



Russia: Biologically Active Supplements

Yuliya Vinogradova
June 2014

Summary

In the last decade, Russia's market for biologically active supplements (BAS) has shown substantial growth. According to industry experts, in 2013 the sales of BAS in pharmacies were \$845 million in wholesale prices and \$1.17 billion in retail prices. The Russian BAS market cannot be compared to the one in U.S., which is twenty times bigger, simply because mass production of BAS in the U.S. began more than 50 years, versus the Russian market that is only 20 years old.

The consumption of BAS in Russia and other countries is also very different. In the U.S. more than 80% of the population uses BAS and in Europe this number is 50%. But in Russia, according to the marketing agency Comcon-Pharma, this number is only around 20%, but growing. The Scientific Research Institute of Nutrition says that the growth rate is about 3-5% each year. The demand for BAS is growing because they are relatively easy to develop, produce and register, especially when compared to pharmaceuticals. In the early nineties most BAS sales were accomplished via a "grey market" but now the government is attempting to make the BAS market more transparent. More progress can be expected because of the growth of pharmacy chains and stricter regulations imposed by the government on the registration process and distribution channels.

In the early nineties, foreign manufactures played a dominant role in the BAS market, but now the situation has drastically changed and 70% of the market is occupied by Russian companies, and three Russian companies are in the "top five" list.

Market Data and Demand

According to Technical Regulations “About Safety of foods” (Article 24, TP TC 021/2011) Biologically Active Supplements to food (BASs) - natural and/or identical to natural biologically active ingredients, and also probiotic microorganisms, intended for consumption with food or inclusion in products to enrich the diet with them.

<http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/TR%20TS%20PishevayaProd.pdf>

Consumers can take BASs in the form of tablets, capsules, syrups, and powders. According to the above definition, the following products can be identified as biologically active supplements:

- Polysaturated acids
- Mineral substances, micro and macro elements
- Some amino acids
- Some mono and disaccharides
- Food fibers
- Microorganisms present in human body
- Vitamins, whose daily dose does not exceed the one needed for the human body

BAS officially appeared in Russia in 1994, when the Ministry of Health started registering them as a separate group of substances. Since 1998, BAS have been actively promoted on the Russian market.

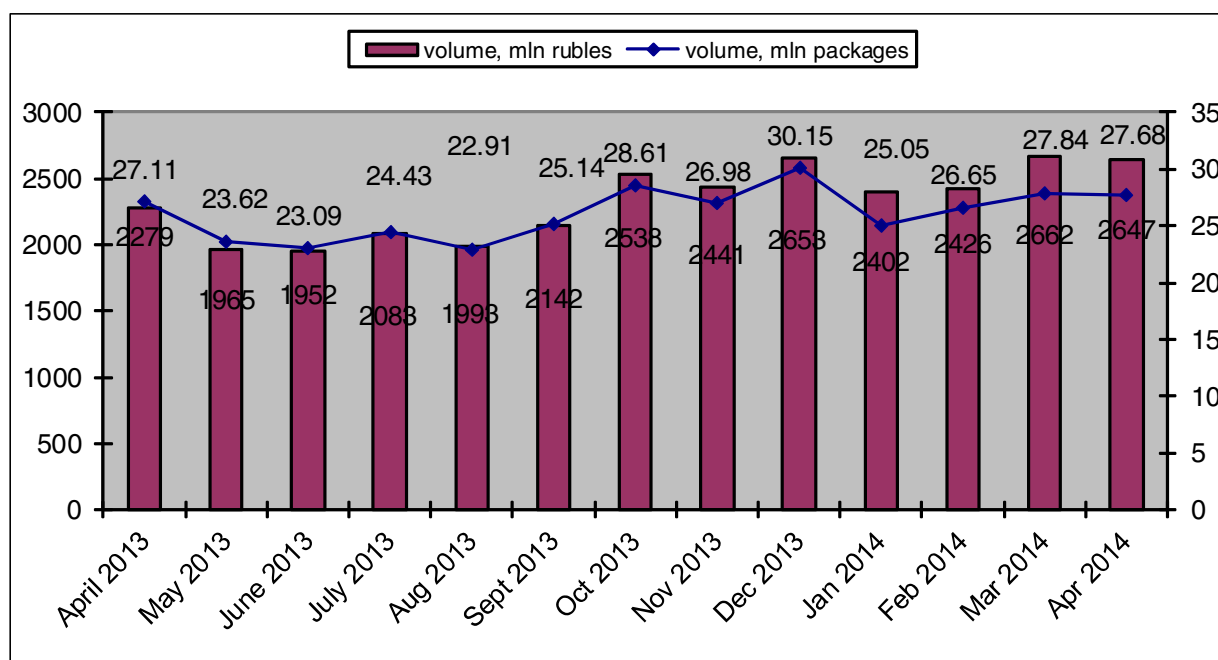
There are various distribution channels selling BAS:

