

Interview: Roeland Van Dam - CEO, Bilthoven

Biologicals, The Netherlands



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Roeland Van Dam, CEO of Bilthoven Biologicals, a historical Dutch company which remains at the forefront of vaccine production, explains how being integrated into the Serum Institute of India has helped the company to become profitable and consider ambitious new objectives.

Bilthoven Biologicals has a very unique history, having started out as the National Institute for Public Health and the Environment, then as the Dutch Vaccine Institute (NVI) from 2003, and now as a daughter company of the Serum Institute. What were the benefits of being integrated into Serum?

Initially, Bilthoven Biologicals indeed started as the National Institute for Public Health and the Environment, which was obviously a publicly owned company with a focus on human vaccine production. Fifty years ago, this kind of activity was quite unusual, as vaccine production was far from being at the core of the pharmaceutical industry's focus. In 2003, the Dutch Vaccine Institute split from the National Institute of Health as a separate organization, mainly for administrative reasons. Nevertheless, the recent economic crisis led the government to wonder whether it was still relevant to hold a state-owned vaccine manufacturer, which by that time was moreover extremely expensive and loss-making. Finally, as our products were already manufactured by other pharmaceutical companies and would still be available in the upcoming years thanks to other manufacturers, the government initially decided to divest the Bilthoven manufacturing facility.

Nevertheless, the government finally revised its position, and the Dutch Vaccine Institute was thus acquired by the Serum Institute of India, member of the Cyrus Poonawalla Group. However our relationship with the Serum Institute truly dates back from the seventies, when the government decided to launch a fully-fledged vaccination program primarily targeting Dutch patients. But, social considerations led the Dutch public authorities to open the gates of our manufacturing plant to other countries, in order to help them build up a similar vaccination program. The first person who knocked on our door was Mr. Cyrus Poonawalla, the founder of the Serum Institute of India!

In 2012, when the Serum Institute acquired Bilthoven Biologicals, the two companies were thus already bonded by a forty-year old common history. Furthermore, the product portfolios of the two organizations were particularly complementary, as Bilthoven Biologicals is particularly focused on the polio vaccine, which was the only vaccine category missing in the Serum Institute's product offering. The Serum Institute currently produces around one billion vaccines annually, while Bilthoven's production accounts for around 25 million vaccines each year.

The Serum Institute has made substantial investments for the acquisition and expansion of Bilthoven Biologicals, promising 70-80 million euros at the acquisition in 2012. What impact have these investments had in strengthening Bilthoven Biologicals?

At the time the Serum Institute acquired Bilthoven Biologicals, the company was a structurally loss-making organization. As the acquisition agreement ruled out any potential firing, structural investments were absolutely required to turn the situation around and make Bilthoven profitable.

Nevertheless, Bilthoven Biologicals is a very lucky company, as we produce two semi-exclusive products: the inactivated polio vaccine, for which the Education Program of the WHO, which is our unique buyer, already creates such a demand that we still lay behind their growth expectations! For this vaccine, the whole production is thus sold beforehand. For inactivated polio, we are moreover among the only three or four producers in the world, with other notable manufacturers being GSK and Sanofi-Pasteur. Nevertheless, the production capacity of all the manufacturers combined together still doesn't meet the quantity requirements of the WHO.

Furthermore, the situation is really similar for our second product, the Bacillus Calmette-Guérin (BCG) vaccine for bladder cancer treatment, for which we also cannot meet our market requirements in terms of quantity. All our products are immediately sold to a Hamburg-based company called Medac, which is a treatment-specialized company.

We indeed really needed the investments that would render us profitable, moving from a BCG production of 200 000 units to a target of one million by 2018, and from 15 million to 100 million

polio doses by 2018. These investments have already paid off; as of 2015 Bilthoven Biologicals is now a profitable company! Finally, regarding other structural investment, we realized the purchase of our manufacturing facility's site in 2014, which could not be completed at the time of acquisition. The National Institute of Health is set to completely leave the Bilthoven site by 2018, and we thus decided to take this opportunity to become the full owner of the whole site.

During its phase as the NVI, this Dutch facility provided some 25 countries with over 20 million vaccines. What is the current geographical breakdown of your clients, and how is this evolving?

The BCG product is primarily sold to Europe and the Middle-East, while our polio product is distributed through the UNICEF organization to all around the world. We are supplying around 50 countries, but our entire production is in the hands of only two or three buyers, which will take charge of our production from Schiphol airport, in Amsterdam, and then ensure it is rightfully distributed.

Furthermore, the inactivated polio vaccine can only be produced in certain areas that fall within really strict conditions: 95% of the local population should be vaccinated, the manufacturing facility has to comply with a cutting-edge waste management program and facilities with adequate biosafety levels. These requirements explain why production is mainly focused in Western Europe and in Canada, and also why it hasn't been moved to India, within the Serum Institute's walls.

It is estimated that worldwide more than 30% of the current vaccines are produced based on technology from Bilthoven. Given the importance of Bilthoven Biologicals' contribution to the field so far, in which partnerships are you currently engaged with other stakeholders?

Obviously, our collaborative culture started when the Dutch government decided in the seventies to open our manufacturing facility's gates to anybody interested in our material or technology, in order to ensure children from all around the world could access the best vaccines. As a consequence, most of the child vaccines produced in the world are based on a technology or on materials that were originally used or invented by Bilthoven, including the vaccines of GSK and Sanofi-Pasteur! Furthermore, for the inactivated polio vaccine, 95% of all polio products manufactured in the world follow a production technology that was primarily elaborated in Bilthoven.

Furthermore, our partnerships go far beyond the manufacturing side. The Dutch Vaccine Institute was initially a research-based organization, while Bilthoven Biologicals only continues to operate as

a vaccine manufacturer. The former Research and Development branch of the NVI moved into the National Health Institute, before ultimately being split up to become Intravacc, a translational research institute with a not-for-profit mission to develop safe, effective and affordable vaccine concepts in order to find sustainable solutions to improving public health worldwide. Intravacc now carries research projects and animal testing in partnership with Bilthoven Biologicals, which helps us to always remain at the forefront of the field in terms of innovation and technology.

Looking to the future, what is your vision for Bilthoven Biologicals?

I foresee an important increase of Bilthoven Biologicals' activity on two different sides: vaccine production of course, while also adopting a closer focus on R&D-rooted activities. Finally, considering that we are now part of the Serum Institute, we want to enlarge our product portfolio by producing some of their products that are mainly targeting Western European markets. Our goal is to provide immunisation for every child in the world, and we want to contribute to this objective thanks to safe and high-quality production.

You have been working for Bilthoven Biologicals since 2003, what explains this loyalty to the organization?

I have spent all my active life in the immunology and vaccinology fields, in both veterinarian and human spheres. It is extremely rewarding to work in such a discipline that basically allows you to consider that, in your daily routine, you contribute to saving lives everywhere in the world. Finally, at a local level, Bilthoven Biologicals, and its 300 employees is now creating employment opportunities in the area, although the manufacturing facility was initially supposed to be divested, and this local impact is also extremely rewarding at a personal level.

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