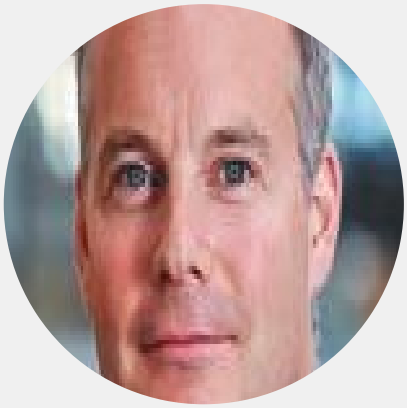
Kieran Leahy – General Manager, Takeda Czech Republic & Slovakia



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Kieran Leahy, general manager of Takeda in the Czech Republic and Slovakia, recounts how he has led the transformation of Takeda into a specialty care organization at the local level, and his priorities to successfully integrate Shire along this journey. Leahy also breaks down the market access challenges in the Czech Republic, especially for orphan drugs, and how the company navigates them, but is optimistic that new legislation will provide smoother access, whilst sharing his understanding of the Takeda-ism philosophy, and his priorities to continue driving Takeda's transformation.

Kieran, you became GM of Takeda in the Czech Republic and Slovakia in May of last year, a month after the company announced its acquisition of Shire which closed in January 2019. What were your priorities to make the integration a success at the local level?

Between the announcement in April last year and January, we were under strict guidance to continue operating as two separate entities. Before the acquisition, Takeda was going through a rapid transformation from a primary care to a specialty care organization focusing on rare diseases. During my first year as General Manager in the Czech Republic and Slovakia, my priority was to lead this transformation within Takeda itself. Then, in January, the acquisition was approved, and

the integration at the local level started in earnest. At that point, we received a lot of information regarding the Shire organization which we did not have previously. Moreover, I was announced as the General Manager of the new entity in the Czech Republic and Slovakia. The priority at that point in time was to gather information as quickly as possible about the organization, the portfolio, the finances, and most importantly for me, about the individuals.

From my experience overseeing the acquisition of Nycomed in Ireland, the actual physical integration is not overly complicated: once systems are in place, you can quickly run as one organization. However, it is the cultural integration which takes time, sometimes several years. Finding a catalyst to accelerate the cultural integration so that people feel like one entity is crucial.

The first thing we did was to set up a series of two-day offsite meetings where small groups made up from both legacy Shire and legacy Takeda were asked to share their concerns, but also their aspirations of what the new organization could look like. We tried to get a feel for the culture of both Takeda and Shire to understand the differences, without forgetting the similarities. The goal was to pull the strands of the two organizations together.

Luckily, the cultures of both entities, whilst different, shared a central pillar around which we could build the new organization: patient-centricity. As a company focused on rare diseases, Shire lived and breathed patient-centricity. For Takeda, it has always been a key pillar of the organization during its 238-year history. As we move into specialty care, we are further reinforcing this patient-centric mindset.

Moreover, there was practically no overlap between our portfolios, thus we could not succeed without their expertise. We thus communicated early-on to our Shire colleagues that we needed them as much as they needed us and reassured them that this was not a hostile takeover. We all work and collaborate under one roof, both those from Czech Republic and Slovakia. While the office feels a little bit cramped, this move was vital to driving the cultural integration.

On the 1st of January 2020, we officially became a single legal entity. The Czech Republic and Slovakia are part of the Wave One Legal Entity Optimization, so will be among the first countries to actually become one entity. The situation is more complicated in Slovakia where Baxalta and Shire were never legally joined, and still operate as two entities. As a result, there we are bringing three companies together. After January, once we are finally operating under a single legal entity, the integration will further accelerate.

How have you driven Takeda’s transformation into a specialty care company?

To put things into perspective, this time last year, about 85 percent of our revenue derived from primary care. Today, thanks to both the internal transformation and the acquisition, about 75 percent comes from specialty care. By next year, we expect to completely reverse the revenue structure, with specialty care representing 85 percent of sales. Within specialty care, 85 percent of sales will come from orphan drugs.

In order to make the shift, we had to make difficult choices. While we previously had quite an extensive primary care field force visiting general practitioners (GPs), we made a conscious decision to change our structure and invest in the right capabilities in order to focus on two key strategic areas in specialty care: Gastrointestinal (GI), specifically ulcerative colitis and Crohn’s disease, and Oncology. Many associates who were previously involved in the established business transitioned to other roles within specialty care. However, we also had to find people with different skillsets. Last year, we recruited 28 people with the skills and experience required to succeed in specialty care: market access, patient advocacy, governmental affairs, public policy, and real-world evidence generation. All this was done prior to the acquisition, so when it came time to integrate Shire, we already had the right structure in place.

Aside from the established business, we now have five main revenue streams and focus areas: Immunology, Hematology, Oncology, Gastroenterology, and Rare Diseases. Each business area is quite comparable in terms of size and new products coming to the market. None are underperforming versus the previous year. On the contrary, they are all exceeding growth and revenue expectations.

This success has a lot to do with the fact that we tried to insulate the commercial team, specifically the field force, from the disruption brought about by the acquisition. We made sure that the customer-facing roles could keep on doing their job undisturbed. On the other side of the coin, the burden of the integration fell heavily on the other individuals in the organization, which was a tactical decision to allow us to keep growing while integrating.

