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## Registration of Nutraceuticals in Russia: Challenges and Solutions

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Nutritional supplements have become part of a common lifestyle in Russia and the market is developing actively. Moreover, the supplements market in Russia, now estimated at \$1.021 billion, has significantly outstripped the pharmaceuticals market, showing unprecedented growth of 35 percent in 2005. In other words, the Russians, as their living standards have improved; have begun seriously spending on health products. Currently, foreign brands make up only one-third of the supplements on the market. The main reasons for low foreign penetration are the underestimation of the Russian nutritional market potential, on the one hand, and complexities of entering the market, on the other.

### How does it work?

Maintaining positive thinking, let us admit that there is at least one good thing about bureaucratic procedures: everything is spelled out and cast in paper so the rules, if complied with, do deliver the desired results.

All products that in the Russian classification fall under the categories of nutraceuticals, parapharmaceuticals, and food supplements are subject to State Registration. The authority that issues those certificates of State Registration and enters the product in the Federal Registry is the Russian Ministry of Health.

The branch that handles the documents and carries out all the regulatory procedures pertaining to the State Registration is the Russian Health Ministry Certification Center, which recently was renamed FGU Expertiza. After having ensured that the product dossier is complete and the paperwork is proper, this agency assigns the product samples to the State Nutritional Institute for appropriate testing. The conclusions of the Institute are binding, and their comments must be complied with. Based on the report of the Institute, the Health Ministry either issues the registration or denies it. Registration has no expiration date—once registered, a product is legitimate on the Russian market as long as it continues to be consistent with the original specifications. At present, there are no additional certification requirements for the custom clearance of Nutraceuticals if the State registration license has been obtained. It covers all the safety requirements that otherwise, for example for cosmetic products, would include GOST-R and Hygienic certification. Of course this relates to public safety aspects only – requirements for regular commercial customs documents remain standard.

### Why so complex?

There are two main reasons why the Russian nutritional market seems so uninviting for foreign companies. The first is the red tape and bureaucracy that Russia has not only in full measure inherited from the Soviet system, but even augmented significantly. The second is genuine concern for the well-being of consumers, which has been fueled by the influx of fake and low quality products flooding the market, mostly from China. For example, recently a large quantity of Chinese supplements was confiscated for containing kava-kava extract, which is outlawed in Russia. Distributors are facing a serious charge and a fine of up to 500,000 Rubles (about \$20,000).

Is the situation going to get better in Russia anytime soon? Doubtful. The Russian government's Sisyphean battle against illegal and low quality nutraceuticals will continue, terms and regulations will likely keep getting stricter, and their enforcement will become even more rigorous.

### What are the Pitfalls?

An existing American company dealing in nutritional supplements that has already complied with all relevant U.S. regulations is likely to have everything it needs to successfully register products in Russia; Standards are similar in both countries. Nonetheless, such a company should be aware of the pitfalls that can delay registration for years!

#### *Pitfall 1. Paperwork*

Many companies wonder why the registration process is so lengthy. The answer could be very simple: their application was found incomplete and put aside by the respective agency. To expect proactive advice from the Russian government on incomplete documents is wishful thinking. Eventually, you may find out that Document X is missing a notary seal, for example, and rush to correct it. Nice! Yet, you see no progress. Why?! Another document, which was sitting a sheet or two under that one, has been found faulty...

**Advice:** Make sure you are well familiar with the list of required documents, and the documents you submit look as close to sample documents as possible. Yet, the Russian business environment is fluid, it is important to double check to determine which documents are required immediately before submitting an application.

*Pitfall 2. Testing*

The Russian State Nutrition Institute is an internationally renowned scientific entity. It has excellent scientists and advanced laboratories. It is also housed in an old, dilapidated building, dramatically understaffed, and the staff is terribly underpaid. The institute has set work hours, and it is not concerned with applicants' "urgent" matters. It has a long line of applicants, and if it finds something objectionable in the formula or label or packaging or whatever of any one applicant, it will simply return the dossier to the Health Ministry with their comments and move on to the next application. In due time, the applicant will be apprised of these objections, take care of them and resubmit them to the Health Ministry. They will forward it back to the Institute, and the dossier will turn up in the bottom of the pile on somebody's desk... It can be a rather protracted merry-go-round.

**Advice:** Do it right the first time. Make the dossier as complete and consistent with current Russian regulations as possible. Deliver enough samples. Avoid submitting on the eve of major Russian holidays. Be nice to people you have to work with.

*Pitfall 3. Guidance*

The gates to the Russian nutritional supplements market are guarded by the Government and the Government only. A company may expect from the Russian authorities as much or less compassion or concern as from FDA or INS in the United States. Impartial meticulousness is what you may anticipate on contact with them.

Ah, there's the rub! For who will make this contact on behalf of the company? There is no way around having an agent or consultant who will speak directly to the Russian authorities. And that agent or consultant is the key to those rather rusty locks on the government gates. If the agent is efficient, has a good reputation in the right circles, and takes your interests to heart, registration may be accomplished in three months. On the other hand, if the U.S. company is planning on utilizing its own resources either assigning this task to a local company representative or a distributor who has never done it before, the process could easily take 12 to 18 months. Another danger is to engage with a shadowy company after being swayed by their alluring rates and fantastic promises—in which case, a company may easily end up with a fake certificate and huge problems with Russian authorities.

**Advice:** Choose a consultant or agent carefully. A mistake can cost you the market. Ideally, the company you engage with would go beyond executing product registration assignments and become an exporter's consultant who suggests the most efficient ways and optimal solutions for doing business in Russia. The chosen service provider should be bilingual with verifiable, solid experience in registering nutraceuticals in Russia, as well as strong connections with the relevant Russian Health Ministry departments. It would be also be most helpful if the agent was a U.S. corporation. This way, all financial matters can be handled in the United States and under U.S. laws so as to avoid additional costs and complications in dealing with the cumbersome Russian accounting and banking systems. There are very few eligible choices in the United States. Yet, whatever the choice, the company should invite the candidate over to the company's headquarters for a meeting/presentation, which would show how competent they are.

**Endnote:** The Russian Federation customs authorities require that each shipment of a given registered nutraceutical is accompanied by: (1) a notarized copy of the registration document, and (2) a manufacturer's statement issued on company letterhead stating that the enclosed was produced in conformity with the registration.

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**NB: Good news for desert.**

Very recently there has been adopted a new regulation which allows Voluntary Certification of Nutraceuticals. Although it has no impact on customs clearance and is not mandatory, it may be extremely valuable for US exporters, as it offers a way to include medical claims, which are otherwise indisputable taboo, into products' labels and promotional materials. We at Rosstandard have been apprised of this development by the Russian Health Ministry, and are prepared to provide necessary guidance.

Please, let us help you with your needs or concerns as regards the registration of your products in Russia.

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