Long-term procurement arrangements in the pharmaceutical sector: New options or additional risks?

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From 1 September 2016, investors under special investment contracts (SPICs), as well as regional investors, may benefit from additional preferences during the procurement of various types of product for state and municipal needs. Whether these preferences will create long-term procurement options in the pharmaceutical sector is one of the key questions for pharmaceutical companies planning to invest in localisation in Russia.

Legal framework

The new procurement options derive from Federal Law 365-FZ, "On Amendments to the Federal Law 'On the Contract System in the Sphere of Procurement of Goods, Works and Services for State and Municipal Needs, and Certain Normative Acts of the Russian Federation'", of 3 July 2016 (Law 365-FZ), which takes effect on 1 September 2016 and creates a direct legal connection between certain types of investment agreement and procurement from a sole supplier.

The amendments introduced by Law 365-FZ may apply to various economic sectors, but for the pharmaceutical sector may have additional factors to consider, briefly described below.

New procurement options

Law 365-FZ provides the following procurement options for, inter alia, pharmaceutical companies:

(i) direct purchases of medicines manufactured under a SPIC for state and municipal needs;[1]

(ii) direct purchases of medicines manufactured under a regional investment contract with an investor who creates or upgrades and/or sets up the production of pharmaceutical products in a Russian region (a Regional Investment Contract or RIC).[2]

KEY CHARACTERISTICS	SPIC	RIC
1. Procurement from a sole supplier	Yes	Yes
1.1. How the sole supplier is approved	Through a normative act of the Russian government	Through a competitive tender
1.2. Who may be approved as the sole supplier	An investor under a SPIC[3] who creates or upgrades and/or sets up the production of unique products (the Manufacturer)	An investor who creates or upgrades and/or sets up the production of unique products in a Russian region (the Investor)
1.3. Additional requirements for the investor	The Manufacturer must be a Russian entity	The Investor must be a Russian entity
2. Investment threshold	More than RUB 3 billion	Not less than RUB 1 billion
3. Procurement period	SPIC term[4] (+ 1 year in case of product export[5])	Maximum 10 years

1 See the new Art. 111.3 of Federal Law 44-FZ, "On the Contract System in the Sphere of Procurement of Goods, Works and Services for State and Municipal Needs", of 5 April 2013, as amended by Law 365-FZ (Law 44-FZ).

2 See the new Art. 111.4 of Law 44-FZ.

3 In certain cases a third party appointed by such an investor. See Art. 111.3(1) of Law 44-FZ.

4 The maximum term of a SPIC is 10 years. The actual time period within these 10 years is calculated as the time needed for the project to generate operating revenue plus 5 years (see Para. 3 of the Rules on SPIC Conclusion, approved by the Russian government Resolution 708, "On Special Investment Contracts for Certain Industries", of 16 July 2015). Within this period, state purchasers may enter into direct supply agreements with the Manufacturer under the SPIC.

5 A federal authority that has entered into a SPIC may extend the procurement period for 1 year after the SPIC expires, if during 1 calendar year or more the product manufactured under the SPIC has been exported outside Russia and the volume of exports was not less than 10% of the production volume in the respective calendar year.

4. Price	Regulated	Regulated
4.1. Who approves the general pricing guidelines	The Russian government	The Supreme Executive Body of the Russian region / Russian government[6] (if appropriate)
4.2. Who determines the contract price / price for each product item	A federal executive authority determined by the Russian government	A regional regulatory authority determined by the Supreme Executive Body of the Russian region
5. Possible procurement volume	30% of the annual production volume[7]	Not restricted, but supply volumes depend on the actual needs of the respective Russian region
6. Automatic exclusivity	No / the Russian government may approve several Manufacturers of similar or identical products as sole suppliers	No / Several RICs may be concluded for similar or identical products
7. Automatic acquisition of local status	Not clear	Not clear

Pharma sector specifics

The regional procurement option provides more flexibility for purchases of medicines than procurement under a SPIC. For instance, Law 365-FZ directly excludes:

(a) the application of Art. 31(10) of Law 44-FZ (e.g. restrictions on using regional mark-ups in price-setting) in the procurement of essential medicines manufactured under a RIC; and

(b) the application of Art. 33(1)(6) of Law 44-FZ (e.g. procurement of medicines under their international non-proprietary names) in the procurement of medicines manufactured under a RIC.

Therefore, in theory risk-sharing mechanisms or other innovative contracting options may be tested under a RIC. At the same time, each of the relevant projects will require individual assessment (specifically, if the general pricing guidelines are approved by the Russian government).

Conclusions and recommendations

Law 365-FZ is a significant advance in the development of the regulatory framework for long-term procurement arrangements. At the same time, it does not provide a fully transparent regulatory picture for long-term procurement options in the pharmaceutical sector:

(a) Law 365-FZ does not directly provide exclusivity for an investor who manufactures a relevant medicine under a SPIC or under a RIC;

(b) price-setting remains regulated and requires the adoption of a number of regulations by the Russian government and authorised government stakeholders; and

(c) there is a number of legal gaps, which require additional clarifications from the respective government stakeholders (e.g. exactly when a product acquires local status).

[6] Under Art. 111.4(3)(3) of Law 44-FZ, the Russian government may determine the regulatory specifics of the pricing guidelines to be approved by the respective regional regulatory authority.

[7] The volume of sales under a SPIC cannot exceed 30% of the annual production volume. We believe that the remaining 70% must then be sold through tender procedures. Sales exceeding the 30% threshold may lead to a fine in the amount of 50% of the excess.

As such, pharmaceutical manufacturers planning to invest in localisation in Russia and considering entering into a SPIC/RIC should carefully analyse the new opportunities provided under Law 365-FZ, and the associated legal and commercial issues.

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