AN OVERVIEW OF THE MEDICAL DEVICE REGULATIONS IN THE RUSSIAN FEDERATION

Russia has a population of 149 million and is a potentially lucrative market for medical device companies. In 2007, the Russian market for medical devices and related supplies totalled US$1.8 billion. This puts the market among the top 20 in the world, although per capita spending remains very low compared to the European or US markets.

The registration of medical devices and medical equipment in Russia is, however, challenging. Russia has made efforts to improve the process in the last few years but there are still many areas of ambiguity. In 2006, the government initiated a Priority National Programme in Public Health Service, which aims to improve Russian healthcare standards and a regulatory process that was bureaucratic and lacked clarity and transparency. Since the project’s implementation, numerous medical facilities have been upgraded. This plan is benefiting equipment manufacturers as around 80% of the market is supplied by imports. Germany, the USA and Japan were the leading suppliers in 2007, accounting for more than half of all imports.

Perhaps most problematic for foreign manufacturers seeking device registration is that Russia still relies on a system of product testing as a tool for determining product safety and efficacy. As Russia has its own national standards, such testing is also required for products that already possess CE marking, US Food and Drug Administration 510(k) clearance or other national approvals. Even products that have been for sale on the US and European markets for many years require product testing to Russian standards as well. Russia’s policy of requiring product testing in addition to obvious language issues are significant barriers for foreign companies to register medical equipment in the country.

Regulatory authorities
Several major government entities currently oversee regulation of medical equipment and devices in Russia.

Roszdravnadzor
This is the short title of the Federal Service for Control of Healthcare and Social Development in the Russian Federation. This agency oversees all domestic and imported medical devices in Russia. It governs and controls the registration procedure, approves or rejects applications for state registration, and works to ensure clinical safety and efficiency of medical devices and medical equipment. Roszdravnadzor has a website (www.roszdravnadzor.ru) where it publishes contact information, telephone numbers and a list of documents required for registration of foreign-made medical equipment and devices. However, all the information is in Russian only. In addition, officials do not generally provide any consultation via email or telephone and prefer to meet in person regarding registration issues. Having an experienced local representative to assist with registration is imperative.

Gosstandart
Known as the Federal Agency for Technical Regulation and Metrology, this agency makes sure that medical equipment imported into Russia meets established Russian standards. This agency is responsible for GOST-R certification, which will be discussed later in this article. The Gosstandart website can be found at www.gost.ru and is available in Russian and English.

Rospotrebnadzor
Not to be confused with Roszdravnadzor, this is the Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection. This agency makes sure that products meet Russia’s sanitary and epidemiological regulations for products that come into contact with the human body or which may otherwise negatively affect patients or doctors. They issue Sanitary-Epidemiological
Conclusion (Hygiene Certificate), which will also be discussed later in this article. The Rospotrebnadzor website is found at www.rospotrebnadzor.ru. More detailed information regarding how to obtain a Hygiene Certificate can be found at www.crc.ru, but all the information is provided in Russian only.

Registration procedure
The Russian medical device registration process is complicated and, since very few documents exist in English, it is essential to work with a local expert who understands the process and can navigate your device through to successful registration. This person/company is referred to as the ‘applicant’ throughout this article and should not be confused with the ‘manufacturer’ for whom the applicant is seeking approval.

Provided below is a summary of the order in which certain activities occur during the registration process:

1. Determine if an already approved and equivalent device exists in the Russian Federation.
2. Confirm the classification of your device.
3. Meet with officials to determine the testing requirements for your product.
4. Apply for permission to import testing samples.
5. Conduct testing at government authorised testing and medical centres within Russia.
6. Receive results of testing and medical reports.
7. Prepare the registration dossier, including testing results and medical reports.
8. Submit all documents to the relevant officials and receive a Registration Certificate.
9. Apply for a Hygiene Certificate (if applicable to your product) to Rospotrebnadzor.
10. Apply for GOST-R Certificate to Gosstandart.
11. Product is added to Roszdravnadzor database, which is published on their website.
12. Device can be imported into the Russian Federation upon presentation of Registration, Hygiene (if needed) and GOST-R Certificates, plus other typical international commercial shipping documents (e.g. a Cargo Customs Declaration and a Declaration of Conformity with Russian standards and regulations).

The first step for a company that would like to sell a medical device in Russia is to identify an equivalent device which has been registered already in the Russian Federation, and to provide documentation certifying equivalence with this predicate. (N.B. In the Russian Federation, this is called an ‘analogue’ device).

