

Registration of dietary supplements in Russia



About the speaker



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In addition, he is the International Advisor to the Russian Alliance of Dietary Supplements Producers. Mr. Temkin is frequent speaker at regulatory events within the United States and internationally.

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Naming convention

- **In Russia, dietary supplements are also known as:**
- Biologically active substances (BAS)
- Biologically active food supplements (BASF)
- Nutritional supplements
- Food supplements
- Health supplements



Definitions.

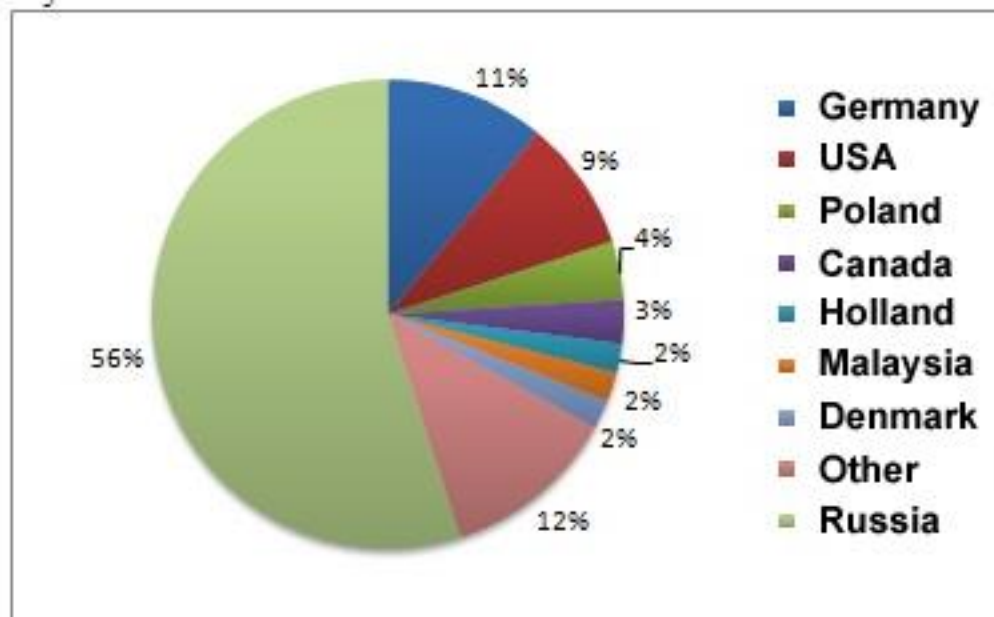
- Russian definition of BAS: *concentrated biologically active ingredients for enhancing human diet with allowed daily amounts of health components. Those supplements are produced mostly from mineral, herbal or animal based raw materials.*
- **BAS sub-categories:**
- *Nutraceuticals* – products diversifying diet composition and enriching it with proteins, amino acids, vitamins, minerals and other microelements;
- *Parapharmaceuticals* – preventive and enhancing preparations for internal organs;
- *Eubiotics* – bacterial preparations and ferments for gastrointestinal tract



2018 Russian Market Volume.

- Emerging in mid 90-ies, the Russian market of food supplements has been growing by the average of 1,300 new products a year. Now, about **11,000 registered products** are being sold in the markets of the Customs Union of Russia, Belarus, Kazakhstan, Armenia and Kirghizia.
- According to DISCOVERY Research Group, the aggregate volume of dietary supplements market in Russia is now assessed at **\$4.3 billion.**
- In 2018, it was growing at the rate of 12% in volume and 32% in value.
- The average retail price for an item in a pharmacy was \$2.2. The average price of an item outside of pharmacies was \$3.64.

