

ASHWAGANDHA ADVANTAGE

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The Global ASHWAGANDHA MARKET



ASHWAGANDHA ADVANTAGE

September 2017

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From whisky and vegetarian energy bars to nontraditional supplement forms, ashwagandha is showing up in an exciting range of new products. Combine that with the increasing number of global consumers looking for solutions to address fatigue, stress and mental stamina, and the future for ashwagandha holds great promise. **Brenda Porter-Rockwell** examines the global market potential and key considerations for product developers.

12 Food Supplements Containing Ashwagandha: A Pathway to Market in the EU

In principle, several European Union (EU) member states are open to allowing ashwagandha to be used in food supplements, and many countries have a record of products containing the botanical. **Josh Long** reviews the differing regulatory approaches, underscoring the opportunities as well as the need to retain qualified legal counsel or consultants before introducing botanicals in products around the world.

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The Global Reach of Ashwagandha

For thousands of years, ashwagandha has been considered among the most valuable herbs in India. Its reach to the rest of the world has been comparatively limited, primarily used by those already familiar with Ayurveda. All of that is changing. In fact, we launched the Ashwagandha Advantage website earlier this year because we recognized this burgeoning market.

So far, much of this expansion has centered on the U.S. market. As we report in this issue, sales of products that contain ashwagandha are up 40 percent in the United States for the 52 weeks ending June 2017. These products include dietary supplements, sports nutrition products and functional foods such as beverages, bars and snacks.

And while the growth for ashwagandha in the United States is still in its early stages, there are also opportunities in other markets around the world. We have seen this firsthand at our Vitafoods Europe event in particular. In this issue, you will find overviews on both the market opportunities and the evolving regulatory position of ashwagandha in different global markets.

The sponsor of Ashwagandha Advantage, [KSM-66](#), is also once again the Title Sponsor of our upcoming [SupplySide West](#) show. The significant investments that KSM-66 continues to make in building the global market for ashwagandha (both with us and via investments in research, regulatory approvals and outreach) have played a major role in the acceleration of this market.

At SupplySide West, you will be able to find KSM-66 right at the Expo Hall entrance in booth EE-142, where you can see real-world product applications of ashwagandha and meet with the people who have brought this ingredient to the world market.

In the meantime, please enjoy this latest Digital Magazine from Ashwagandha Advantage, and find out if perhaps your next big product opportunity could include this ancient and modern botanical.



Jon Benninger
Vice President

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 [@jonbenninger](#)

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KSM-66 Ashwagandha has been clinically proven to :

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*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



The Growth of Ashwagandha

An Herb Poised for Continued Success

by *Brenda Porter-Rockwell*

With more than 4,000 years of use promoting good health, Ashwagandha (*Withania somnifera* Dunal) should be on the minds of stressed-out people everywhere.

Also known as Indian ginseng, poison gooseberry or winter cherry, ashwagandha was traditionally used as a stress reliever, but also as an enhancement for sexual function, and an immune booster.

GlobalData’s Q1 2017 consumer survey found Americans have high levels of concern over stress as well as tiredness and fatigue. Relatively few are buying products that address these conditions.

According to the survey, 18 percent of Americans *are concerned* about stress and *actively buying* products to relieve it. Almost twice as many—33 percent—said they would *consider buying products that address stress*. Twenty-four percent said they are concerned about tiredness and fatigue and *are actively buying* products to alleviate these conditions. Some 26 percent said they “*would consider*” buying products like this in the future.

Given that more Americans continue to weigh their purchase options before taking action, there’s still time to reach them. Boasting such diverse use, it’s no wonder domestic product sales of ashwagandha are a commercial success.

The good news is there’s room for growth in developed countries around the world. Innova Market Insights tracked the majority (46.2 percent) of product launches with Ayurvedic ingredients as coming out of America from 2011 to 2015, but other regions are catching on. The U.K. had the second-highest number of related product launches, followed by India.

Top Countries for Product Launches With Ayurvedic Ingredients

America led with 46.2% of product launches from 2011 to 2015, followed by



Source: Innova Market Insights

For brand manufacturers looking to tap into a very young global market, supply chain governance and delivery system innovation will become important factors, among others, to market growth.