- Pharmacies
- Specialty stores
- Websites; direct marketing sales

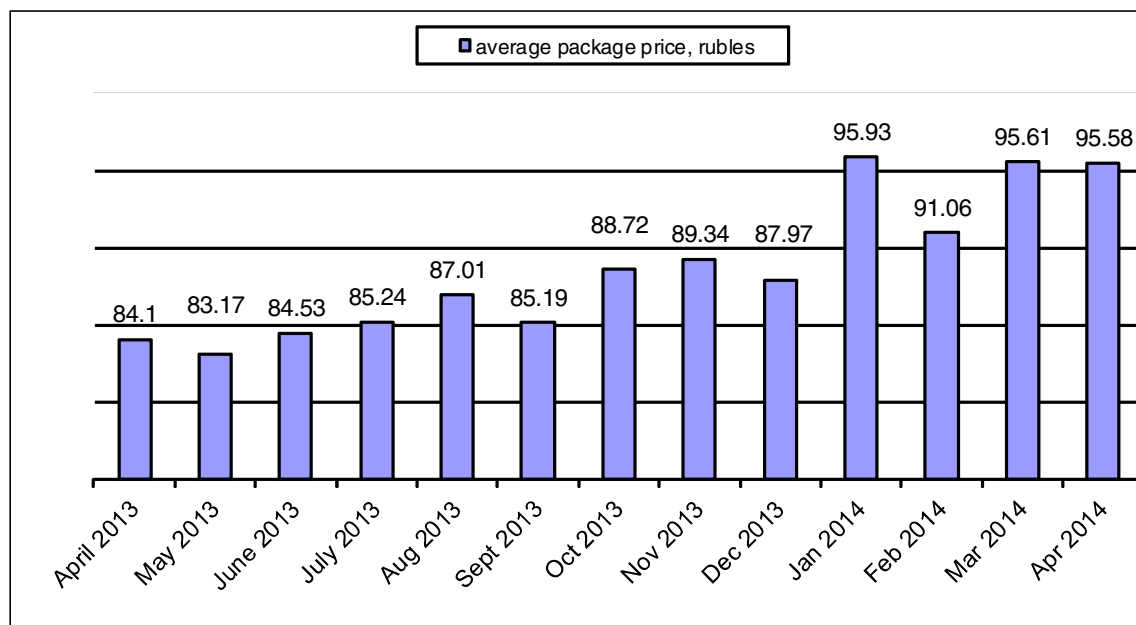
In spite of the fact that websites’ market share was quite substantial in 2005, now most manufacturers prefer to sell via pharmacies because consumers trust these stores more than

other ways of distribution. In April 2014, 692 manufacturers sold 3681 brand names BAS in pharmacies.

In April 2013-2014 the increase in sales was 16%, and 2% in volume. The average price per package was 95.58 rubles (\$2.73), which is 13.7% higher than in April 2013. (See following two graphs.)



Source: DSM group pharma market of Russia, April 2014



Source: DSM group pharma market of Russia, April 2014

Best Prospects

The most popular BAS, sold in pharmacies, are ones that help with men's potential including such products as Sialeks Forte and Ali Kaps by Ria-Panda.

Key Suppliers

The first two positions in the top ten manufacturers of BAS (see table below) are taken by the Russian firms Evalar and Ria-Panda. According to Ecomir, this is because from the start big foreign companies preferred multi-level marketing as the main distribution channel, contrary to the Russian companies that sold via pharmacy chains from the very beginning. Also a number of pharmaceutical firms are interested in the BAS market due to the fact that channels of distribution and promotional methods are similar for both BAS and pharmaceuticals.

