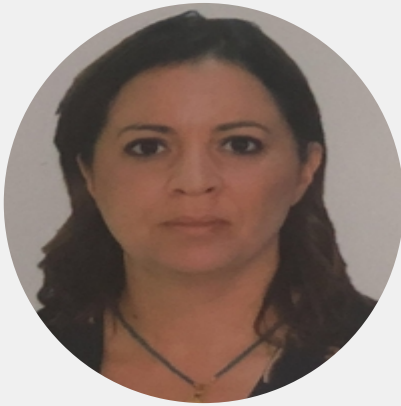


Radwa Terbeche - General Manager, Amgen Algeria



24.09.2018

Tags: [Algeria](#), [Amgen](#), [Biosimilars](#), [Clinical Trials](#), [R&D](#)

Radwa Terbeche, general manager of Amgen in Algeria discusses the potential for biosimilars in Algeria and the company's role in developing a local clinical research infrastructure.

What has been your journey to becoming country manager of Amgen Algeria?

By education I am a pharmacist specialized in industry. After graduating, I joined Aventis, which later became Sanofi. I stayed within the company for some 16 years, holding a range of functions encompassing commercial, regulatory, marketing and sales. During my final two years I oversaw the Genzyme business for the Maghreb region after Sanofi had acquired the rare disease business unit.

Following this, I was approached by Amgen and asked to manage their operations in the Maghreb region. I was excited to take up this position because of the evolution of the industry. In the last two to three years, it has become clear that biotechnology will be critical in defining the future of the Algerian healthcare system. Only by embracing this branch of medical science will the country's public health system be able to provide hope to patients with previously untreatable illnesses. Amgen is very much a pioneer in this field. The opportunity to play a proactive part in bringing these cutting-edge therapies to Algeria was thus the primary reason I decided to join the company.

How has the affiliate evolved over time?

When I originally joined Amgen back in 2014, we operated through a third party and employed only 2-3 people. We had just begun promoting the company brand and its products. Medical practitioners were nonetheless highly interested by what we had to offer. The most exciting aspect of the job is actually to be the intermediary between this iconic company, advanced science, and the people in Algeria who don't yet have access to the latest generation of biologics.

We start by educating people about our products and the impact they could potentially have, both on the patients and on the healthcare system. Then, work is conducted to ensure best possible availability within the market place. Of course, the real satisfaction derives from reaching the point where you realise the patient will be able to access these treatments, and have their lives transformed for the better.

We have come a long way within a relatively short space of time. In 2011, the strategic decision was taken to support our operations by opening up a representative office in Algeria to act as the local legal representative. Looking back, having that extra visibility and support structure that the representative office gave us was useful in enabling us to perfect our product launch capabilities. 4 years later, we are now proud to have as many as 10 products registered on the local market.

Globally, Amgen's portfolio spans onco-haematology, inflammation, nephrology, bone health. How is this reflected at the local level?

The primary focus in Algeria is very much on onco-haematology. We simultaneously maintain a small presence in nephrology. Out of the 8 products registered in onco-haematology, the stand out therapy is, without question, Vectibix® (panitumumab) for the treatment of Metastatic Colorectal Cancer. We are also doing a good business supplying Xgeva® (denosumab) injections for supportive care, essentially to treat bone metastases from solid tumours. I am also happy to announce that we received registration for Kyprolis® (carfilzomib) which is a treatment option for people who have already received 1 or more previous treatments for relapsed multiple myeloma. This represents a truly breakthrough innovation for this market. The current therapeutic offering, by contrast, is very limited so this new development will have a big impact on real patient lives.

How would you describe the market structure for onco-haematology in Algeria?

The local market can be broken down into the retail and hospital segments. The former constitutes 85 percent market share and the latter only 15 percent. Amgen's products, however, are exclusively present in the hospital segment. Based on a tender market, there is a clear process to follow once you secure product registration.

Amgen has distinguished itself internationally by its strong biosimilars portfolio. What are the prospects for, one day, introducing these therapies to the Algerian market?

We have already entered into discussions with the health authorities, including the Ministry of Health and the PCH with a view to preparing the ground for the eventual arrival of biosimilars. I think there is already understanding on all sides about how biosimilars could greatly reduce public healthcare costs and free up money that could then be channelled towards financing future innovation. There is a natural sequence, however, that we need to pass through and this will take time. Biosimilars really require their own bespoke registration process given the scientific complexity of the therapies in question.

Within Amgen, Algeria has been selected as one of the priority markets to launch biosimilars, and we will, for sure, be participating in the first wave of biosimilar products launched here. The normal time for registration from submitting the application to receiving permission is 24-36 months, although we are working to optimize these timelines. The beauty of biosimilars is that they offer a more cost-friendly pathway to delivering latest-generation innovative medicine.

How prepared is Algeria to receive biosimilars in terms of regulatory infrastructure?

The major issue is that there is currently no specific legislation for biologic products in Algeria. However, the authorities have been working on that and the legislation is almost ready. We hope this will be published at some point in 2019. In the meantime, they did not block access to biosimilars, instead introducing more stringent legislation for new drug requirements, so there has been a work-around solution and temporary fix prior to the introduction of some kind of bespoke registration pathway specific to biosimilars. The authorities have been transparent about this. As an industry stakeholder, Amgen has participated in consultations with the government on biosimilar regulation, providing international experts to these consultations to offer new perspectives so that we can implement the correct regulation.

