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SPECIAL REPORT

Market Intelligence and Business Strategy: Strategic Globalization

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by Steve Myers

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Companies want to know how to build intelligent strategies to effectively operate around the world. A sound strategy considering the research, market and regulatory factors will help companies soar passed domestic borders to capitalize on the global marketplace. At Supplyside MarketPlace, executives from SPRIM, including managing partner Reza Afkhami, co-founder and managing partner (USA) Ivan Jarry, and co-founder and managing partner (Europe) Olivier Shleifer, joined Haeri Roh-Schmidt, Ph.D., technology and research regulatory policy strategist at Amway for a detailed discussion of how to effectively develop a global strategy for natural product businesses.

Jarry advocated adoption of a global mindset. For U.S. companies, it can be important to consider the international consumer, even if global marketing is reserved for sometime in the future. The name of the product(s) and ingredients should consider cultural and linguistic differences, including translations. In addition, he said building a robust science file for your product that people around the world will believe in; consider adding another non-US population to a study. Parry pointed out whiles elf-affirmed GRAS (generally recognized as safe) status is becoming a popular tactic the US market, but GRAS might be achieved and recognized differently in other parts of the world. It might also be helpful to find some scientists outside of the States, and to consider if your existing partners or future partners have international experience and follow your business outside of North America. Jarry also advised, "Make sure you are aware of the regulations in other countries to make sure when you define products or make claims, you can duplicate and replicate this in other countries."

Jarry recommended companies prioritize their markets using filters, including size of price, science and technology, regulations and intellectual property, and marketing. He also suggested when companies design their U.S. activities, they should keep in mind future globalization. "It is important the data you have is on the characterized product, so when you go to another country and need to adapt the product, the data is still useful," he said. Proof of safety is important to win registration in other countries. Proof of efficacy data also needs to be highly reliable for claims approvals abroad. Consider the use of key opinion leaders (KOLs) for help with registrations and approvals in international markets. And try to target international and foreign journals with research results. In the end, Parry advised to maintain the highest standards early in your developments in order to help meet regulations and requirements around the world at a later date.

Shleifer detailed three keys to being ready for the global market. Fast decision-making skills are needed to assess the price size, scientific and technological competitiveness, regulatory feasibility (safety and claims), and intellectual property

defensibility. Path-to-market requires a sound business model for globalization for ingredients and products, and awareness of the regulatory and registration process I'll need to undertake to get my products to market. The path-to-claim challenge is showing the link between the science and the benefit. This requires planning for global consumer messaging from the start, a solid scientific and clinical strategy for claims substantiation, and creating a master file and individual dossiers for each target country at the same time.

Roh-Schmidt said Amways products are primarily developed in the United States, but certainly looks out for its global opportunities whether market opportunities from a consumer standpoint, competitive standpoint, or internal or partner intellectual property. "The regulatory and policy environments are changing in that global framework, so we look to maximize our product development efforts," she said.

From a cost-effective point of view, developing one product that launches across the globe would be most efficient; however, it is not always practical, because of different circumstances and regulations. Roh-Schmidt said it is important to consider market preferences.

In terms of launching products in various international markets, safety, substantiation, adverse event awareness, labels and claim possibilities, and the quality of ingredients all address regulatory hurdles. She reminded a particular product may be positioned as a dietary supplement or vitamin in one country, but might be considered a food in another. Then it could be a general food or a functional food. "Depending on in what categories you will be able to position your product, what you would be allowed to say about that product would be very different," she noted. What is well-defined in the U.S. market as dietary supplements, is called food supplements in the European Union (E.U.). Japan doesn't have a supplement category and considers them as foods, so claims—such as U.S.-allowed structure-function claims—are severely limited there. Korea considers these products as "health function foods," which offer a little more leeway. ASEAN (Association of Southeast Asian Nations) is going through lot of efforts to have harmonized framework for dietary supplements, Roh-Schmidt reported. A draft is expected by end of 2012 and

Supplement Categories Around the World

Codex: Vitamin & Mineral Food Supplements
USA: Dietary Supplements
Europe: Food Supplements
Japan: Foods (no supplement category)
Korea: Health Functional Foods
China: Health Foods
ASEAN: Health Supplements
Russia: Biologically Active Supplements
Canada: Natural Health Products
Australia: Complimentary Healthcare Products

should look a bit like a mix of CODEX, U.S. and E.U. regulations. She called the Codex claims guideline reasonable from a scientific standpoint, easy to understand and a good basis for harmonization.

