

Movers & Shakers Interview With Victor Ferrari - CEO, Horphag Research Ltd.

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Victor Ferrari

The profound impact that Horphag has made in the Nutraceutical industry through the flagship brand Pycnogenol® is clearly the outcome of tireless research efforts. Would you give us a brief overview of the important milestones in the development of brand Pycnogenol® as a benchmark within the pine bark extract market?

Obviously, we will have to go a little back in time because it explains some of the strength and quality of the product that we have today. In the 1970s, Pycnogenol® was developed as a pharmaceutical drug and as such, the obvious milestone was in obtaining a drug registration a couple of times in Europe, and at the same time establishing a complete drug-master file. This was the key in moving ahead. In 1987, we entered the U.S. market for the first time. By about 1995, Pycnogenol® had been promoted by most of the vitamin labels in retail and mail-order, several network marketing companies and we were able to nicely penetrate North American businesses by 1995. From 1996-2000 and beyond, we were able to duplicate our efforts and were able to make Pycnogenol® available worldwide and in a much more pro-active way and more strategic way. We added numerous countries over the years, especially with the implementation of our Horphag office in Asia, which we established in 1996, and were then able to enter countries like Japan, Taiwan, China, and Singapore. So far we have been able to successfully penetrate many other markets in the world, much more importantly South America, the Middle East, North Africa, South Africa. These are important milestones with regard to getting the product into the markets.

Other milestones include obtaining GRAS status for North America, having being able to obtain TGA registration in Australia and having been able to obtain health food status in Korea (three years ago). All of these steps were a part of further establishing our market presence.

Do you think there is anything with regard to your company being able to convince some of the leading companies in the world to use your Pycnogenol®, which you probably consider a milestone?

Well obviously, we were able to convince some of the leading pharmaceutical companies, as well as food and dietary supplement makers through the steps I previously discussed, including:

- Having a product of the highest quality (Pycnogenol® is GMP certified and USP conform)
- Having impeccable safety documentation and records (Pycnogenol® is GRAS in the US)
- Most importantly, having a well researched, evidence-based product. Furthermore, effectively communicating the research carried out on the product.

These steps were absolutely key in gaining partnerships with leading companies such as Novartis, Nestle, L'Oreal, and various pharmaceutical companies.

Your Pycnogenol® has become an industry standard in the pine bark extract market, don't you think it is a remarkable achievement for your company?

Of course, because we could see a huge gap in the kind of research and evidence needed to drive the pine bark extract market. When we came out with the kind of documentation and clinical evidence

supporting the Pycnogenol® brand of a pine bark extract we were able to fill this gap, which in turn helped us to become an industry standard. For example, on Medline, 98 percent of the publications pertaining to pine bark extract have been performed based on Pycnogenol® by Horphag Research. There is a market of generic pine bark extract products out there, but most of them are lacking the necessary documentation that is needed – and as is even more pertinent now – in the challenging regulatory environment.

Research and Development has been the strong point for the growth of your company. Looking in the future, what new opportunities do you see for Pycnogenol® in the food, beverage, supplements, cosmetics and pharmaceutical space?

Today's consumer is more educated than ever. We can see that consumers can differentiate between real science and marketing. Hence, we see a specific opportunity for us here where we think that we can further solidify our position. Our greatest opportunities are in the area of functional foods and beverage, since those products look for ingredients with functional properties. In order to provide added value to consumers, functional food manufacturers are looking to use safe and evidence-based ingredients that will deliver added health benefits that consumers can directly identify. For example, this year in the area of food and beverage, a company in Asia has already launched several products with Pycnogenol® including teas, coffees and dairy foods. Hence, functional food and beverage is an interesting area where exciting opportunities lie ahead for us in addition to the dietary supplement market where we enjoy a constant growth since 9 years.

In the pharmaceutical area, Health Care itself is going through a change, where the pharmaceutical companies are not only looking at mono-substances to treat certain disease conditions, but are also looking at powerful nutritional solutions to prevent further disease developments. Such companies are showing special interest in our ingredient, Pycnogenol®.

Now that Pycnogenol® has established itself as a multi-functional health ingredient, with more than 600 Pycnogenol® dietary supplements, cosmetic formulas and functional food and beverages available worldwide, are there any plans of exploring synergies with other branded ingredients (such as those already seen with Indena's Mirtoselect®)? What kind of synergies Horphag looks at while deciding upon a business partner such as Indena?

Absolutely, we are working on several projects of this kind. Some will be launched very soon, while some are still in development. But what we are trying to do is identify the ingredients that comply with the same kinds of standards that we have, for which Pycnogenol® is known. For example, strong brand identity, high safety standards and impeccable safety records, proprietary clinical data, so that we can ensure that when we work with another ingredient the added value of both ingredients is real. We try to only work with companies that have thorough research and published science. We want to make sure that we have a winning team.

