Price Regulation Mechanism for Implantable Medical Devices

THE RUSSIAN MEDICAL DEVICE MARKET

June 2018
IMEDA Mission

- Be the advocate for a legal, regulatory and economic climate that advances public health care by assuring patient access to the benefits of medical technology and ensures equal opportunities for national and international industry;

- Promote and encourage ethical business principles and practices among its members and the industry in general;

- Actively present the interests of the medical technology industry within the Executive, Legislative bodies of the Russian Federation, Media and Public organizations;

- Encourage the development of new and innovative technologies and ensure that these are accessible to patients
**IMEDA in action**

**Consolidates** Voice of international medical device industry in Russia

**Moderates** Dialogue between industry and government

**Initiates** Ideas how to modernize MDs industry legislation in Russia/Eurasian Economic Union (EAEU) to make high-tech medical technologies accessible to citizens of Russia/EAEU
RUSSIAN Medical Device Market
2017 - 2018
Key features
Russian Medical Device Market: FEATURES

• High dependence rate on state procurements, up to 80-85% of the total market, on some segments – 100%

• High dependence rate on import of the foreign high-tech MDs. 20% - share of the locally produced MDs on the market. Local industry is seeking for state support;

• Growing market with relatively good potential (recently formed EAEU – Eurasian Economic Union), growth rate of the Russian MDs market is higher than global average rate;

• Complex Market Access mechanism

• Fragmentary legal regulation

• Free price policy (Price regulation for Implantable MDs – first pilot)
Russian Medical Device Market: FIGURES

- Russia has a population of approximately 140 million with an average life span of 72 years;

- Russia’s MDs Market is about 4.5 bln USD. It’s about 1.3% of the Global Medical Device Market (roughly 390 bln USD);

- The growth of the world MDs market is expected with an average rate of 5.5% annually, The growth rate of the Russian MDs market is about 8-9 %;

- The share of medical devices produced domestically in 2017 in the total volume of the Russian market is about 20%;

- According to the National MedTech Development Program, by 2020 the volume of locally produced MDs will amount to 2.2 bln USD and the share of domestic MDs should be 40%;

- Export of Russian MDs in 2016 amounted to 75.36 mln USD;

- The volume of imports of MDs in 2016 amounted to 2.87 bln USD.
4.5 bln. USD (266.3 bln. RUR) – total volume of the Medical Device Market in Russia in 2017 only 20.2% – locally produced Medical Devices.
Legislation landscape

• The Government has adopted the National MedTech Development Program 2020 and the consolidated investment program for financing the national Health care system;

• New regulatory legislation has been developed by the Ministry of Health; a new classification of MDs adopted based on the international system of GMDN (January 6, 2015);

• The new system for registration of MDs at the national level in Russia has been launched since 2013 (GD №1416);

• The Ministry of Finance is now developing universal Catalogue for MDs for state and municipal needs /purchases (GD №145);

• The Russian Government imposed restrictions on the purchase of a number of foreign-made MDs for state needs (GD №102, February 5, 2015);

• Localization of production, localization requirements for access to state procurement market;

• Formation of the Eurasian Economic Union (May 2014); launch of a single MDs market for the EAEU member states 2017 (Russia, Kazakhstan, Belorussia, Armenia, Kyrgyzstan) but so far it does not function de facto;

• The Ministry of Health has developed a mechanism for price regulation for Implantable MDs (GD № 1517)
Price Regulation Mechanism for Implantable Medical Devices in Russia

Reasons for implementation, theory vs. reality
**CHALLENGE:** Background for implementation of price regulation mechanism

- Economic crisis in Russia started in 2014 with the collapse of oil prices that resulted into national currency sharp decline (Russian ruble);

- The financial crisis aggravated the problems that the Healthcare system had been facing;

- Government anti-crisis plan that included **import substitutions and reductions in public Healthcare budget** was approved in January 2015;

- In 2015 the Russian Government **announced a government decree that introduced a pricing mechanism for implantable medical devices**;

