

Ece Kaşıkçı - General Manager, Bristol-Myers Squibb Turkey



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Ece Kaşıkçı, General Manager, Bristol-Myers Squibb (BMS) Turkey, outlines how BMS' groundbreaking immuno-oncology therapy has proudly become the first product of its kind to be registered and reimbursed in the country. She also highlights the company's collaborative approach to reach this remarkable milestone. Ece also discusses her vision for BMS Turkey, and the company's commitment to Turkey, to the patients, and its alignment with the objectives of the government's Vision 2023.

You have been driving the Turkish affiliate of BMS for the past 25 months. What have been some of the key achievements reached during this time?

Bristol-Myers Squibb has a long history in the pharmaceutical industry, established over 130 years ago. Our mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. Looking at the Turkish affiliate, BMS Turkey has been operating in Turkey since 1995 (firstly as Squibb), we have a history in Turkey, which reflects its importance to the global organization.

We started as a company with an extended product portfolio, however, throughout the years, we have been transforming into a pure biopharmaceutical company at a global level, and this new approach began to trickle down to a local level in 2014. This overhaul was focused on establishing

the company as an innovation-orientated organization, most prominently in the field of oncology, so the product portfolio in the country has begun to change accordingly.

Primarily, we were associated with mainly OTC products, but through a new direction, we channeled our energy into the unmet, medical needs of the patients in five niche therapeutic areas: immunology, virology, rheumatology, hematology, and oncology. This transformation was set in stone with the recent launch in Turkey of the groundbreaking immuno-oncology (I-O) therapies for cancer, which is the first product of its kind to be registered *and* reimbursed in the country, so we are extremely proud of this. Although the journey was not easy, we leverage our success on a lot of collaboration with health officials and the government, paving the way for the country's patients to acquire access to innovative therapies.

What has been your experience in getting the first ever immuno-oncology product registered and reimbursed in Turkey?

Our immuno-oncology drug is a multiple-indication product which requires a different regulatory and access approach for the Turkish environment. As a result, navigating the reimbursement system has not been easy for this product, because of the multiple indications and combinations it has already received in the US and European markets. In Turkey, when you file the product for registration under one indication first, the government cannot predict when the next registration will occur for another indication, so negotiations are complex and exceptionally different from registering a one-indication product. We work closely with government bodies and fully support the system to ensure the smoothest possible process to enable patients to access innovative therapies. In April 2017 two indications were approved for our I-O product and towards the end of March 2018, reimbursement approval for three new indications were received.

Furthermore, I want to highlight that BMS's I-O therapy used to be accessible - for cancer indication and reimbursed for RCC, melanoma and Hodgkin's lymphoma - through the Turkish Pharmaceutical Association's access program. This allows some products to be directly imported from abroad (at the price of the country of origin), reimbursed by the SGK and accessible to Turkish patients without being locally registered. However, it is important to ensure we work with government bodies to register products directly to enable the smoothest path to access for patients and better efficiencies. Our approach has now meant that the product is fully registered and reimbursed in these indications in Turkey to make it available in pharmacies.

This decision clearly shows that BMS is truly committed to the country's health system.

Exactly. It is not always easy to make such decisions, but some products have been available through the Turkish Pharma Association Scheme for the last ten years. This approach however creates a huge burden for the SGK, as products are directly imported from markets where there are complexities for imports, which takes time and prices may be higher than in Turkey. It is our responsibility to do all we can to work with the government to ensure we have a smoother and more efficient path to access for patients.

We have met many different innovative companies in Turkey, who commented on how hard it is to get registration and reimbursement for immuno-oncology products - and even more for multiple indications. What differentiates BMS from these other companies and your strategy to achieve this?

The main action is to engage and collaborate closely with the authorities, listen to and understand their perspective, and ensure we do all we can to demonstrate the medical value of the product through real-world data, the experiences of the physicians with the product and most importantly the patients experience and benefit too. In Turkey, we ran a compassionate use program with 1101 named patients for I-O, a record-breaking number and one of the largest I had ever heard of before registration. Of those more than 120 patients are still using this therapy and reaping the benefits of it three years after the beginning of the program. Seeing the efficacy and the value of IO really helped us during discussions with the authorities.

This engagement and collaboration with the authorities has played an important role for BMS Turkey to receive approvals for two new indications.

Acknowledging we are a commercial company; our main objective is to service the patients and address unmet medical needs. In this context, stakeholder engagement is absolutely crucial. BMS endeavors in collaborating with the authorities to create win-win relationships throughout the pharmaceutical community, ensuring ground-breaking therapies come to Turkey faster.

Through improvements in technology, patients have significant access to the internet and the products we create at a global level, so they have a better understanding of what benefits IO can bring to them. In this context, even they are lobbying for the authorities to access these products because they feel that they will be beneficial to survival and their quality of life! Moreover, Turkish oncologists and specialists are very supportive of our actions; as a result of our programs and

clinical trials, they see firsthand the benefits. Having support of both patients and the medical community really help to convince the regulatory authorities that we are focusing on the unmet medical needs of the population, whilst striving to meet their budget expectations.