Managing the Supply Chain

Ashwagandha grows well in arid, dry, drought-tolerant soil like that found in its native region of India. It takes about seven months for this shrub-like plant to reach full harvest potential. The entire plant—root and all—is harvested. This is important since the root offers the most benefits.

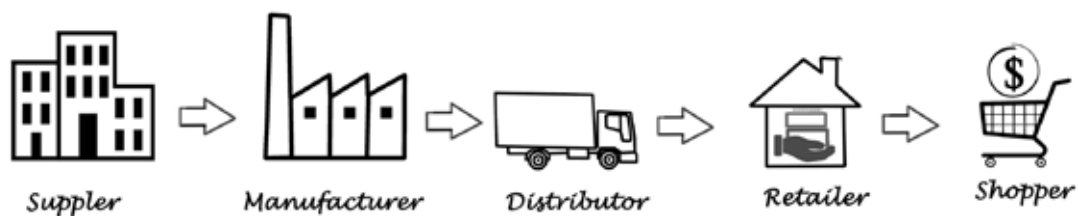
According to the American Herbal Pharmacopoeia and Therapeutic Compendium on Ashwagandha Root, the crop should be protected from light, moisture, air, heat and insect infestation; and the plant roots trimmed, inspected for quality and sorted by grade.

Inspections and validation at Ixoreal Biomed are done throughout the transportation process—including at the extraction facility. The extract is tested for bioactives and safety, then packaged into drums for export out of India.

A far cry from the ancient days of boiling the herb in a pot over an open fire, today's plant is carefully grown, cultivated and manufactured in a tightly controlled process. The problem is some suppliers may be willing to produce a cheaper product without the full strength of the herb. The widespread demand for ashwagandha raises concerns about supply constraints.

“Most ashwagandha makers buy ashwagandha plant parts on the open market. The problem with this is there may be no consistency from year to year because different farmers provide the ashwagandha crop,” explained Kartikeya Baldwa, director at Ixoreal Biomed. “Farmers may move from one crop to another, according to what they see as profitable. There is no assurance that today's supply will be there tomorrow.”

Deanne Dolnick, science director at Alpharetta, Georgia-based TR Nutritionals, said due to her company's close working relationships with the growers in India, there have been no issues with being able to supply this material.





Market Overview

A year ago, TR Nutritionals became the exclusive U.S. distributor for [Prakruti Products Pvt Ltd.](#), a global manufacturer of ingredients—including ashwagandha—for dietary and food supplement manufacturers from its GMP (good manufacturing practice)-certified facility in Karnataka, India.

“Our role is to offer the highest-quality raw materials, along with all essential support documentation,” Dolnick said. “We assist our customers with test methods, if necessary. We are also able to work with Prakruti on various levels of standardization, if our customers require it.”

Ixoreal, the maker of KSM-66 Ashwagandha, has tried to be far-sighted about heading off a potential shortage by buying farms. Baldwa said that makes Ixoreal the only supplier of a branded ashwagandha ingredient with full control of the supply chain—from the farms and the extraction facility to the labs and the distribution.

It may be that ensuring a consistent, reliable supply is what has led to noticeable product gains in the last few years.

Room for Every Product Type

According to Jamie Phillips, M.S., R.D.N., director of scientific affairs at SPINS, cross-channel growth of products including ashwagandha is up 40 percent from the 52 weeks ending mid-June 2017. She said in the United States, ashwagandha is showing positive growth both in the functional foods category and supplements.

Natural product store shelves are filled with a very wide variety of products, especially dietary supplements. Growth rates in categories such as sports nutrition (760 percent) and general wellness supplements (199 percent) present exciting whitespace opportunities for the supplement market, per SPINScan data.

At Concord, Massachusetts-based Debra’s Natural Gourmet, Chief Miscellaneous Officer Adam Stark said the store sells ashwagandha-based products mostly in capsule form and largely in formulas intended to address stress, energy and sleep.