- The price control policy was approved in December 2015. The implementation of the policy shifted from Y2016 to Y2017.
Policy aims:

• Increase efficiency of budget spending: Reduce variability and enhance predictability in the price policy for implantable medical devices;

• Improve transparency of the state procurement system;

• Ensure the availability of high-tech medical care to a larger number of people in Russia.
Pricing Policy Overview

Government Decree №1517: Regulation of Prices for Medical Devices Implanted in Human Body for Treatment Purposes

The Decree stipulates the regulation of:

• Weighted average prices for certain TYPES of implantable MDs;
• Manufacturer`s maximum sale prices for implantable MDs;
• Maximum wholesale mark-ups (in all regions) for implantable MDs.
Government Decree № 1517: Regulation of Prices for Medical Devices Implanted in Human Body for Treatment Purposes released (December 30, 2015);

List of Implantable Medical Devices developed and approved (December, 2014);

Manufacturers/importers were to submit customs (import + customs fees) prices based on customs docs (ex-factory for domestic) regarding the MDs included in this Decree to the Regulator (RosZdravNadzor);

Regulator had to calculate and approve weighted-average prices with Antimonopoly Service (FAS) and publish it;

Manufacturers/importers were to register max sale prices (lower or equal to weighted-average prices);

All regional healthcare governments had to determine maximum amount of wholesale mark-ups in reference to the actual selling price.
Policy Implementation process
Government Decree №1517 released

List of Implantable Medical Devices developed and approved

Manufacturers / importers are to submit customs prices and customs docs to Regulator

Regulator has to calculate weighted-average prices

Regulator has to approve weighted-average prices with Antimonopoly

Manufacturers / importers have to register max sale prices (cannot exceed weighted-average price)

Regional HC Governments have to determine max wholesale mark-ups

Once the decree is fully implemented, maximum prices of hospitals’ contracts should not exceed the registered maximum ex-factory prices for medical devices, including mark-ups and VAT (for medical devices subject to VAT).
List of Implantable Medical Devices developed and approved

Manufacturers / importers are to submit customs prices and customs docs to Regulator

Regulator has to calculate weighted-average prices

Regulator has to approve weighted-average prices with Antimonopoly Service

Manufacturers / importers have to register max sale prices (cannot exceed weighted-average price)

Regional HC Governments have to determine max wholesale mark-ups

The wholesale mark-up is based on customs price submitted by manufacturer, not on max registered price!!!
Policy Implementation process
Weighted-average price calculation

EXAMPLE MODEL (based on Super-categories approach):

<table>
<thead>
<tr>
<th>Pacemaker 1</th>
<th>Pacemaker 2</th>
<th>Pacemaker 3</th>
<th>Pacemaker 4</th>
<th>Pacemaker 5</th>
<th>Pacemaker 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>120</td>
<td>140</td>
<td>170</td>
<td>175</td>
<td>190</td>
</tr>
</tbody>
</table>

Average price = \(P_1 + P_2 + P_3 + P_4 + P_5 + P_6 / 6\)
Average (max sale) price for all pacemakers would be: 149 $

Result: P4/P5/P6 will be out of the market

✓ Baseline prices come from *customs docs not shipments* – no expenses could be included – risks for local offices of International companies
✓ Risk for therapies – several innovative/high-tech devices will not be accessible for hospitals
✓ Risk for the most sensitive category of medical devices
Summary of Timelines

- By March 15, 2017 Manufacturers are to submit info to Regulator;
- RZN and FAS collect all IMDs prices to calculate average prices for each TYPE of IMDs based on special Supercategories;
- By July 1, 2017 FAS publishes average prices to let producers / importers register max price (Max price cannot exceed average price);
- Producers must register max prices by July 15, 2017;
- All 85 regions to set regional mark-ups by Sept 1, 2017;
- After Sep 2017 – go live and integration into procurement system.
Policy Implementation process: reality

✓ Government Decree №1517 released (December, 2015);

✓ List of Implantable Medical Devices developed and approved (December, 2014). Initially there were 382 items, then they left only 250 items in the List. All IMDs were divided into SuperCategories.