Rating	Company	Ruble market share April 2014	Volume Market Share (packages) April 2014
1	Evalar	17.17	11.56
2	Ria Panda	10.01	1.92
3	Polyaris, OOO	4.07	0.41
4	Pharma-Med Inc	3.53	0.9
5	Natur Produkt	3.39	8.87
6	Quiesser Pharma GMBH & Co. KG	2.98	1.1
7	Solgar Vinatmin and Herbs	2.65	0.29
8	Polens (M) SDN BHD	2.53	0.24
9	Diod, OAO	2.07	1.27
10	Ferrosan AG	2.02	0.59
	Sum	50.42	27.15

Source: DSM group pharma market of Russia, April 2014

Prospective Buyers

According to information from Comcon-Pharma, 50 % of BAS's consumers are 20 to 44 years old, while 50% of pharmaceutical consumers were 45 to 65 years old.

Most consumers prefer BAS made in Russia due to their lower price and quite good quality.

In December 2012 the All-Russian Public Opinion Research Center (VTsIOM) conducted a study among 1,600 people in 138 villages in 46 Russian regions. The results of this study show that 60% of the respondents perceive BASs as additions to food, 16% - think of them as vitamins and only 5% - say that they are drugs.

As for frequency, only 2% of respondents take BAS regularly, 6% -by regimen, one in five - by season, and one in ten - periodically.

Consumers are more interested in BAS than in pharmaceuticals due to:

- Lower price
- High attractiveness because of natural origin
- Lower risk of side effects

Main directions of work with consumers:

1. Formation of necessary regular use of biologically active supplements to nourish the food diet with biologically active substances and complexes.
2. To create a system of measuring effectiveness and quality of foreign and domestic BAS, which is understandable to an average consumer and informs him about the results.

Market Entry

At the moment there is strong competition on the BAS market due to:

- Both foreign and Russian manufacturers using large promotional budgets
- Increased campaigns for market share and customers' loyalty
- Different prices, package designs and distribution channels
- Many Russian brands entering the market

Experts and industry analysts predict that the market will develop in two directions: increased share of regional sales, and involvement of new age and social consumer groups.

Interest towards BAS is growing because of the following two factors.

1. The process of registering most BAS is relatively simple compared to pharmaceuticals, namely:

- For most BAS only toxicology hygiene and studies. For pharmaceuticals: compulsory clinical and pre-clinical trials;
- BAS have only recommendations for usage that allows flexibility in their promotion, but pharmaceuticals are designed for curing particular diseases, so that the promotion for treatment of other illnesses is strictly prohibited.
- BAS can be distributed both in pharmacies and other retail stores that have a license for selling food products, while pharmaceuticals can be sold only in pharmacies.
- Mark-ups for BAS are very high, in some regions they can exceed 50%; but mark-ups for pharmaceuticals (29-30%) have a cap in most regions.

2. In theory, all BAS can be advertised. On the contrary, advertising laws on pharmaceuticals are very strict, and accordingly, only OTC drugs can be advertised.

In spite of the large potential for BAS promotion there a number of restrictions imposed for BAS advertising:

- Commercials in mass-media should not contradict the materials agreed during the BAS registration process.
- BAS which are not registered with Federal Service for Supervision over Consumer Rights Protection and Human Welfare cannot be advertised.
- Commercials should not discuss BAS being the most effective and safest in terms of side effects.
- Commercials should not mislead consumers regarding the contents of BAS.
- Advertisements should not convey the impression that natural origin of raw materials can guarantee the safety of BAS.
- The commercial should not undermine other treatments and preventive medicine.
- Commercials should not convey an impression that doctor's advice is not necessary for BAS, especially parapharmaceuticals.

Manufacturers design the commercials using the above guidelines, though now advertising has become more complicated because of the introduction of a new federal law that came into effect in 2006. According to that law, advertising of BAS as pharmaceuticals are subjected to fines ranging from 40,000 to 500,000 rubles (\$1540 to \$1920) for legal entities. The use of doctors and medical imagers, or references to successful clinical and laboratory studies, are prohibited by this law as well.

Potential sales volumes depend on the promotional budgets that manufacturers can allocate. That is why the major manufacturers use TV commercials, where smaller ones use press. Radio and billboards are less frequently used compared to the above. Manufacturers of vitamins use advertising most often.