Nationally, the pill form isn’t the biggest seller, though. Ashwagandha has started to make its way into hot and cold drinks, candies, food and more. SPINS reported the ready-to-drink (RTD) shelf-stable tea and coffee category saw notable growth of more than \$100,000 in sales—up 9,413 percent—from the year before. Products like REBBL Ashwagandha Chai, which includes KSM-66 Ashwagandha and promotes the botanical’s potential to bolster energy, recovery and cognition, are the types that have helped boost the category in the last year.

Carlsbad, California-based Buddha Teas’ boxed ashwagandha tea bags include powdered ashwagandha root and have helped to grow the shelf-stable tea category by 58 percent in the last year, according to SPINS data. Other hot beverage products such as Sebastapol,



Ashwagandha

has started to make its way into hot and cold drinks, candies, food and more.





California-based Spice Pharm's Golden Goddess Chocolate Elixir powder also count KSM-66 among their primary ingredients.

SPINS reported the refrigerated juice and functional beverages category is up 14 percent from one year ago.

Tom Vierhile, innovation insights director of London-based GlobalData, said there's a parallel in consumption habits between the days of old and today that contributes to growth patterns. The herb is traditionally consumed as a tonic. It's said to relieve stress, fatigue and anxiety; improve cognitive ability; combat insomnia; and relieve pain and swelling.

"This image has great relevance in the energy drink market, where the search is on for 'jitter-free' energy," Vierhile said, pointing to Uncle Matt's new ashwagandha-based energy drink.

At Expo West 2017, the Clement, Florida-based organic orange juice maker added a new functional juice offering to its lineup. The organic Orange Energy drink with added organic coffeeberry and ashwagandha is said to boost physical and mental energy levels without overdoing it.

Since 2014, there have been 77 products launched featuring ashwagandha, per the NEXT database. Back then, product launches primarily focused on the juice market. New product launches continued through the start of 2017, when a total of 22 products included ashwagandha. Again, the beverage category dominated the product offerings. But three years later, new categories such as snacks, cookies and candy are starting to incorporate it as well.

Vierhile pointed to Ashland, Oregon-based NatureWise's three Whole Body Sparkling Vitality Drinks that he saw at Natural Products Expo West. The zero calorie ashwagandha-based, white tea beverages are marketed online as having a dual purpose of calming and energizing, "so you can go forth and Conquer the Day!"

"A product claiming this unique combination of benefits could be an untapped opportunity for the beverage industry," Vierhile predicted.

Ixoreal's Baldwa said he easily sees how the non-supplement category is poised for continued growth.

The refrigerated juice and functional beverages category is up

**14% from
one year ago**





Market Overview



“The last two years have been amazing in the range of products introduced that contain ashwagandha,” Baldwa said. “While Baby Boomers are fine with taking supplements in pills, the younger generations prefer it in their foods.”

Baldwa said KSM-66’s taste profile makes it easy to use in powders, as well as food and drinks. He said the ingredient works well across delivery systems because it’s extracted without using alcohol or chemical solvents. KSM-66 uses a water-based extraction process, leaving a neutral taste that makes it conducive for easy incorporation into foods.

According to Baldwa, “These advantages—the taste and the full-spectrum nature and consequent clinical superiority—are in fact among the primary reasons cited by functional food/beverage manufacturers for adding KSM-66 ... in their products. “

He said the vast majority of ashwagandha extracts on the market use hydroalcoholic extraction. “One consequence of this is that it leaves out certain components of the raw root and therefore is less beneficial than the full-spectrum extract like KSM-66. The second consequence of hydroalcoholic extraction is that the residue is bitter and needs additives to mask that taste when used in foods.”

From products that meet specific needs to finding the right delivery system, it’s about helping consumers solve their problems on their terms. Otherwise, today’s superstar could be tomorrow’s Facebook meme. So it pays to tell them what they’re getting right up front.

Adhering to the ‘Free-From’ Movement

In today’s highly connected and very social world, consumers can now dictate what they want—and do not want—in their foods. Ingredient suppliers and manufacturers around the world have an opportunity to listen to their customers and meet their needs while still owning a piece of ashwagandha’s category growth.

“People are increasingly aware of eating philosophies and regimens that were previously much less known. It is very important to us that we respect our consumers’ dietary specifications,” Baldwa explained.