2018 Russian BAS Market. By country of origin.

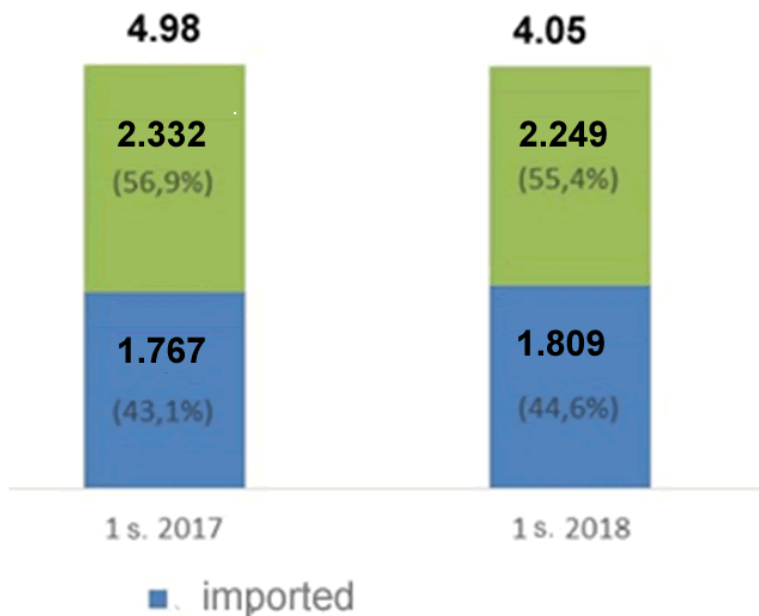


Segmentation by BAS producers

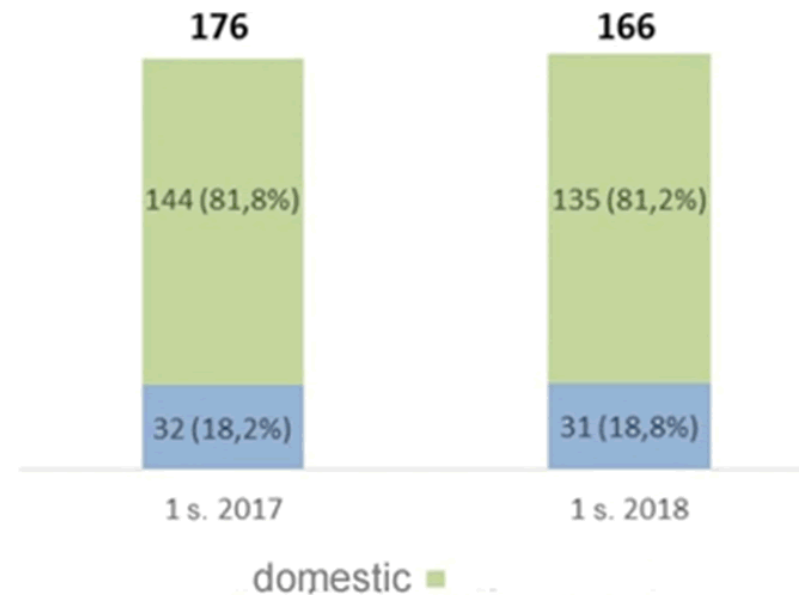
56 per cent of over 11,000 products currently on the market have been manufactured in Russia. The second largest contributor is Germany, then goes the USA.

2018 Russian BAS Market. Domestic vs. Imported.

Imported and domestic
BAS, mln USD



Imported and domestic
BAS, mln items



2018 Russian BAS Market. Sales Dynamics.

Rating	Brand	Use	Growth dynamics in 2018	Market share
1	Solgar	Vitamins	+35,2%	4,5%
2	Doppelherz	Omega	+5,6%	3,5%
3	Femibion (Russia)	Reproductive	+10,3%	2,8%
4	Fitolaks	Laxative	-4,4%	2,7%
5	Maxilac	Probiotic	-1,3%	2,3%
6	Turboslim	Weight	-7,7%	2,1%
7	Normobact	Probiotic	+6,8%	1,9%
8	Vitamishki	Vitamins for kids	-22,7%	1,9%
9	Gematogen	Immunity	-28,9%	1,8%
10	Bac-Set	Probiotic	+83,5%	1,6%
11	Glicyn Forte Evalar	Nerve	+9,1%	1,5%
12	Complivit	Vitamins	+16,0%	1,5%
13	Supradin	Vitamins	+11,4%	1,3%
14	Alphabet	Vitamins	-19,9%	1,3%
15	Pustirnik	Cardiovascular	-24,3%	1,3%
16	Indinol	Reproductive	+118,4%	1,2%
17	Ovesol	Bile	-3,7%	1,1%
18	Univit	Vitamins for kids	-31,6%	1,0%
19	Linex for kids	Probiotic	-8,9%	0,9%
20	Ascorbic Acid	Vitamins	+5,2%	0,9%