Market Issues & Obstacles

Mandatory BAS registration

Mandatory registration, introduced in 2004, could be considered one of the main obstacles for BAS entering the Russian market. In order to sell BAS on the Russian market a manufacturer/distributor should have a Certificate of State Registration used for both customs clearance and distribution in Russia, and issued by the Federal Service for Supervision over Consumer Rights Protection and Human Welfare.

Establishment of the Customs Union (CU) between Russia, Belarus and Kazakhstan, and later on Eurasian Economic Union (EEU) affected the regulatory regime because the technical regulations developed by three countries must be consistent with each other. The information about new technical regulations, approved by the three countries can be found on the website of the European Eurasian Commission, permanent supranational regulatory body of CU (<http://www.eurasiancommission.org/en/>).

The registration of BAS in Belarus is done by the Republican Center of Hygiene and State Health, and in Kazakhstan - Ministry of Healthcare of Republic of Kazakhstan.

The procedure in all three countries is the same, and includes the three stages:

1. Analysis of provided documents
2. Tests (microbiological; toxicological; for BAS, containing herbs - tests for pesticides; authenticity tests that proves the ingredients listed are really there; in some cases - tests on Genetically Modified Ingredients.

3. Issuance of Certificate of State Registration.

It should be taken into account that the results of the negative tests are not only given to the applicant, but are also sent to Rospotrebnadzor. This fact can make it really difficult to register these BASs without changing the names and starting the whole process from the scratch.

The following Technical Regulations govern the process of registration:

“About Safety of foods” TP TC 021/2011 Article 24

<http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/TR%20TS%20PishevayaProd.pdf>

“Requirements of Safety of Food Additives, Fragrances and Technological Additional Products” (TP TC 029/2012) if such ingredients are in BAS

http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/P_58.pdf

“Technical Regulations for Oil-containing products” TP TC 024/2011, if oils are in BAS

<http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/TR%20TS%20MasloGirov.pdf>

“Food products and labelling” TP TC 022/2011, if such ingredients are in BAS

<http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Documents/TrTsPishevkaMarkirovka.pdf>

Before starting the process of registration, a manufacturer should keep in mind that:

- Not every BAS could be registered in Russia despite holding all registration documents in the country of origin. (The list of allowed BAS’s ingredients is in Addendum 7 to the Technical Regulations “About Safety of foods” (TP TC 021/2011). Also according to the Decree of Chief State Sanitary Doctor N 2, from January 17, 2013 the ingredients that are

not normally used as foods (including not only bark oak, but also extracts from exotic plants, for example shell of snail, are banned in Russia. Belorussian authorities allow them, but the Registration Certificate, obtained in this country, will say “not for sale in Russia”.

- A set of documents used for the registration in the country of origin is not always enough for the registration authorities in Russia.
- The full list of proposed medical use approved in the country of origin could be approved only partially by the Russian registration authorities.
- Each BAS should have its own Certificate of Registration, even if the only difference is its flavor.

Because the registration procedure is quite complicated and rather expensive, and since the required documents tend to change due to constant changes in the regulatory requirements, the only way to accomplish successful registration of BAS in Russia is through one of the following types of companies: a company incorporated in Russia and belonging to the U.S. parent company, a Russian distributor/authorized agent, or a consulting company. We recommend that U.S. companies to work with reliable partners and consulting companies on BAS registration issues.

Following is the list of documents which the manufacturer or its authorized representative must submit along with an application in order to obtain a Certificate of State Registration.

1. Copies of the documents by appropriate authorities in the country of manufacture confirming that this product is classified as BAS and is not a drug, and also proving its safety for human beings (Free Sale Certificate). These copies should be properly legalized.

2. Document containing a full list of ingredients. In case BAS is based on herbs - their name in Latin as well as the method of preparation. Also an explanation, how these ingredients are commonly used in foods.
3. Documents (standards, technical regulations, bylaws, technological instructions, specifications, recipes) that are used for the manufacturing process.
4. Consumer label or its draft in the Russian language as well as a sample of the original label used in the country of manufacture.
5. Usage instructions, annotations (in case not all necessary information could be placed on the label).
6. Explanatory note containing the scientific grounds for BAS compositions; scientific recommendation for use and duration, doses, and side effects.
7. Materials on toxicological, hygienic and biological efficiency, and other protocols, if requested.
8. For BAS containing live microorganisms - document the type in the Latin language, information about culture (passport, certificate or some other document).
9. Declaration stating that BAS does or does not contain genetically modified components.
10. Declaration verifying that this BAS does not contain drug or psychoactive-related components or substances.

