Interview: Tim de Gavre â?? Country Head, Sandoz UK

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Tim de Gavre, country head of Sandoz UK, discusses the role of biosimilars in driving innovation, the threats and opportunities of Brexit to the biosimilars industry, and how Sandoz partners with the NHS.

In addition to your role at Sandoz, you are also one of the founding members of the British Biosimilars Association (BBA). Can you start by giving us the rationale behind setting up the BBA and the role that you think biosimilars can bring in driving innovation?

Before I start with BBA, I would like to go back in time and give a little bit of context. Before I became head of strategy for biosimilars with Sandoz, I lived in New York. I had little interest in moving to Munich from the US to work for Sandoz. It is only when I met the team, felt the passion they had for what we were doing around biosimilars, and saw the quality of people that Sandoz was attracting, that I decided to move to Europe. It was an irresistible opportunity.

When I was starting off at Sandoz, there was an incredible passion about improving access for patients to these products. We were at the forefront in developing these new proteins and complex molecules, in addition to helping define an approval pathway in the US and Europe. We were e trying to figure out how to develop a monoclonal antibody biosimilar with an EMA and FDA that really didnâ??t know how they should approve it. We didnâ??t have the final approval guidelines for these products as we were developing them.

[Featured_in]

There was this passion for biosimilars that I adopted early in my career because itâ??s really an area where you feel like you can do well by doing good. You can improve access for patients to these medicines, help health systems and bring these amazing products to market.

When I came to the UK, I felt like we didnâ??t really have a strong voice for biosimilars. They are not generics, and although the British Generic Manufacturers Association (BGMA) is an excellent organization, it is a different set of companies that do biosimilars and some of them donâ??t do

generics. So, the BBA became a conduit, for the companies to come together around biosimilars. The BBA enables these companies to develop a strong voice around these molecules and have a strong platform to work collaboratively with the Association of the British Pharmaceutical Industry (ABPI) and with NHS England.

The other thing was we were behind. It felt like there was this huge opportunity â?? the NHS needs the savings â?? and for some reason we werenâ??t getting where we needed to be with these products. As a result, BBA became an important to do that.

Tell us about the role that can be played in driving innovation.

I think there are a few areas. First of all, we can deliver substantial savings. Simon Stevens, CEO of NHS, has talked about saving GBP 300 million by 2021. That money can go back into the NHS, back into innovation and into the medicineâ??s budget. We would actually be able to use that money to then fund the next round of innovations.

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But what we have also seen, and there are some very specific examples â?? like in Southampton where they shared the savings from implementing biosimilar Infliximab between the trust and the CCG â?? you are actually able to use those savings to directly impact patient care â?? to invest in more nursing support, more pharmacist support, to do patient reviews, and to make sure that patients are getting the right amount of drug. At the same time, you are also evaluating if these patients will go on a biosimilar.

What do you believe can be the role of a country like the UK in leading the trends in biosimilars?

The National Biosimilars Medicines Programme Board (NBMPB), chaired by Chief Pharmaceutical Officer, Dr Keith Ridge CBE, leads the way in how government and industry can work together to speed up the implementation and the uptake of biosimilars. We had everyone sitting around the table â?? innovators, generics, the MHRA, NICE, people from procurement and NHS England. You have all of the key parties around the table ultimately working towards common goals such as how we educate on the science of biosimilars and what we need to do around procurement and commissioning guidelines.

And as each round of monoclonal antibody has come through, , the actual rate of uptake has increased. Another important feature is that we included patient groups. We had for example the National Rheumatoid Arthritis Society (NRAS) [â??the voiceâ?? of people affected by Rheumatoid Arthritis (RA) across the whole of the UK] at the table, who were actually quite sceptical on biosimilars four years ago when I arrived in the UK, and in the end began to see the benefits.

Youâ??ve talked about how all the different stakeholders have been brought together. How much is this kind of leadership position in biosimilars under threat through Brexit?

Thatâ??s a very good question and I think it is too early to say. It will depend on what the final deal is like.

But what do you see are the potential risks?

The biggest risk concerns regulatory alignment. If we get a deal where we are going to continue to recognize EMA decisions and to stay and adopt their regulations for the foreseeable future, we are fine. If we see regulatory divergence from EMA, there may be a risk for biosimilars. EMA has led the

way on biosimilars with 44 approved, whereas in the US, only 12 have been approved.

The UK has traditionally been the first market within Sandoz globally to launch a biosimilar, followed closely by Germany. The reason for that is we have very little bureaucracy around price, thereâ??s not a lot of language translation work to do, and as a result we get the EMA approval and we are â??out the doorâ?? so to speak. It is rapid access for patients, the health system gets their savings quickly because they are driving uptake, so everybody benefits.

