provided
Other forms of the state participation in SPIC

- Financial support in the form of subsidies from budgets of all levels
- Tax credit
- Provision of the state and municipal reassurances
- Provision of the state and municipal preferences
- Other measures of stimulation
DISTRIBUTION

The exclusive supplier status issues:

• A right, but not the obligation of the state customer to purchase the production under SPIC

• SPIC products ≠ Made in Russia

• Several suppliers of the similar pharma products (1 or more lucky winners)

• Authorized state body to initiate a regulation act determining an exclusive supplier is not known

• Anti-monopoly risks

Production distribution (shelf life of the produced pharma products)

The procedure of the price regulation for the goods manufactured under the SPIC, authorized state body
MANUFACTURING

- Threshold of investments
- Accuracy in planning (penalty for overshipment)
- The Eurasian Economic Union requirements
- Reports procedures
THANK YOU FOR YOUR ATTENTION!

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