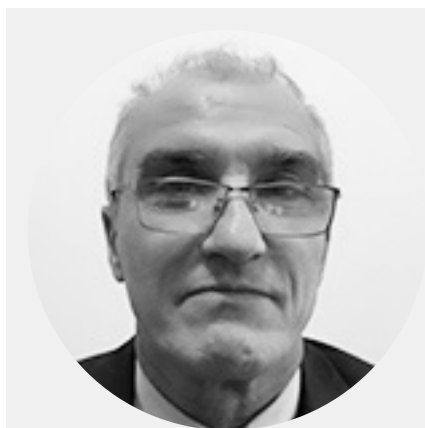


Interview: Sasho Ganov - General Manager, BB-NCIPD Ltd. (BulBio), Bulgaria



"One of my main priorities as general manager of BulBio is to develop the production capabilities of our BCG vaccine since there is a huge and unsatisfied global need in this area."

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Sasho Ganov, general manager at BB-NCIPD (BulBio), explains the role of the company in the national health system as the only state-owned enterprise in Bulgaria as well as shares his ambitions moving forward in support with its recently built laboratory/manufacturing site.

Could you please introduce to our international audience the history as well as the main responsibilities of BulBio?

BulBio is the only State-Owned Enterprise (SOE) in Bulgaria and its roots started more than 130 years ago. Nonetheless, as a trade company, it was legally established back in 2000 since before that year the company was in the same organization with the National Institute of Infectious and Parasite Diseases. Currently, BulBio is more in charge of the manufacturing capabilities while the National Institute of Infectious and Parasite Diseases manages the scientific development of existing and new drugs.

The company offers a broad array of solutions such as vaccines, immunostimulators, human blood products, allergens, and diagnostic preparations to target different therapeutic areas like diphtheria, tetanus, among others. However, its unique positioning is within the vaccines' arena with its BCG vaccine, which is recognized as a golden standard globally and it targets tuberculosis. Indeed, there are only four players in the globe that produce this vaccine being BulBio one of them.

Looking ahead, we are closely working with our scientific team in order to continue expanding our portfolio in other areas such as multi vaccines and immunoprofilaxi medicines.

As the only SOE in Bulgaria, what is the importance of the company within the national pharmaceutical context?

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BulBio participates in all the tenders organized by the Bulgarian Ministry of Health but also by private hospitals providing high quality and affordable medicines, which ultimately enhances the Bulgarian patients' access to life saving drugs.

Expanding on BulBio's role, Bulgaria has a National Health Management Program for 2020 in place that is being led by the Ministry of Health and, obviously, BulBio plays an active role within it as the only SOE in the country. Indeed, I am proud to confirm that BulBio is considered as one of the main structures within the national health security system and, in this sense, our vaccines cover 100 percent of the national immunization calendar.

Before 2000, there were others SOEs in Bulgaria, why is BulBio the only one that remained?

There are two main reasons: assets and national health strategy. Firstly, the Bulgarian Ministry of Health owns all patents and rights of the drugs that are manufactured and commercialized by BulBio – which some of them such as the BCG vaccine have historic legacy of more than 130 years in the market. Secondly, as aforementioned, BulBio is a cornerstone within the national immunization calendar, which is a duty of the government and having a SOE in this frond gives full control on the vaccines' manufacturing and ensures the successful implementation of such national health program.

BulBio is taking steps towards internationalization and external markets already represent 40 percent of the company's sales. Can you talk about the next steps for the company's internationalization?

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We are committed to serve the national needs but, in parallel, we already enjoy strong presence in international markets exporting to more than 90 countries. We are really proud about the international recognition of our products and, in this sense, our medicines have several certificates based on international audits from global institutions such as the World Health Organization (WHO)

as well as we comply with the highest standards of the Good Manufacturing Practices (GMP).

Regarding our international strategy, our objective is to maintain our presence in the existing markets while identifying new ones in which our solutions can add value. Our internationalization strategy is based on two different directions. On one side, we are looking to enter with our current portfolio to new markets in Europe, Africa and Asia – the latter especially in former Soviet Union countries such as Kazakhstan in which our company and solutions are already well known. And, on the other side, we are presently developing a partnership with a South Korean company in which we share know-how as well as manufacturing capabilities to develop multi vaccines as well as market them in Europe and Asia – our timeline in this project is to be already marketing this type of vaccines by 2020.

BulBio has agreements with the WHO and UNICEF to distribute vaccines to developing countries. What are the results obtained through this agreement and what are your ambitions moving forward?

Thanks to these agreements we have a quite unique and well-reputed commercial footprint in developing markets such as Africa. Indeed, these partnerships have given solid stability as well as sustainability to our business since, through them, we have had the chance to participate in many international tenders that have ensured the sale of our production. Additionally, based on that global visibility, we are able to identify what are the trends in a global level and position BulBio at the forefront of any healthcare direction such as legal quality requirements, technology introductions, and medical needs. Furthermore, from the business development standpoint, there are several countries that accept the WHO certification as a market approval giving us a fast track and more affordable go to market process to these countries.

Are any investments planned in the future to support your ambitions in the country and globally?

One of my main priorities as general manager of BulBio is to develop the production capabilities of our BCG vaccine since there is a huge and unsatisfied global need in this area. Hence, we have recently built up a new laboratory with top notch manufacturing capabilities that will increase nearly three times more our current production of BCG vaccine from 1.8 million units up to six million units per year. The new laboratory is currently under the process of receiving the certification of the Bulgarian Drug Agency (BDA) and we expect to have this laboratory full in place by mid-2018. Furthermore, I want to highlight that this investment has been fully financed by our own operations with no need of either public or private funds.

Last June 2017, you had a meeting with President Rumen Radev to discuss about the challenges and opportunities for the development of BulBio. Can you share some insights about this meeting?

It is important to mention that, by our constitution, the president is responsible of the national security and health is within this subject. Having said that, this meeting was a great initiative from our president to better understand what BulBio's manufactures as well as the company's vision for the future and how the president can help BulBio to accomplish its goals.

This meeting was really important for us since our president is really well internationally connected and he could act as a bridge between our capabilities and those countries that need our solutions. Indeed, he commented that the global recognition of BulBio is a great branding for the country being one of the Bulgarian international flagships. Regarding our ambitions, the next steps resulted from that meeting are not still defined but we expect outcomes once our new manufacturing site is fully in place.

What are your main objectives that you would like to accomplish in the upcoming years?

The main priority on my agenda is to extend our manufacturing capabilities for our medicines in general and BCG vaccine in particular in which, as said, there is a huge unmet need – the timeline in this front is mid-2018. Secondly, one of my main objectives is the successful ongoing of our joint venture with the South Korean company to develop our multi vaccine business in terms of capabilities and market outreach, which is expected to be fully run by 2020. Finally, together with our scientific department in the National Institute of Infectious and Parasite Diseases, I want to develop innovative medicines in new fields different from vaccines such as immunoprofilaxi.

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