These opportunities have obviously been coming to us based on the research we have published on Pycnogenol®. We have seen major interest in our ingredient from various other ingredient companies in the world to work on developing combination products with Pycnogenol®. For example, we already have a combination product with Kaneka in Europe as a proprietary ingredient in combination with their CoQ10. There are a few others such as an Indena's product for weight-loss, Indena's bilberry extract, and some of the leading amino-acid manufacturers, to name a few. There is a variety of co-marketing and co-development agreements in process that we are actually working on.

don't think you can prevail in the long run if you just sell a mono-substance. You really need to find out what the consumer needs are and then come out with an ingredient, solution or a targeted formulation. This is where we step in, by preparing and suggesting formulations, while at the same time conducting the required clinical research on the formulations to have a powerful marketing advantage. This helps because the customer can then relate to the benefits of the formulations, rather than going back to the benefits of the single ingredients.

Pycnogenol® is currently positioned for its eye, heart, bone, skin, immune and menstrual health benefits but without many affirmative health claims been publicised on your website? Can you elaborate on these health claims that Pycnogenol® has been able to get , so far?

Ours is a global website and as such is not related to any specific region. Health claims are generated or prepared by legislators in different regions, and are country specific. For example, there are different sets of laws in the U.S., in Europe (EFSA), in Korea and in Japan. We comply with all these sets of laws and wherever there is a possibility for us to go and file for a proprietary health claim we do it. We obtained such a claim registration in Korea, for instance. In America, going for a qualified health claim filing is not in our interest at this stage, because the FDA does not protect your proprietary data. This would mean that if we were to go for a qualified health claim in the U.S. we would basically allow any pine bark extract manufacturer to use our research. We rather prefer staying under the DSHEA which is the current set of laws as structure/function claims. We comply entirely with the law, which helps our customers work with health claims, and in Europe where we have established food supplement status in most of the EU countries like UK, Belgium, CZ, France, Italy etc. We also have submitted several filings with EFSA under article 13 and are ready to file for article 14.

Currently, EFSA is taking steps to modify the current laws in Europe for various ingredients. The future of many Nutraceutical products seems to be challenged by the health claim laws. What measures are taken by Horphag to overcome the regulatory hurdle?

Obviously the challenge is huge, not only for us but for many other companies in this arena. However, there is a large and a very important positive effect too. Products will be scrutinized for their quality and the value of their provided research. The current case with EFSA is that we are required to go for a structure/function claim and then a disease–reduction claim, which is the next stage. But so far the EFSA regulations are not clear. I recently read that DANONE has withdrawn its application; I can imagine they would have a solid file. Also, Cranberry Products got their claims refused by EFSA.

At this point in time, we are moving forward very cautiously, without exposing ourselves to the possible dangers of getting victimized by EFSA due to still unclear interpretation of Health Claim Regulation and the technical guidelines. It is still difficult to evaluate what the clear parameters for a EFSA approval are. For example, at one stage they were requiring human studies and a couple of weeks ago they required animal studies and a claim structure based on animal studies. It is difficult to measure it, but our company has been very active in making positive filings and listing procedures.

At this point, there is a tremendous amount of confusion based on the huge amount of files that are in front of these people (officers who are reviewing applications by companies). They are sending these back and forth to check the validity of information. There is a need for much clearer information and better parameters for those officers who are given these files. Some of their opinions are clearly contradictory. But the fact that we have lot of supporting and genuine data puts us still in a much better position than many other players in the market who have to come with one or two studies to get the

EFSA claim. I am sure having one or two studies as compared to multiple clinical studies performed to support each health claim really makes a difference.

How would you rank the importance of parameters such as: cost; multi-functionality; quality; research back-up; branding; and regulatory support for the success of a functional/health ingredient in the current scenario and why?

1. Quality has to be number one. It has to be impeccable. You can't exist in today's market unless you have high quality product.
2. Safety – you cannot promote a product if it is not safe.
3. Trying to offer evidence that your product works. That's an ethical approach as well because you are making a promise to your business partners or to your consumers.
4. A branding strategy has to be in place, so that your partners /customers can take advantage of the value of the ingredients that go into their products.
5. Regulatory support – Without it, your customers won't be able to successfully launch their products with your ingredient or introduce it for new applications.

In current scenario, most of the leading ingredient companies are taking steps towards sustainability in the area of environment, economics, and social responsibility. What are Horphag's initiatives in this space?

Oh yes, obviously, because in today's world not only does it make a lot of sense, but we owe a lot to the consumers and the industry, so it is our duty to take care of these aspects very seriously.

Pycnogenol® is obtained from the bark of a tree, which is grown in an area where law indicates for every cut tree you have to replant another one. We use the bark which comes from the by-products of the timber. So we think we are very lucky that the industry from which we source our raw material already takes care of itself from the sustainability side. Also, in this area fertilizers and pesticides are not being used. Since the products is manufactured in France we are complying with stringent laws concerning labour.. Additionally, all the water that is being used during the manufacturing process is treated and cleaned, so that there is no chance of damage to the environment. We have a very positive Carbon-dioxide balance, because part of the energy or steam that is used in the manufacturing process is produced from renewable sources like wood chips and by-products of bark which we don't need.