2018 Russian BAS Market. Segmentation.

Rating	Category	Share
1	General health support (V)	30,8%
2	Gastroenterology (A)	21,4%
3	Potency (G)	11,8%
4	Central nervous system (N)	9,0%
5	Cardio-vascular (C)	4,6%
6	Weight loss and cleansing (W)	4,5%
7	Bones (M)	3,1%
8	Skin and hair (D)	3,0%
9	Sensory organs (S)	2,8%
10	Blood (B)	2,3%
11	Respiratory (R)	2,2%
12	Urinary (U)	1,4%
13	Poisoning and intoxication (T)	1,0%
14	Internal secretion glands (H)	1,0%
15	Immune system (I)	0,7%
16	Oncology (O)	0,2%
17	Virus, bacteria, fungi (J)	0,2%

Group 1 has been the leader for many years

2018 Russian BAS Market.

Top 20 players.

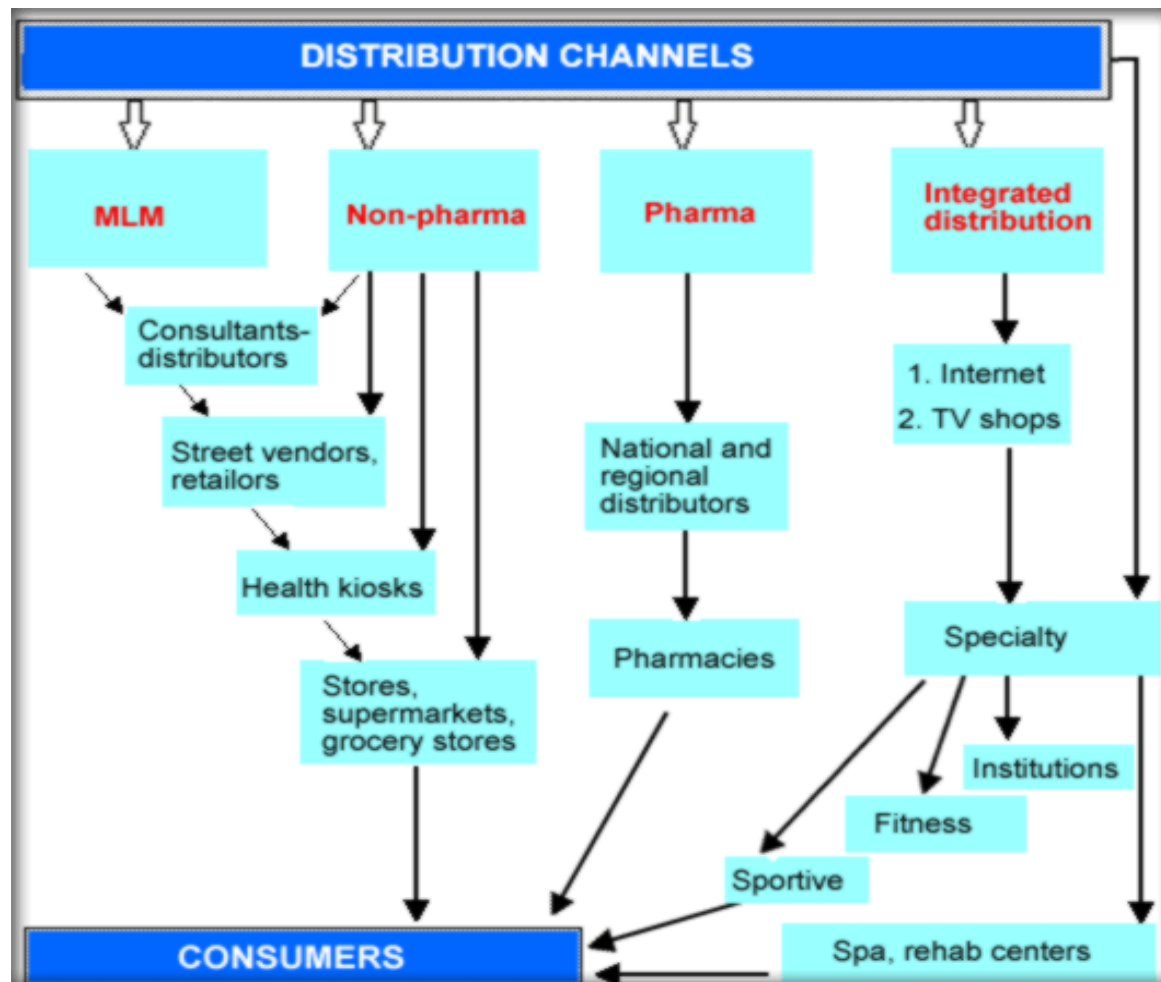
Rating	Company	Country	Growth dynamics in 2018	Market share
1	Evalar	Russia	-3,4%	16,2%
2	Pharma-Med	Canada	+2,2%	5,8%
3	Solgar Vitamin And Herb	USA	+35,2%	4,5%
4	Oticipharm	Russia	+2,8%	4,2%
5	Queisser Pharma	Germany	+5,6%	3,5%
6	Merk Selbstmedikation	Germany	+10,3%	2,8%
7	Valeant	USA	-11,2%	2,7%
8	Vneshtorg Pharma	Russia	+4,0%	2,4%
9	Genexo	Poland	-1,3%	2,3%
10	Stada	Germany	-0,3%	2,3%
11	Recordati S.P.A.	Italy	-12,9%	2,2%
12	RIA Panda	Russia	-43,9%	1,8%
13	Parm-Pro	Russia	-17,9%	1,7%
14	Diod	Russia	+15,3%	1,6%
15	Takeda	Japan	+6,7%	1,6%
16	Bayer	Germany	+19,3%	1,5%
17	V-Min	Russia	-17,8%	1,4%
18	Miracsbiopharma	Russia	+115,8%	1,3%
19	Biokor	Russia	-4,8%	1,0%
20	Medana Pharma	Poland	+7,1%	1,0%