As noted in Ministry of Public Health and Social Development of the Russian Federation Order No 735, dated 30 October 2006 and entitled Administrative regulation of the Federal service for supervision in the sphere of health and social development of performance of the state duty of registration of medical products, medical devices are classified in much the same way as in Europe. The four classes of medical devices are:

- Class 1 – low risk;
- Class 2a – medium risk;
- Class 2b – increased risk;
- Class 3 – high-risk.

Detailed information on medical device classification can be found in Roszdravnadzor Order No 3731 (dated 9 November 2007) and GOST-R 51609-2000.
According to Order No 735, it is illegal to purchase and use foreign-made medical devices in Russia without that product being registered with Roszdravnadzor:

‘Registration is mandatory for all medical products designed for medical application in the territory of the Russian Federation and including devices, apparatus, instruments, appliances, kits, complexes, systems with software, equipment, accessories, dressing and suture, dental materials, sets of reagents, referencing materials and standard samples, calibrators, analyser consumables, products of polymeric, rubber and other materials, software applied for medical purposes either apart or in combination with each other, and which are designed for:

- preventive treatment, diagnostics (in vitro), sickness treatment, after-care treatment, medical procedures, medical research, replacement and modification of parts of human body tissues, organs, recovery or compensation of disrupted or lost physiological functions, impregnation control;
- production of effect on human organism so that their designated purpose is not implemented through chemical, pharmacological, immunological or metabolic interaction with human organism, but of which effect can be supported by such means.’

The registration process must be completed through Roszdravnadzor and is based on the results of testing. According to the Russian regulations, testing must be performed by local expertise centres and hospitals (a list is provided on the Roszdravnadzor website) and the results must be included in the registration dossier.

Products are evaluated for their efficiency, safety and quality. Efficiency is determined by the degree to which the medical product achieves its designated purpose. (N.B. Russian Order No 735 uses the term ‘efficiency’ and not the more widely used industry term of ‘efficacy.’) Safety is measured by balancing the risk of harm to the patient/personnel/environment to the significance of its purpose. Quality is defined as compliance of a product’s characteristics with the requirements.

The registration dossier should contain a table of all functional characteristics of the predicate compared with similar characteristics of the applicant’s (manufacturer’s) device. If some characteristics of the device differ from the equivalent device, each must be justified as to why the difference cannot affect efficiency or safety.

Order No 735 notes that there are two ways to register products in the Russian Federation:

- **Type 1**: Class 1 and 2a devices with a clearly identified equivalent device already registered in the Russian Federation (same classification, applied in the same manner, same efficiency characteristics) must demonstrate that the product is essentially similar to the predicate. This can be accomplished by preparing a document that demonstrates the lack of differences or by submitting technical testing/safety evaluation certificates comparing the new device to the predicate.
- **Type 2**: Class 1 and 2a products without an equivalent device and all Class 2b and 3 devices must be tested for product quality, efficiency and safety. These tests are specified by Roszdravnadzor and must be conducted by government-appointed testing centres. Tests conducted outside the Russian Federation, regardless of how similar, are not accepted.

According to Order No 735, all documents and information for registration of a medical product must be provided in Russian. Official documents such as a Power of Attorney, Certificate of Free Sale, Certificate to Foreign Government, Certificate of Incorporation, ISO certificates and others must have a Notary stamp and corresponding Apostille (i.e. legalisation). The original documents must be provided with a notarised document translated into Russian.
Upon registration, all imported medical equipment and devices are added to a database of medical products available on the Roszdravnadzor website. The product registration number and date must be shown on the device packaging, label and instructions for use, and included in advertising for products intended for the end user.

**Documents needed to obtain a Registration Certificate**

All required documents and certificates must be translated into Russian. Official documents must be additionally notarised and legalised. Some documents also require a stamp and signature by the applicant. Registration Certificates do not expire as long as no changes are made to the:

- product quality, efficiency or safety;
- side effects or use limitations;
- rights to a medical product or the manufacturer’s name;
- product trade name;
- packaging;
- registration documentation.

According to Order No 735, any changes to the items listed above must be submitted to Roszdravnadzor.

Roszdravnadzor has specific requirements for completeness of a registration dossier. The dossier must consist of the following documents:

- **Application request.** The application request should include the elements mentioned below, which need to be submitted by the applicant on letterhead:
  - applicant’s legal name, address, contact telephone, fax, email;
  - name, address, contact telephone, fax, email of the manufacturer;
  - name of the device;
  - intended field of application of the device;
  - acknowledgement of responsibility for possible negative effects of correct application of the medical product, signed by the applicant;
  - acknowledgement of responsibility for infringement of another person’s rights in the production, import and sale of the medical product in the Russian Federation;
  - expected potential risk class of the medical product;
  - information on equivalent devices already approved for sale in the Russian Federation (if any).
  