Schleifer expanded on the regulatory opportunities and challenges of globalization, noting varying regulatory requirements can place time-to-market at one year in some countries, but up to as much as eight years in others. He said to decode the regulatory complexities, it is important to evaluate thoroughly the time-to-market, as well as to understand the heterogeneous nature of and find the potential common denominators of regulatory frameworks to sequence and scale the regulatory and scientific affairs efforts. He noted sometimes, when there is no regulatory framework in a target country, the company can work with regulators there to create a framework.

There are new safety requirements emerging in Europe and China for cosmeceuticals. Schleifer said it is changing the registration process in Europe for these products. Among the parts of the E.U. regulation that are changing are CMR substances (carcinogenic, mutagenic or toxic for reproduction), safety assessment, product information file, notification process and nanomaterials.

The globalization process is complex, Afkhami said, with many moving targets. You have to multiply all your efforts from the U.S. market to reach all these other countries. Tools and expertise are needed to assess matters quickly, he said, noting this is the same case for clinical trials.

A perfectly implemented study that is poorly designed is going to be useless," he said. "Starting with the proper study design is absolutely critical." At first glance the basics are simple: population choice, endpoints, etc. However, the situation becomes very complex when you try to find the common denominators across multiple countries.

He advised not trying to rush implementation, but rather spend time and money strategically designing studies for maximum global impact.

When you create a good design, it is time to implement. Afkhami stated globalized implementation can cut costs in half, accelerate the time to implementation, gain access to large populations in some countries, access to top medical facilities and scientists, access to naive populations unavailable in U.S. and E.U. markets, and you can do multi- centric, multi-ethnic and multi-market studies. However, the challenges are also present, including screening trusted partners, gaps in technical capabilities (GCPs, data management, data integrity, etc.), acceptability of results, importation of study product, and review and approval process timeline differences. He advised conducting a feasibility analysis in select countries or regions.

A sounds approach, according to Afkhami, is to have a clinical research plan. Make sure this plan is inline with your commercial and regulatory strategies. Find a partner or consultant to complete gaps—there are very few companies that can cover all these aspects globally (strategy, design and execution), he said. Further, using sound scientific methods will be appreciated by regulators, scientific community and your leadership. Justify larger studies with smaller studies, he advised. It is also important to

maintain high standards of quality controls in all aspects of implementation, including hiring and training. "Definitely have independent and professional monitoring," Afkhami said. "It will add a l t of value to the data you have in the end and your ability to leverage it." Blinding is key, and Afkhami suggested going beyond double blinding to triple blinding: site, CRO and staff. Finding partners that are global and have local expertise in a particular country, have high standards and control, and speak English. ❑

Globalizing Study Design

Basics -
Population, Endpoints, Design. Complications lie in finding the common denominators across geographies

Global Goals -
- **Commercial:** US goals leveraging international implementation vs. Global goals for global market
- **Regulatory:** Challenge of finding commonalities between regulations, and tying those to global commercial endpoints
- Within framework of expected technical potential

Right Population -
- **Variability:** Metabolic pathways, diets and lifestyle, environmental factors
- What's normal vs. what's healthy. Not study the overweight and obese in the US?
- Diseased or generally healthy? Ex: IBS vs. GI symptoms, EU vs. US
- Local population requirements Ex. China, Japan, EU vs Brazil
- Local, multi-centric, or both?

Right Endpoints -
- **Pre-set protocols:** some protocol aspects challenging/expensive and not needed elsewhere. Ex: China nutritional health claim studies
- **Categorization by design:** drug, food, medical food, supplement, cosmetic, or device? Ex: most probiotics in India are drugs
- What is the intent? Ex: a simple cosmetic that could be a drug/device combination