11. Copy of the trade mark certificate, legalized properly, in case a trade mark exists.
12. Protocols of tests and trials wherever available.
13. Documents on sample selection indicating the dates of selection, number, name of the product, manufacture's address, date of manufacturing as well as names of individuals who participated in the selection process.
14. Power of attorney to obtain the registration certificate.
15. Brief description of the manufacturing process.
16. For BAS used by sportsmen and designed to enlarge the muscles- document from the manufacturer proving that they do not contain components attributed to steroids.
17. Certificates of conformity of major BAS ingredients.
18. A document, properly legalized, confirming that the manufacturing process for BAS complies with national and international standards, for example GMP or ISO 9000-9002.
19. Copies of invoices for samples that will have the Customs phrase on them "Entry allowed"
20. Samples, usually 6-8, 200-300 grams each.

Items: 2-6, 8, 9, 13, 15, 16 should be stamped and signed by the manufacturer

At the end of the registration process a manufacturer/authorized representative receives the following documents:

- ✓ Registration certificate that is valid indefinitely (until some changes occur)
- ✓ Expert conclusion of Scientific Research Institute of Nutrition that confirms BAS safety
- ✓ Conclusions of other laboratories, if during the process extra tests were required

In addition, during the registration process, the label, packaging, and instruction for use are confirmed.

Trade Events

Apteka

21rd International Trade Fair for
Pharmaceuticals and Related Products
December 8 -10, 2014
Moscow, Exhibition center “Expocenter”
www.aptekaexpo.ru/

Ingredients

18th Moscow World Exhibition
March 17-19, 2015
Moscow, World Exhibition Center “VVC”
www.ingred.ru/en-GB/ingredients_russia/about.aspx

Resources & Contacts

Consult Business Group - consulting company assisting in registration

127015 Moscow
ul Butyrksaya, 77, Business center “Diagonal House”, 8 floor
www.c-b-g.ru/en/
tel.: + 7 495 797 4963
fax: + 7 495 730 2482
e-mail: info@c-b-g.ru
www.c-b-g.ru

Comcon - Pharma - marketing agency
www.comcon-2.com

Business - Expert K - marketing agency
www.bizexpert.ru

DSM Group - a marketing agency
www.dsm.ru

Federal Service for Supervision over Consumer Rights Protection and Human Welfare
www.rospotrebnadzor.ru

Russian association of BAS and food supplements manufacturers
www.assoc-bad.ru

For More Information

The U.S. Commercial Service in Moscow can be contacted via e-mail at: Miguel Hernandez Miguel.Hernandez@trade.gov; Phone+7-495-728-5580; or visit our website: <http://export.gov/russia>. For a more comprehensive report on doing business in Russia, download the latest Russia Country Commercial Guide at <http://export.gov/russia/marketresearchonrussia/index.asp>.

The U.S. Commercial Service – Your Global Business Partner

With its network of offices across the United States and in more than 80 countries, the U.S. Commercial Service of the U.S. Department of Commerce utilizes its global presence and international marketing expertise to help U.S. companies sell their products and services

worldwide. Locate the U.S. Commercial Service trade specialist in the U.S. nearest you by visiting <http://www.export.gov/eac>.

Comments and Suggestions: We welcome your comments and suggestions regarding this market research. You can e-mail us your comments/suggestions to: Customer.Care@trade.gov. Please include the name of the applicable market research in your e-mail. We greatly appreciate your feedback.

Disclaimer: The information provided in this report is intended to be of assistance to U.S. exporters. While we make every effort to ensure its accuracy, neither the United States government nor any of its employees make any representation as to the accuracy or completeness of information in this or any other United States government document. Readers are advised to independently verify any information prior to reliance thereon. The information provided in this report does not constitute legal advice. The Commercial Service reference to or inclusion of material by a non-U.S. Government entity in this document is for informational purposes only and does not constitute an endorsement by the Commercial Service of the entity, its materials, or its products or services

International copyright, U.S. Department of Commerce, 2012. All rights reserved outside of the United States.