Ixoreal’s KSM-66 conforms to a number of label requirements, including certified organic, Non-GMO Project Verified, Halal and more. This allows the company to offer an ashwagandha ingredient “in a way that fits in with the consumers’ diet and the manufacturer’s delivery needs,” Baldwa said.



Market Overview

TR Nutrionals' Ashwagandha is certified vegan, gluten-free and non-genetically modified organism (GMO). "As a raw material supplier, it is extremely important to us that we work with manufacturers that are Halal and Kosher certified. Prakruti has been granted both certifications," Dolnick said.

Manufacturers are listening. Food and beverage products show synergistic growth when labeled with attributes such as vegan (up 43.3 percent) or plant-based positioning (up 14 percent), according to SPINS data.

Beyond food or ingredient certifications, there is growth in environmental claims. According to SPINS, Non-GMO Project Verified is one of the fastest-growing label claims in all retail channels. For products featuring ashwagandha, Non-GMO Project Verified is up approximately 47 percent. Organic—defined conditionally by National Organic Program (NOP) requirements as a minimum 95 percent organic—is up 35 percent, showing clean label claims resonate with consumers seeking high-quality ashwagandha, Phillips said.

She added eco-social certifications like Certified B-Corp are up approximately 44 percent and labeled Fair Trade is up 34 percent. This supports consumer interest in third-party certifications and label claims that help differentiate the product.

Across all of the products seen at the Natural Products Expos in the last three years, the NEXT database found the top certification types are:



Growth Will Continue

Ashwagandha has grown rapidly over the last three years. The following factors will aid its upward trend over the next decade:

Awareness. Continued exposure from daytime doctors such as Dr. Oz and Dr. Manny (Fox News) and industry experts steeped in tradition, like the "Medicine Hunter" Chris Kilham, will help keep the herb in the spotlight. "Once a formulator or a manufacturer is made aware of ashwagandha, the herb almost sells itself because of its compelling set of benefits," Baldwa noted.

Science. More scientific knowledge continues to come forth about the benefits of ashwagandha and how it works in the human body. To date there are 15 scientific studies on KSM-66 as a standardized extract, with more in the publication pipeline.

Delivery Systems. KSM-66 is found in a wide range of delivery forms, including chocolates, beverages, bars/balls, gums, energy drinks, energy shots, functional waters, burgers, gummies, soft chews, meal powders and, of course, capsules, tablets and softgels.

Baldwa said his partners have been able to try new delivery formats due to KSM-66's neutral taste, which does not require additives to mask unpleasant flavors. Plus, KSM-66 is very concentrated, so a little goes a long way in delivering the clinical effects. Lastly, KSM-66 is heat stable and has a high degree of solubility.



Market Overview

While today's consumer may opt for supplements based on their convenience and want specific formulas for specific goals, SPINS' Phillips believes future ashwagandha products will show the most growth in foods.

"Consumers are increasingly viewing food as medicine. Functional foods with health benefits hit the sweet spot," she explained. "Functional foods are expected to continue growing as consumers seek clean label products that help them meet their dietary needs."

Some exciting new introductions have been launched outside the United States, especially in India. For example, the vegetarian Nourish Veda Energy bar from Nourish Organic Foods Pvt. Ltd., is made and distributed in India. According GlobalData's 2016 Q3 global consumer survey, the natural vegetarian bar may appeal to the 77 percent of Indian consumers who believe a product seems more authentic if it is natural.

Bridge Herbal Whisky from Innovative Herbal Distilleries Ltd., is also made and distributed in India. "The inclusion of Ayurvedic herbs—which is widely known in India—in different products has recently become very trendy, and including them in whisky is pretty new and interesting," reported GlobalData's Q2 2015 global survey. "This new launch may appeal to the 40 percent of Indian whisky shoppers who said they consume it either daily, once a week or once a month."

Additionally, ashwagandha's growing popularity as an adaptogen make its inclusion in functional foods a natural fit.