How easy is it to access the appropriate data in Turkey to support your reimbursement case?

The national payer SGK has a huge supply of data, but, it is confidential. However, with the help of associations and market research that we conduct internally, we can make approximations. Our data thus supports our health economic studies when communicating with the authorities, and we can validate the arguments of our negotiations, which is the difficult aspect of the process. With these studies, we can strengthen the medical value and the long-term benefits of our offer, focusing on finalizing its registration and approval.

You have honed a long-standing experience at finance positions, including as finance director at BMS Turkey, before taking over the affiliate. How advantageous has this extensive experience been when it came to negotiate with the payers?

When communicating with the national payer, there is not only a medical value to convey but also a financial one, which has to be convincing, enticing but ultimately economical. Indeed, it is of incredible help to speak the finance language, because normally the authorities are used to dealing with those who have a medical or commercial background and find it difficult to compromise on the value for the patient.

Do you believe Turkey's current reimbursement system is sustainable given the looming epidemiological shift that is set to transform the country in the coming decade?

On one hand, the country has an extensive universal healthcare coverage, and once a product is reimbursed it remains so, which is unique, making life easier for both the patients and the companies. On the other hand, this healthcare model creates a lot of challenges, because demand increases as the population ages. Thus, the coverage is not sustainable, and this is one of the main topics on the agenda of the Association of Research-Based Pharmaceutical Companies (AiFD), along with the health authorities, due to the long-term budget increases that will begin creeping

into double-digit figures soon.

To combat this, Turkey can take inspiration from different practices applied in Europe; for example, implementing alternative reimbursement schemes, which Turkey has tried to introduce since the end of 2015 to manage the budget. In addition, technology assessments are a crucial part of the decision-making process in reimbursement systems in Europe and the US, and this aspect could also be enhanced in Turkey. Finally, Value Frameworks developed for oncology products are getting more importance for both payer and decision makers in Europe and the US. I believe that they will be on the agenda in Turkey soon. Furthermore, we see that many OTC products in the country are still reimbursed, which creates significant financial burden and could be combatted.

How has BMS set in motion their Vision 2023 and where does the company stand right now?

The government announced its future vision in 2015, taking a lot of actions in the healthcare sector to set a precedent for the companies. Looking at Turkey now, it is the sixth biggest pharmaceutical market in Europe and positioned seventeenth worldwide, with a target position of fourteenth expected by 2023. For BMS, Turkey will be one of the top three countries in the Central & Eastern Europe & Middle East region.

BMS has also gone through a transformation, identifying Turkey as an important country for the company, especially when considering size and the aging population, increased access to health care services and therefore increased medical demand. We have adapted well to Turkey's vision, trying to engage in the localization policies and produce in the country, and we have a good deal with the government in this regard with one of our products set to remain available in the market for the next three years. Ensuring a win-win situation with the government does not always mean manufacturing here, and there are always alternative solutions that can benefit both parties.

Moving forward, we will always try to be supportive by bringing products to the country as soon as possible. Looking at the organization, we are small in comparison to most pharmaceutical companies in the country, but we endeavor to be as productive as possible with the aim of working together with the government, doctors and the patients. Recently we have introduced different campaigns to promote awareness of immuno-oncology and lung cancer, in addition to working with respective speciality associations to create roadmaps in virology and hematology. Furthermore, we try to involve employees in these campaigns, with most of our employees running sponsored marathons to help promote our mission, which ultimately serves the patient.

Of these activities, April 2018 unveiled the biggest awareness campaign of them all during cancer week and will span until 2019, looking at disease awareness and trying to appeal to as many people as possible through different mediums, including a digital aspect which has already reached an audience of 1.5 million. During November, which is Lung Cancer Awareness Month, we will start another campaign in cooperation with specialty associations and patient advocacy groups, looking at how we can prevent this disease in the country, which is one of the top cancer types in our country because of the excessive smoking of the population.

Our clinical trials will also continue. As of today, there are 11 active studies at 40 centers with 140 patients. We intend to increase the number of studies to 16 this year and in 2019 our goal is to add 14 new studies.

As an outward-looking organization, we collaborate with the key stakeholders to implement critical changes and increase awareness, but companies need to change their mindset when dealing with different countries, and I feel this affiliate has adapted well to the local atmosphere, becoming an inspiration for other pharmaceutical giants in the market.

To conclude, what would be your final message to our audience of 150,000 readers?

At BMS, we are achieving our best in our therapeutic areas, pushing for new approvals for different indications to increase access to the Turkish patients as soon as possible. The country is very open to new opportunities and investments and has undergone a lot of developments over the past five years, especially in the healthcare sector.

Looking forward, Turkey will be an opportunistic market and will continue to grow, despite the challenges it currently faces, because of the economic growth and well-educated young population that will remain as an asset for the country, leveraging its potential to entrench its position as one of the most strategic markets for the global pharmaceutical and healthcare sectors.

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