  The application request must be notarised and legalised by a Russian Consulate office if the applicant is not a legal Russian resident.

- **Device information sheet.** The sheet should provide information on the medical device’s intended purpose and basic characteristics.

- **Documents certifying registration of the manufacturer in the country of origin.** A common example is a Certificate of Incorporation. This document must be notarised and legalised by a Russian Consulate office.

- **Power of Attorney for the applicant.** The manufacturer must officially authorise the applicant (consultant or distributor) to conduct the registration on behalf of the manufacturer. This document must be notarised and legalised by a Russian Consulate office.
• Documents certifying compliance of the medical product’s manufacturing with the laws of the Russian Federation. This sounds confusing but essentially it is a way to demonstrate that the manufacturer meets manufacturing process requirements in their home market. Examples of documents proving this include ISO certificates, CE marking certificates and Certificates of Free Sale. These documents must be notarised and legalised by a Russian Consulate office.
• Draft statutory document accompanied by documents certifying compliance of the medical product with its requirements, technical conditions or standards.
• Instructions for use for the medical device or in vitro diagnostic.
• Documents certifying equivalence with a predicate device already approved for sale in the Russian Federation (if any).
• Results of testing. This includes technical tests, safety evaluation (toxicology, electromagnetic compatibility) and medical testing of efficiency and safety of a medical product from two different, independent hospitals or clinics. The documents must be originally signed and stamped by the applicant and the expertise centres and hospitals.
• Photo of the device.
• Advertising/promotional materials.
• Inventory of all provided documents.
• Product samples, if required.

Testing requirements
To clear medical devices through Russian Customs, the products must also have one or both of the following certificates, which can only be issued after the Registration Certificate has been obtained. These include the:

• Sanitary-Epidemiological Conclusion (Hygiene Certificate);
• GOST-R Quality Certificate.

Russia relies on product testing and, as such, actual samples of the product must be imported. To do so, the manufacturer or applicant must apply to Roszdravnadzor and get the appropriate permission so that the samples can be cleared through Customs. All documentation and correspondence must be in Russian.

Once samples have been received, the second step of the registration process is to submit the product sample with the necessary documents to authorised expertise centres and hospitals to have the required tests and medical reports performed. Medical reports are performed upon positive completion of corresponding technical and toxicological tests. The medical reports should be conducted by two different, independent hospitals or clinics accredited by Roszdravnadzor. This stage is called Pre-Submission Expertise and it requires a personal meeting between the authorised experts and the applicant before testing begins.

Rospatrebndazor requires devices which come into contact with the human body/skin, and those which may negatively affect patients or doctors, to undergo hygienic testing. Upon successful completion of the technical and toxicological tests, the Department of State Sanitary and Epidemiological Surveillance within Rospatrebndazor issues a Sanitary-Epidemiological Conclusion (Hygiene Certificate). Devices with a measuring function undergo special tests to confirm that they can be used for measuring.

Submission to Roszdravnadzor for evaluation
Once all testing and medical reports have been received from the authorised expertise centres and hospitals, they are combined with other required documents for registration and submitted to Roszdravnadzor. At this point the applicant must meet with officials from the Department of Registration of Foreign Medical Equipment and Devices within Roszdravnadzor and submit the
registration dossier. The Department will review the dossier and make a decision on whether the documents will be accepted for registration.

If Roszdravnadzor is satisfied with the contents of the registration dossier under the Type 1 registration procedure, which includes the comparison with the equivalent device, a Registration Certificate will be issued for the product. For products under a Type 2 procedure, additional expertise will be needed. Roszdravnadzor specifies which authorised expertise centres will perform the assessment of quality and/or efficiency and/or safety of a medical product. Products can be re-tested if required. If the testing is positive, a Registration Certificate will be issued.

The Certificate will be sent to the applicant (consultant, local representative) but will be issued in the name of the manufacturer. The Registration Certificate number and date must be printed on the product label, packaging, instructions for use and marketing materials.

In the case of a negative opinion, a notice of denial of registration specifying grounds for such denial will be sent to the applicant.

**Sanitary-Epidemiological Conclusion (Hygiene Certificate)**

As noted, devices that come into contact with the human body and which may negatively affect patients or doctors (e.g. electrocardiography electrodes, condoms, implants, bandages, contact lens, syringes, needles, anaesthesia-respiratory disposables, disposables and equipment for transfusion therapy, and x-ray apparatus) must obtain a Sanitary-Epidemiological Conclusion, more commonly known as a Hygiene Certificate. This testing confirms that the product conforms to applicable hygienic standards and sanitary regulations in Russia. There is obviously a lot of room for interpretation of which products ‘could negatively affect’ the patient or use and there is no published list of products that meet this criteria. Thus, it is often necessary to consult with Rospotrebnadzor to determine if a Hygiene Certificate is needed if it is not obvious that the product touches the skin.