2018 Russian BAS Market. Bestsellers.

- **Five leading product groups are:**
- General health support
- Gastroenterology
- Weight loss
- Central nervous system
- Cardiovascular

Imported BAS retail price is 3.23 higher than that of a domestic BAS. Mean price of a domestic BAS in 2018 was \$1,67 (+3,2% from 2017); mean price of an imported BAS was \$5.8 (+5.4% from 2017).

2018 Russian Market. Sales channels.



EAC Overview

What Is EurAsEC



Member states of Eurasian Economic Community, founded in 2000, occupy a total area of 20.3 m sq. km. Their population exceeds 182 m. They account for 4% of the world's GDP. EAC countries produce 14.5% of the world's oil and 19.3% of the world's gas; their share in the generation of electrical energy is 5%, steel production amounts to 4.8%, and wheat production has reached at 10.5%.

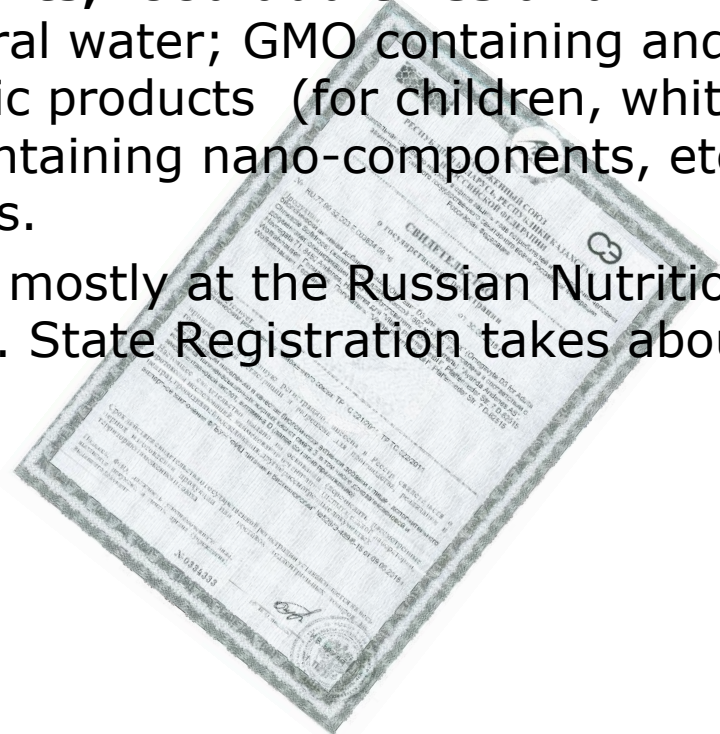
Customs Union

- The Uniform Customs Code came into force on 6 July, 2010, and the Customs Union became fully functional on 1 July, 2011.