Specifically, social responsibility is very critical. As a company you cannot successfully do business without empowering your own people and supporting them in becoming better and helping them to grow. Horphag is supporting a social institution in Philippines, called the Cebu Hope Centre. We had our annual regional Asia meeting in Cebu where I was invited to an orphanage for abused children. Horphag is taking care of the entire cost of maintaining those 40 children at Cebu Hope Centre. I visit the centre in two weeks on my way to Singapore. So, we try to act responsibly by giving those less fortunate a chance for a better life.

We understand that your customers value Pycnogenol® for its profound research back-up. Apart from providing the ingredient, at what scale does your company aid its customers with respect to any kind of research support?

Just imagine, if we were to produce a raw material and just make it available to a variety of customers, the relationship would end with the buyer. Then we would just walk away and do the next thing and find

a new buyer. But this is not our business model. Our business model is very different. We have a set of Horphag people around the world, PhDs, professors, other in-house people, who go together with the customers to develop their products. We take it a step further, where we sit down with our customers and co-develop products. Then we can even conduct a single clinical trial or several clinical trials or a complete research program which we run on these products and make it available to the customers. For example, Prelox® which we sell through Kobayashi pharma and other companies worldwide, that we have co-operated with. Another product is Reliv® (where we looked at a product to improve metabolic rate, glucose uptake and weight-loss) and another is with Market America "OPC -3" for which we co-developed and help publish two clinical trials that are on Medline. So, we try to take the perspective further, co-operate with the customers on specific products or unique formulations and create a new standard for them where they can be successful in the market.

We also spend a lot of efforts on key accounts (such as NBTY, GNC and Vitamin Shoppe, Pharmanord, DHC) around the world, in co-branding.

In your view, the plethora of ingredients available in the health & wellness market is a healthy sign of competition or is it creating a void/ambiguity in the minds of consumers?

I would agree with you when you said that today when we look at the marketplace, look at the websites, they sell products of various brands and it gets very difficult for consumers to make a choice and to verify the data. But this is changing over time, the companies are increasingly realising that consumers have become more active in searching on Google or products' websites and checking the background of products, and the risks and benefits of the products. So, the Internet has been playing a vital role in educating consumers today, with regards to dietary supplements.

Is it a source of misunderstanding or creating confusion? Yes, it is, but at least we have the tools today to provide some kind of data to the consumers. Having said that, it is still difficult for them to find easy ways/resources to access the information. We are still ending up with Medline. It is still difficult for them to qualify scientific publications. But we also try to relate to other websites, such as the Natural Standard and the American Botanical Council etc. where consumers may find better, more understandable information.

We are a raw-material, research, marketing- providing company. To cover the entire world of consumers is very difficult. So, we have to do it together with our customers and we are actually doing it. There are a lot of activities going on around educating customers; be it through seminars, web portals, books or other means of information. This is what we are doing with our customers. Obviously the Internet is a great source of information, and in our extremely informative website we provide all the data and information about our product that we have, assembled in simple files so that people find it easy to understand. We are getting up to 50 consumer requests daily, asking questions such as "what does the product do?", "how does it work?", "is it safe?", "does it work in these conditions?" and so on. We are putting enormous effort and time into addressing these requests, because for us it is also important to know what the consumer thinks. The Internet helps us to be in direct touch with the consumer. Any consumer can go on your website, and there is a special link "ask the expert," that the consumer can use and ask any questions. These are addressed as quickly as possible by Horphag.

What do you think is the contribution of the multi-functionality factor of any ingredient in getting it successful in the marketplace?

It's a blessing in disguise. On one hand, multi-functionality is a huge advantage because it gives you the opportunity to continuously be looking for new applications. So, technically speaking, this is the true advantage of the ingredient/product, which is enormous for us. On the marketing side, it is a tough call, to convey the message that the product has so many benefits. This is very challenging. So we have to provide additional efforts and information to be able to convince the customer that this single product has so many benefits and can work in a number of conditions.

Hence, it is a true advantage as well as a challenge.

Is there anything you would like to share in the end with us?

No, I think you made it very clear. It is important to see that there are some high standards being applied by a lot of companies in this industry, and the threshold is going to be raised. You will see more and more people not doing the exact same things but good things, moving ahead, in trying to provide all those necessary aspects. I think you really touched it very nicely.

We are in the modern world, and the regulatory challenges are many, the consumers are getting more and more educated, and companies should not risk working with ingredients that are not backed by research. If an ingredient is not of the highest quality, not safe, and lacking evidence, it may not be able to be legally sold in future. I think all your questions were quite pertinent.

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