Four years ago, there was enthusiasm around the concept of establishing the “vision 2020 biotech hub.” What happened to that initiative and what role can Amgen aspire to play in such an initiative?

Before I joined the company, Amgen was part of the initiative as one of the 6 original signatories. The willingness to collaborate remains. Our role is to better interact with local stakeholders and explain that we can bring more than just manufacturing. We can bring science, education, development of clinical research. The authorities are more aware of this today and are beginning to realise that they need to diversify and benefit from the full expertise of international pharmaceutical companies.

This 2020 vision initiative has itself evolved. It was initially a biotech hub at Sidi Abdallah, but has been remodelled into a more concrete plan, focusing rather on creating a science and education cluster.

Within this cluster there are several projects. One of which is to develop clinical research in Algeria, which we are assisting the Ministry of Health with, so that in the future we can include Algeria in international development studies. The plan was reformed after communication improved between the authorities and the major players. In the past there was a lack of understanding about what innovation is bringing to the market. There were some false ideas about market operations. Now there is a more profound understanding. From our perspective, we have also become more sensitive to the priorities of the government and the healthcare system. We are here to help improve the healthcare system here in Algeria, not just to generate money.

You mentioned clinical research, are you currently performing in-country clinical trials?

Not yet. At this moment in time we are trying to create the enabling environment so that in the future clinical trials would be possible. Before this can become a possibility, multiple hurdles must be overcome: namely in regulation, infrastructure, and in education.

Amgen has been partnering with the government on biomarkers and next generation sequencing of cancers. Tell us more about this initiative.

These programs are still operational. All the projects set up by Amgen in Algeria were part of an agreement with the Ministry of Health to support the national cancer plan, which has been

earmarked as a strategic priority by the authorities. We believe that the programs we have conducted over the last few years have improved the cancer patient management. We equipped the Mustapha Pasha hospital with advanced equipment and training in the domain of biomarkers and next generation sequencing of cancers. This ultimately helps personalise diagnoses, and provides access to targeted therapy, and better prescribing of drugs. Our products are expensive, so we want them to be used properly on the correct patient and the correct diagnoses.

You mentioned that the rep office structure is under threat. Is this a concern for Amgen, and what strategy have you implemented to deal with that?

Our rep office agreement has expired, and we are currently awaiting the renewal.

We understand that at some point changes will be necessary, as the rep office by law is only meant to be a temporary step, providing international companies the opportunity to explore the Algerian market before making a long-term commitment. We have benefited from the rep office for 4 years now.

However, in our discussions with the authorities, we have argued that the rep office structure when applied to the life sciences domain should be regarded more as a scientific office. In other words we would like to see a new kind of structure created outside the existing legislation. Having a presence as a scientific office where employees are invested in the company would be more beneficial to the healthcare system. Unfortunately, this framework does not exist at this moment in time. We are therefore carefully monitoring developments and will adapt accordingly.

How will handing your activities through a third party disrupt your business? Can everything continue business as usual?

Yes. Because we operate in the hospital market, which is an export market with an international tender, there will be no tangible impact on product availability or supply irrespective of whether we are locally embedded or acting through a third party. When we discuss this with our peers, we don't see any threat to our interactions with our peers or with the authorities either, given that we will proceed with a third party. If we were to plan to invest in the retail market, that is where we would be limited in scope. That is the arena where some multinationals might find their business model disrupted.

In 4 years, a lot has changed. There is a new health ministry, new law, new economic environment. What would you surmise are the main trends over this period?

First, the crash in the oil price and the impact on the healthcare system. The Algerian economy relies on oil exports – over 90% of the economy. As the healthcare system is public, a fall in oil rents damages the ability of the government to spend on health. That is why there has been a focus to reduce costs, bringing in generics and biosimilars to the market, while maintaining a philosophy of universal coverage.

Secondly, cancer remains a priority. Despite changes to the laws for other kinds of drugs, cancer was ringfenced and investment levels were maintained. There is a real need for this, and more investment is required for the necessary developments to face the challenges of this disease. How things evolve will be dependent on economic growth and the ability of the government to diversify the economy.

What is the strategic significance of Algeria for Amgen and how much potential is there in the Algerian market relative to other countries of the region?

For the Turkey Middle East and Africa region, Algeria remains one of the top priorities. There is a platform for growth. That is why we are developing the teams and the infrastructure, making our operational structure more sophisticated. What goes with this priority is a willingness from Amgen to invest and make a positive impact on the environment where we operate. We also invest in people. We need people to promote Amgen values and put patients at the centre of our operations. We also need to provide to our global management some predictability in this traditionally volatile market. Therefore, we as an industry are stressing to the authorities that we need to introduce more clarity in current rules. We will comply and work within whatever these are to help the health system to develop.

In 4 years, you quadrupled your number of employees. How do you inspire and motivate your employees to continue to bring value?

It is like building a family. We started with 4 or 5 people who really believed in Amgen values and were committed. From then on, we only hired people when it was essential, and the people added to the team shared the Amgen values.

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