- The members of the Customs Union agreed on common principles and rules for technical regulation, and established a uniform list of products subject to mandatory certification procedures in the Customs Union.
- It was also ruled that none of the CU member-states may add a product to their respective national Mandatory Certification List, if it is not included in the Uniform list.
- All CU compliant goods have to bear the Eurasian Community mark.



State Registration of BAS (biologically active substances)

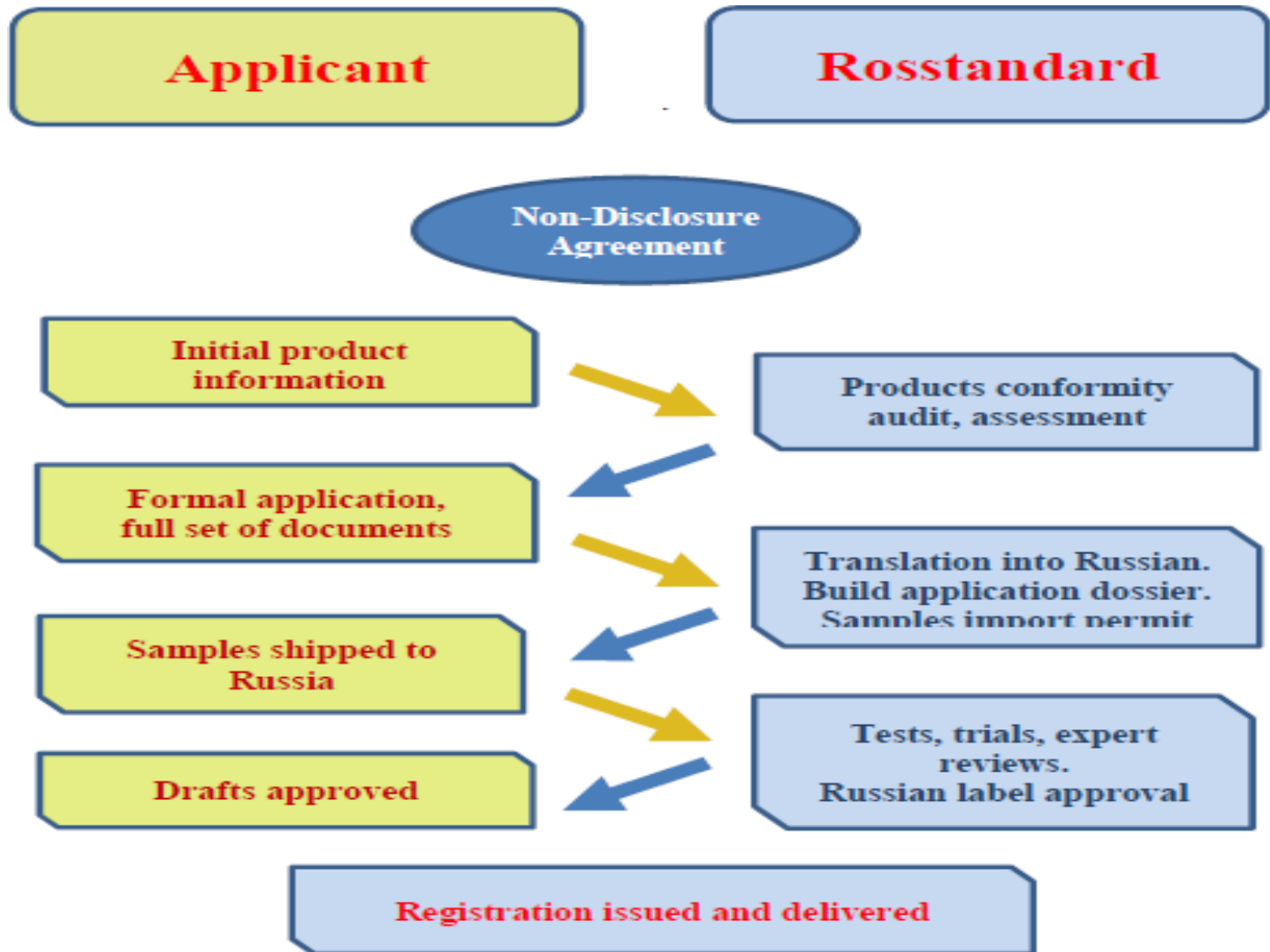
- Products that require State Registration by ROSPOTREBNADZOR, a Russian government department in charge of consumers' safety and well being. Those products are:
- **Dietary supplements, food additives and ingredients**; mineral water; GMO containing and dietetic food; many cosmetic products (for children, whiteners, sunless tanning, containing nano-components, etc); disinfectant cleaners.
- Samples are tested mostly at the Russian Nutrition Institute in Moscow. State Registration takes about 6 – 8 months.