I hear some of our leaders talking about how having all these regulations from Europe are actually hurting business in the UK, but this is a clear example of where European regulations directly benefit patients, benefit the NHS and benefit companies.

Because even with a market like Switzerland, for example, just having an extra layer of bureaucracy there slows down the processâ?¦

It slows down the process and delays how they launch. For some of our biosimilars, they are now close to six to 12 months behind the UK.

Thereâ??s been a lot of noise about the Life Sciences Industrial Strategy (LSIS). If Britain is to become a real leader in promoting biosimilars, shouldnâ??t the country also be manufacturing biosimilars?

In terms of the LSIS, I think we agree that Britain should continue to invest in the life sciences, that there should continue to be substantial investment in clinical trials, and this can help the UK continue to be a priority market. In terms of manufacturing, that really lies with a different area within Sandoz.

How would you describe the state-of-play of Sandozâ??s biosimilar business right now in the UK?

We are taking off. We have launched two biosimilars since June of last year. We have a whole series of additional launches coming in 2018 and we are growing rapidly as an organization; it is an area of focus for us.

Moving broader how would you describe the strategic significance of the British affiliate vis-a-vis the rest of Sandozâ??s European operations?

Sandoz is 100% committed to the UK; however, the UK is a tough market, so sustainability remains a constant question. This is true of biosimilars and generics. The UK has a very effective procurement system. When you actually look at it we have the highest penetration of generics in Europe â?? 86 percent.

Highest penetration, lowest prices, lots of competition. The question is though, will the government, if Life Sciences are a focus area for Britain, create an environment for companies where they are going to want to compete? And having a sustainable market where there are easy regulations. Currently, the UK is easy to access because itâ??s part of the EU. But this is a crunch moment.

I think the government should recognize more the value that we, as an industry, bring. The generics industry brings an enormous amount of value to the UK economy, to patients, to the NHS, and to everything around these products. Sandoz alone saves the NHS Â£1billion / year. However, I think government looks at our prices and says they are still too high. What I would love to see is that government sees pharma and generics as the value they bring, rather than a target where they can cut costs.

Now, one of the big issues that theyâ??ve had over the last year is around shortages. 2017 was difficult for the NHS in generics shortages. I think some of the reasons were quality issues and some were companies withdrawing from the market. If you drive the prices down so low on these products, then companies pull back, or you end up with a sole supplier. Sometimes the NHS is focused too much on short term costs rather than thinking about creating a sustainable environment that is a really productive place long term.

You have mentioned that there is aggressive cost-cutting and then there is also fierce competition. What is Sandozâ??s strategy for navigating this challenging environment?

I think we have to think very hard about our portfolio, getting access to launches and going into new areas like biosimilars. If you just focus on generics in Europe, then itâ??s challenging. You really need a mixed portfolio which is what weâ??ve done at Sandoz â?? we have some generics, branded generics and biosimilars, and thatâ??s our edge.

Youâ??ve been in the position for 10 months now. What would you say are your key priorities at the moment, and what do you see as the main challenges?

The main priorities are making sure that the business is working effectively, that we are delivering on our commitments and growing the business. I think we also have to make sure we have the right portfolio for the future in the UK. Itâ??s also about driving innovation in how we work more effectively with our customers. How do we become indispensable to our customers and not just another supplier?

Also, people are without a doubt a key part of any business priority. If we donâ??t have great people, our business will not operate effectively. Itâ??s about bringing out that passion in our people because with it you get a different level of performance than if itâ??s just people clocking in and out. We also have to continue to be engaged in the political discourse and continue to work effectively with the NHS and government.

With regards to financial viability and sustainable public health, what is the role of Sandoz as a partner to the NHS in helping it take costs out of the system?

I think we at Sandoz are duty-bound to help the NHS and to think about new ways we can work together. There was an example in 2016 where the Cancer Vanguard did something called The Pharma Challenge, which invited 40 pharma companies to come up with proposals on how they could work with the NHS. We were one of four that they actually decided to go forward with. The Pharma Challenge became about developing a process for how you actually implement a biosimilar, where we literally laid out a timeline which has all the key steps needed at certain points in launching a biosimilar. As a business, we did the right thing for the NHS by creating this system, in enabling fast penetration. Sometimes itâ??s not always about our own company interests, itâ??s about what is right for the NHS.

A few final words on Sandoz UK that you would like to send to our audience around the world?

I was talking to our regional Head of Communications the other day and he was pushing me. He said, â??What is inspirational for you about working at Sandoz?â?• And for me what gets me out of bed in the morning is I know that we are doing well by doing good. We are saving the NHS money. We are getting patients access to medicines. We are working collaboratively with the NHS. For me, itâ??s truly an inspirational place to work because youâ??ve got all the pieces coming together.

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