✓ Manufacturers / importers were to submit customs (ex-factory for domestic) prices and customs docs regarding the MDs included in this Decree to the Regulator (RosZdravNadzor);

✓ Regulator had to calculate and approve weighted-average prices with Antimonopoly Service (FAS) and publish it. In 2017 Roszdravnadzor collected data on prices of implantable medical devices that had been imported/sold during the previous 12 months by all producers (foreign and local). RZN calculated the average prices for each product type. These average prices were supposed to be approved by Federal Antimonopoly Service (FAS) and then published. FAS refused to approve average prices for most of the MDs types (only 64 out of 250).

✓ Manufacturers / importers were to register max sale prices (lower or equal to weighted-average prices) 2770 prices.

✓ All regional healthcare governments had to determine maximum amount of wholesale mark-ups in reference to the actual selling price (in accordance with guidelines developed by Min of Health). As an example, the calculation of max wholesale mark-up provided in published guidelines is from 1 to 7% or 6-150 USD depending on actual selling price. About half of 85 regional HC governments have not determined max wholesale mark-ups yet.
Industry concerns with policy
Lack of clarity and differentiation /deadlines

- **Product categories did not account for the diversity within product segments.** Aligning a diverse set of products under one category failed to account for significant improvements in product design and quality that occur in our quickly-evolving industry. As a result, pricing failed to account for possible improvements that put under risks access to innovative therapies.

- **Lack of clarity on what prices manufacturers needed to report has led to inconsistencies and unfairness.** Foreign producers were required to provide customs prices, which didn’t include critical expenditures related to marketing and distribution (depends on the business model that foreign manufacturers use to work in Russia) + poor administration of the data collecting process resulted into the lack of clarity on which prices were submitted.

- **Poorly defined guidelines to calculate wholesale mark-ups.** The decree stipulated formal rules but it did not stipulate a clear mechanism for differentiating markups depending on the product type. This has caused confusion among the regions, which were struggling to meet their deadline without making proper analysis of previous procurements.

- As a result failure to meet deadlines (SHIFT from 2016 to 2017)
Industry Advocacy Activity
Revising classification & methodology

✓ In 2016 successful industry advocacy resulted into the **postponement of the GD 1517 implementation for one year (2016-2017)**;

✓ List of implantable MDs that are subject to price regulation **reduced** (382 – 250 items)

✗ Revising the product categories (instead of basing classification on nomenclature of MDs, industry suggested to define groups of functionally interchangeable MDs). **Government didn’t support idea** to change “Super-categories approach” for more “detailed approach” with diversity within product segments.

✗ Industry proposed alternative method based on **Manufacturer Suggested Retail Prices (MSRPs)**. **Government didn’t accept** it saying there is no price regulation mechanism in it, little experience of MSRPs in MDs sector globally (in food sector);

✓ Issue on what prices manufacturers need to report **resolved** *(customs price = import price + customs fees)*. **Issue clarified**;

- Developing consistent mark-ups methodology for different products **not done yet**.
Industry Advocacy Activity, current actions

✅ Industry prepared amendments to price control mechanism and convinced Ministry of Health to initiate process of amending Price Regulation Decree:

**DRAFT:**

There are four sources to determine initial (max) contract price:

- Approved weighted-average prices;
- List of contracts for the last 12 months;
- Catalogue for all MDs that is now being developed by Min of Finance/Roszdravnadzor;
- Offers of MD suppliers.

Industry estimates amendments to be approved this year

??? Another monster ???
ALL QUESTIONS WHICH REQUIRE INVESTIGATION, EXPERTISE AND PROFESSIONAL DISCUSSION WITH THE INDUSTRY:
THE VOICE OF INTERNATIONAL MEDICAL DEVICE INDUSTRY IN RUSSIA

imeda@imeda.ru
www.imeda.ru