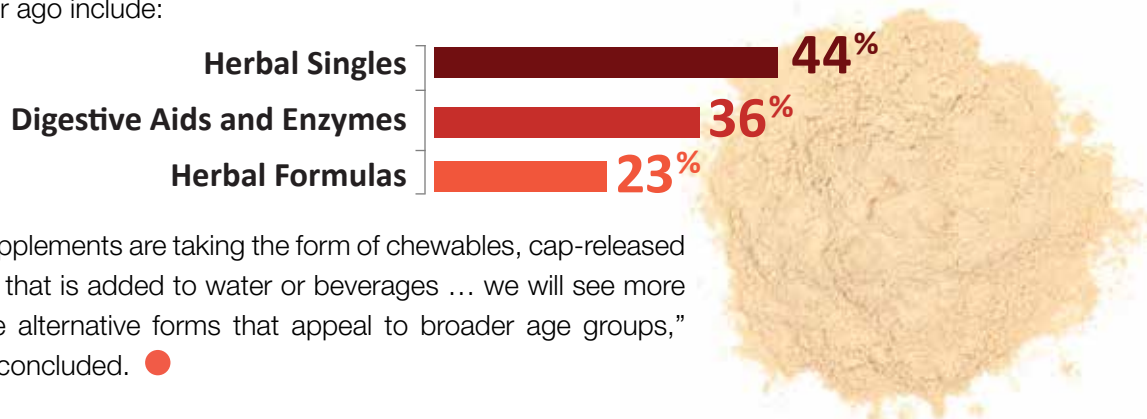
As evidenced by growth in categories such as cookies and snack bars (up 64 percent), candy (up 30 percent), and juices and teas, "We should expect to see ashwagandha's appeal and reach expand into even more food and beverage categories," Phillips predicted.

For the near term, Baldwa anticipates more growth coming from supplements, as "that is where most functional ingredients are consumed now." However, he said because the younger generations favor functional foods, that's where the market should look for long-term growth.

Stark of Debra's Natural is betting on supplements for the near term, too. "Absolute growth, I'd say in supplements," he noted. "Relative growth in functional foods."

Whatever growth the supplements category experiences, pills will not lead the way, Phillips suggested.

Supplement categories already noticeably on the rise from the same period in mid-June one year ago include:



"If supplements are taking the form of chewables, cap-released powder that is added to water or beverages ... we will see more of these alternative forms that appeal to broader age groups," Phillips concluded. ●

Brenda Porter-Rockwell (brenda@writeonporter.com) has a diverse background writing about nutraceuticals and healthy foods for a variety of trade and consumer publications.



Food Supplements Containing Ashwagandha: A Pathway to Market in the EU

by Josh Long

In the European Union (EU), member states' treatment of ashwagandha (*Withania somnifera* Dunal) illustrates the differing regulatory approaches to food supplements, underscoring the opportunities as well as the need to retain qualified legal counsel or consultants before introducing botanicals in products across the continent.

In a January 2015 report prepared for Shri Kartikeya Pharma, EAS Strategies (EAS) examined the regulatory status of the company's ingredient—a water extract of the root *Withania somnifera*—for use in food supplements in the 28 EU member states, Norway and Switzerland. Shri Kartikeya Pharma is the parent company of Ixoreal Biomed (Ixoreal), which markets KSM-66, an ashwagandha extract whose development and refinement was 14 years in the making.

Ixoreal's research and development (R&D) wasn't in vain. In principle, several EU member states are open to allowing ashwagandha to be used in food supplements. What's more, many countries from Belgium to Hungary to Lithuania have a record of products containing the botanical, a small shrub native to Africa, India and the Middle East.

According to EAS' regulatory analysis, many countries belonging to the EU are open to permitting the sale of ashwagandha for use in food supplements, provided the safety is demonstrated and other legal requirements are satisfied.

"The safety should always be established," said Claire Lennon, an advisor of regulatory affairs with EAS in Belgium, in an interview. "That's a general principle of food law. However, you might not need necessarily to notify the product in all member states. And you might not need to provide the same level of detail when notifying in all member states."

Some countries have laws with "a list of plants that may be included in food supplements," Lennon pointed out. Others maintain "negative" lists of plants that are prohibited in the manufacture of food supplements, she added, while some countries may keep both positive and negative lists.

National legislation in the EU is not the only regulatory consideration. Companies planning to market ashwagandha, or any other botanical, in a food supplement must be aware of harmonized rules that impact all EU countries—in addition to the various regulatory restrictions and requirements imposed by member states.