State Registration: other products

- Other product that fall under State Registration requirements:
- **Medical devices** and medical products.
ROSZDRAVNADZOR. Require State Registration and Declaration of Conformity. Takes 8-12 months.
- **Pharmaceutical products**. Health Ministry of Russia.
Takes at least 18 months to register.
- **Pesticides, agrochemical products**, veterinary products, fodders and supplements.
ROSSELKHOZNADZOR. Takes 1 - 6 months.

Registration Flowchart



Application documents

- Detailed Application with product description, HS codes, manufacturers list;
- Licenses and certificates issued by domestic authorities (apostil);
- Full ingredients list;
- Technical documents (standards, specifications, formulas);
- Label or its draft in Russian, as well the original label;
- User instructions, directions, manual etc. ;
- Scientific reports and usage;
- Documents and publications on the efficacy;
- Statement of absence of narcotic or psychotropic substances, GMO, or substances obtain by nanotechnology;
- Random Sampling Protocols;
- Agent-of-Record information (legal entity in Russia or EAC).

- *All documents must be translated into Russian.*

5 registration pitfalls to avoid

- **Pitfall 1.**
- Make sure that your product is potentially eligible for the registration.
- Or else:
- *You may spend a lot of time and money only to find out later that your product "does not qualify".*

5 registration pitfalls to avoid

- **Pitfall 2.**
- Prepare a foolproof application dossier,
- or else:
- *After a long waiting period, the government officers will find an inaccuracy or incompleteness in your application dossier and return you the documents for corrections. This will throw you in the back of the long waiting line*

5 registration pitfalls to avoid

- **Pitfall 3.**
- Obtain quality translation of your documents. For certain translations, obtain apostil and authentication.
- or else:
- *You may again find your dossier returned, and yourself in the beginning of the waiting line.*

5 registration pitfalls to avoid

- **Pitfall 4.**

- Deliver samples legally after having received a samples import permit,
- or else:
- *Your samples, or, even worse, the results of their long and expensive testing, may be found illegal and void.*

5 registration pitfalls to avoid

- **Pitfall 5.**
- Hire a trustworthy registration agency with verified experience of working with Russian authorities, and with an account in a reputable American or European bank. Or else:
- *With "not so good" an agent, you run a chance of waiting for your registration forever, or never finding from a Russian bank where your money had disappeared.*
- *A good agent will have connections with the authorities, and a way to resolve issues if any in a quick and efficient way. He should rather be accountable to you under US or EU laws.*

Main memory points

- Russian BAS market is over \$4 billion and is expected to grow at 12% per year
- An official Importer/representative is now mandatory for most certifications and registration in Russia, like “Agent-of-Record” in EU.
- New registration makes the product valid for all Customs Union member-countries, current and future.
- All CU-compliant certification documents and labels must carry the market sign **EAC**.
- Beware of typical regulatory compliance pitfalls and pre-empt problems

Cosmetic products

- Most cosmetic products are subject to certification via TR CU Declaration of Conformity; only a few categories fall under CU State Registration, like:
 - Sun lotions and creams
 - Skin whitening products
 - Permanent make-up
 - Intimate cosmetics
 - Work-related skin protection products
 - Children cosmetics
- Customs Union does not recognize “cosmeceutical products”. They are handled either as a cosmetic product or as a medicine.





Contact us

- For any support, questions and concerns as regards exporting to Russia and the Customs Union – we are here for you!
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