The Hygiene Certificate is only issued by Rospotrebnadzor (not Roszdravnadzor). Two independent organisations, both part of Rospotrebnadzor, are involved in hygienic certification, namely the:

- Centre of Hygiene and Epidemiology, which evaluates the test protocol, supporting documentation and conducts the testing;
- Regional Office of Rospotrebnadzor, which issues the final certificate based on the expert conclusion drawn by the Centre of Hygiene and Epidemiology provided that the product complies with the Russian Hygienic Standard.

For most products, a Sanitary-Epidemiological Conclusion (Hygiene Certificate) is valid for five years, but some products must be renewed each year. The certificate can be issued in the name of a distributor, but the manufacturer is the holder. The process for obtaining a Hygiene Certificate usually takes one to two months.

Manufacturers can request inspection of their production facilities so they can be issued a Hygienic Certificate for all of their manufactured products. This may be a wise choice for companies with numerous products. The inspection will focus on manufacturing conditions, raw material quality control, technological processes and safety/sanitary parameters of the final devices.

**GOST-R Quality Certificate**

The GOST-R Certificate is similar to a CE marking certificate and is issued to a manufacturer to confirm that the imported product meets Russian national quality standards. The products must pass tests that have to be carried out by a local testing body accredited by the GOST-R system. The tests of conformity with Russian safety requirements should also meet the Essential Requirements of the
European Medical Devices Directive (93/42/EEC). Additional documents should be submitted for certification (e.g. brochures, product description, protocols, test reports from international test laboratories, safety certificates issued by international authorities, ISO 13485 certificate (if available), Declaration of Conformity with the list of product codes and product names, instructions for use and a risk analysis).

Once certification has been achieved, the device must carry the GOST-R symbol (the mark of conformity), which clearly demonstrates product compliance to the applicable Russian standards:

GOST-R Certificates are issued by a testing centre accredited by Gosstandart and are valid for one year (for a shipment or several shipments under one contract), or for three years if experts from Gosstandart visit and assess a foreign producer’s manufacturing facility in the country of origin. The GOST-R Certificate usually takes four to six weeks to acquire after the Registration Certificate has been issued. Fortunately, for those companies that need to acquire the GOST-R and Hygienic Certificates, many of the required documents overlap.

**Timelines and costs**
The overall registration process for medical equipment usually takes between four and 12 months. Estimating the total cost is difficult. Roszdravnadzor does not publish a list of fees. Instead, an expert determines the fees during a face-to-face meeting. This is another reason why using an experienced local consultant is so critical.

The total cost of dossier preparation, testing, translations, notary/Apostille services, and other consulting fees typically amount to US$14,000 to US$16,500 for common devices and US$28,000+ for more complex equipment. Actual costs need to be determined on a case-by-case basis.

Some manufacturers choose to let a distributor handle registration and cover most or all of the costs. In these cases, registrations should only be done in the name of the manufacturer who then becomes the owner of the Registration Certificate. This gives the manufacturer more flexibility in those cases where a change of distributor may be required in the future.

**Post-approval monitoring**
Russia still does not have clear guidelines regarding monitoring of medical devices. However, according to Order No 735, hospitals and consumers using medical devices and equipment, as well as the manufacturer, should inform Roszdravnadzor about facts and circumstances endangering human life and health during correct application of medical products. Order No 735 states:

‘In case of detection of facts and circumstances endangering human life and health in correct application of a medical product, including without limitation any unfavourable clinical implications, which in application of a medical product in accordance with directions (instructions) for use (application) result in death, pose a threat to life, require hospitalisation or its extension, lead to sustained or severe loss of ability to work and/or physical disability, or result in anomalous reproductive effects, or clinical implications, of which character and seriousness do not correspond to available information on a medical product, Roszdravnadzor may take the following decisions:

1) order that additional information on revealed negative effects of medical product application be gathered;
2) order that additional medical product quality, efficiency and safety assessment be performed with provision for revealed negative effects of its application;
3) consider modification of registration documentation for a medical product;
4) suspend a decision on registration of a medical product;
5) withdraw a Registration Certificate for a medical product;
6) refrain from any additional actions, in case revealed negative effects of medical product application are accidental.’

**Conclusion**
While the registration and testing process in Russia is complicated and burdensome with many entities involved, companies that have overcome the obstacles have been very successful selling their products in the Russian Federation. Success, however, depends largely on having an experienced local consultant or regulatory expert that has established relationships with government officials and understands Russian business culture. Success will come faster and often less expensively than might have otherwise occurred.

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