Under legislation in the EU, certain aspects of the food supplements industry have been harmonized, Lennon noted.



“That harmonizes the definition of food supplements,” she said. “That harmonizes the vitamins and minerals that can be used in food supplements. And that harmonizes certain labeling provisions and certain other aspects, but it doesn’t harmonize the use of all ingredients.”

Novel ingredients in the EU, for example, are subject to premarketing authorization per a regulation (EC No 258/97) adopted in 1997. But *Withania somnifera* is not considered novel, EAS divulged, referencing an EU novel food catalog.

“In general, if an ingredient is not novel, but it’s another substance like a plant, then it’s subject to the national provisions,” Lennon noted.

Ashwagandha, nonetheless, could fall under the definition of a novel ingredient under certain conditions, consequently requiring premarket authorization. For example, the EU regulation applies to, among other things, “foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.”

As EAS explained in its report, member states may have their own national approaches or rules that forbid botanicals or allow for them in the absence of harmonized rules that impact all EU countries.

Ashwagandha is a case in point. It is subject to different regulatory approaches in the EU member states. Belgium, for instance, treats *Withania somnifera* differently than Estonia.

Still, EU member states don’t have unfettered discretion to block marketing of a botanical. EAS described a principle of EU law intended to ensure market access for products not subject to EU harmonization.

As the European Commission (EC) explains on its website, the principle of mutual recognition “guarantees that any product lawfully sold in one EU country can be sold in another. This is possible even if the product does not fully comply with the technical rules of the other country.”

EU member states

don’t have unfettered discretion to block marketing of a botanical ... The principle of mutual recognition “guarantees that any product sold in one EU country can be sold in another. This is possible even if the product does not fully comply with the technical rules of the other country.”



Global Regulation



Incorporated in Regulation (EC) No 764/2008, the principle of mutual recognition grants national authorities discretion under limited circumstances to refuse a product lawfully marketed in another country.

“The member state of destination may refuse the marketing of a product in its current form only where it can show that this is strictly necessary for the protection of, for example, health and life of humans,” EAS stated in its report. “In that case, the member state of destination must also demonstrate that its measure is the least trade-restrictive measure.”

Divergent Regulatory Approaches in EU

I. BELGIUM’S POSITIVE LIST

Belgium’s treatment of ashwagandha underscores the regulatory nuances—and opportunities—associated with marketing food supplements in the EU.

Withania somnifera is included in a positive list regarding the marketing and production of foods consisting of plants or containing plant preparations, EAS noted. As of the time EAS published its 2015 report, 14 products with the term “ashwagandha” were identified in a Belgian register of notified food supplements. Belgian authorities respond to a food supplement notification with an answer letter, the regulatory consultancy added.

“The use of *Withania somnifera* extract would . . . likely be permitted in a food supplement,” EAS wrote, “provided that its safety is demonstrated, and following successful product notification with the Belgian authorities.”

The marketing of ashwagandha in food supplements is subject to a special consideration in Belgium. The BELFRIT list, a project of the Belgian, French and Italian authorities, “indicates for *Withania somnifera* that the amount of the steroidal lactones and alkaloids must be determined,” EAS observed.

The regulatory consultancy recommended “manufacturers or distributors notifying food supplements containing *Withania somnifera* extract on the Belgian market determine the levels of these active substances in assessment of the nontoxicity of their products.”

II. RESTRICTIONS IN HUNGARY

The status of ashwagandha in Hungary reflects the restrictions EU member states may impose on food supplements.

According to EAS, an expert panel has included *Withania somnifera* in a list of plants not recommended for use in food supplements. The authorities in Hungary have indicated a dose limit and mandatory warning statement for the use of ashwagandha in food supplements.

Notwithstanding the restrictions above, EAS identified four successful notifications for products containing ashwagandha in the Hungarian register of notified food supplements—and only one product that was marked as refused.



III. LEVERAGING PRINCIPLE OF MUTUAL RECOGNITION

Other countries have no specific regulations for the use of botanical ingredients like ashwagandha in food supplements. This could open the door to leveraging the principle of mutual recognition to market ashwagandha in Luxembourg and Spain, for example. Likewise, Portugal does not specifically regulate the use of plant preparations in food supplements, according to EAS.

“The mutual recognition principle is therefore always an asset at the time of product notification,” the regulatory consultancy advised, “and data should always be available on the non-novel food status of this ingredient.”

IV. UNSUCCESSFUL NOTICES AND MEDICINES

Even if a botanical like ashwagandha is not specifically regulated in an EU member state, there’s no guarantee that a product containing an herb like *Withania somnifera* can be marketed in a country without an objection from the national authorities.

Take Poland, for example. EAS noted the use of ashwagandha in food supplements would be allowed in principle if the final product is safe and not considered medicinal. Nevertheless, while several combination products containing ashwagandha have applied for notification in Poland—a country where the use of ashwagandha in food supplements is not regulated—EAS reported only one “monopreparation food supplement product” was successfully notified.

In some parts of Europe, it may be obvious that marketing a botanical like *Withania somnifera* is going to be an uphill battle. Switzerland is one example. According to EAS, food supplements containing *Withania somnifera* would require an individual authorization prior to marketing from the Swiss Federal Office for Public Health.

A Swiss guidance document identified no recorded food use of ashwagandha, observed the regulatory consultancy, adding ashwagandha would very likely be considered medicinal in Switzerland.

Ample Opportunities in EU

In examining the potential acceptance of a food supplement in EU member states, Norway and Switzerland, EAS recommended careful consideration of the entire formula and recommended daily dose, as well as the labels and claims conveyed to the consumer.

Lennon said the opportunities for marketing food supplements in the EU are plentiful. As EAS’ report on *Withania somnifera* illustrates, marketers of food supplements containing ashwagandha can take advantage of such opportunities in many countries throughout the EU.

“It’s just a question of being aware of the different legislative requirements,” Lennon observed, “and ensuring that you meet them for your ... product.” ●



Takeaways for Your Business

With more than 4,000 years of use promoting good health, Ashwagandha (*Withania somnifera* Dunal) should be on the minds of stressed-out people everywhere.

Also known as Indian ginseng, poison gooseberry or winter cherry, ashwagandha was traditionally used as a stress reliever, but also as an enhancement for sexual function, and an immune booster.

GlobalData's Q1 2017 consumer survey found Americans have high levels of concern over stress as well as tiredness and fatigue. Relatively few are buying products that address these conditions. However, that may change quickly, as ashwagandha is increasingly being incorporated in everything from whisky and vegetarian energy bars to non-traditional supplement forms.

The other good news is there's room for growth in developed countries around the world. Innova Market Insights found America garnered the lion's share (46.2 percent) of product launches with Ayurvedic ingredients from 2011 to 2015, followed by the U.K. (8.6 percent), India (5.1 percent), Germany (3 percent) and Canada (2.7 percent). "Other" countries made up the remaining 34 percent of product launches.

For brand manufacturers looking to tap into a very young global market, supply chain governance and delivery system innovation will become important factors, among others, to market growth.

In terms of the global marketplace, a January 2015 report prepared for Shri Kartikeya Pharma by EAS Strategies (EAS) examined the regulatory status of its ingredient—a water extract of the root *Withania somnifera*—for use in food supplements in the 28 European Union (EU) member states, Norway and Switzerland. Shri Kartikeya Pharma is the parent company of Ixoreal Biomed (Ixoreal), which markets KSM-66, an ashwagandha extract whose development and refinement was 14 years in the making.

According to EAS' regulatory analysis, many countries belonging to the EU are open to permitting the sale of ashwagandha for use in food supplements, provided the safety is demonstrated and other legal requirements are satisfied.

Under legislation in the EU, certain aspects of the food supplements industry have been harmonized. EU member states may have their own national approaches or rules that forbid botanicals or allow for them in the absence of harmonized rules that impact all EU countries.

Some countries have no specific regulations for the use of botanical ingredients like ashwagandha in food supplements, which could open the door to leveraging the principle of mutual recognition to market ashwagandha in Luxembourg and Spain, for example.

So long as manufacturers stay abreast of global regulations, the potential in this space abounds. ●

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