As a result, we do not have all our eggs in one basket. We have five baskets, each of about equal size and opportunities. In addition, there are synergies between them in terms of collaboration and best practices. They do not work in silos. We have set-up Integrated Franchise Teams so that market access, medical, commercial, business operations and patient advocacy operate across all business units. What you end up with are five business units focused on marketing and sales, while other functions run transversal across the company.

When we met with Jakub Dvořáček, CEO of the Association of Innovative Pharmaceutical Industry (AIFP), he explained the difficult and lengthy process for innovative pharmaceuticals to receive reimbursement, as well as high price pressures applied by regulatory authorities and payers. Now that Takeda has transformed into a specialty care organization, how do you navigate this tough regulatory environment?

While the consensus seems to be that market access in the Czech Republic is particularly difficult, having worked in Ireland, the UK and Canada, I can say that every market presents its own set of challenges. In the Czech Republic, the main challenge is getting permanent reimbursement. It is possible for innovative medicines to receive reimbursement and reach patients, but not always on a permanent basis.

However, the country's problem runs deeper than that. Market access in the Czech Republic, like in most European markets, is based on Health Technology Assessment (HTA) which mainly considers cost-effectiveness. The HTA process was not built for the portfolios we have now. It was built to assess treatments for thousands of patients that cost tens of euros, such as cardiovascular or diabetes medicines. We now have treatments for tens of patients that cost thousands of euros.

This being said, market access in the Czech Republic is, in my opinion, quite good. The difference with Western markets is that processes are a bit less structured and transparent, while in the UK for instance there are clear procedures and deadlines which are generally met. However, it is understandable as the Czech Republic, like other countries, is struggling to adapt to this paradigm shift of high-priced innovative medicines which are only targeted at small patient groups but can make a profound impact on their lives.

During these last two years, Takeda locally has been extremely successful in gaining market access for our innovative medicines. We now have more than 20 indications reimbursed in both the Czech Republic and Slovakia. Moreover, we registered 11 rare disease drugs in the last few years. However, very few of them have received permanent reimbursement. Almost all of them receive individual reimbursement through paragraph 16, which is very labour-intensive, not only for us but I assume also for the payers. We invest a lot of effort and time in ensuring patients get access to our medicines by navigating them through the bureaucratic maze. Even so, reimbursement could be rejected based on hospital budgets for instance. While complicated, we have been very successful at it. Fortunately, authorities are now preparing a legislation to put in place a structure for granting market access and reimbursement to orphan drugs. I think the Czech Republic is trying

hard to ensure these innovative medicines do come to the market and thus the patients.

The legislation you are referring to is the amendment to the Act on Public Health Insurance which aims to create a regular pathway for orphan drugs to be assessed, priced and reimbursed. What do you hope this new legislation will bring for your portfolio?

As many of our existing medicines are orphan drugs, and almost every single medicine we will launch is likely to have orphan status, we are extremely interested in this development. Our goals are aligned with those of the Minister of Health, which is for patients to have access to innovative life-changing medicines as quickly as possible in an affordable way.

Through this amendment, authorities want to ensure that the approved medicines are true orphan drugs which are going to make a life-changing impact on patients. The second element is the affordability. Authorities want to have visibility on the budget impact of these drugs by considering their effect on disability costs and tax revenue. I am fully supportive of this approach. I think that medicines should be judged based on their impact, not only on the survival and quality of life of patients but also on society, especially since many of these treatments are meant for young patients. For instance, young patients with Hodgkin's lymphoma treated with our therapy can live an almost normal life, and thus contribute to society by working and paying taxes, which fund the entire healthcare system. I think that this kind of dual view is essential: "this is the impact; this is the price". By following this approach, we can build truly mutually beneficial partnerships.

Through this amendment, the patient voice will be part of the decision-making process on orphan drugs through the Patients' Council, which is relatively new in Europe. How is Takeda working to put the patients' voice on centre stage?

This is a development we have seen in the UK as well where NICE actively looks to include the voice of the patient when making decisions, which I strongly encourage.

As part of the transformation of Takeda, we have been focusing on patient advocacy as well as patient support and services. Patient Advocacy is about making sure that the patients' engagement grows in terms of policy shaping, raising awareness and executing their statutory rights. It is also about empowerment including health literacy, involvement in decision-making and promoting health. Patient support and services is about following-up on our patients once they are put on the

treatment in order to achieve the best possible clinical outcome. This is a paradigm shift in the pharmaceutical industry. Before, once patients were put on your treatment, companies just looked for new patients. Patient support is especially important in Takeda since these new innovative treatments, while providing breakthroughs in terms of efficacy, sometimes come with difficult-to-manage side effects. If patients are not educated, they can drop off their treatments.

We have two individuals dedicated to patient advocacy working closely with patient groups in the Czech Republic and Slovakia. Since we are dealing with rare diseases, these patient groups could be representing a handful of patients in each country. We are trying to pull them together so that they can have a louder voice when it comes to policy-shaping and governmental affairs. The people who are most impacted by these decisions should at least have a seat at the table. Their life should not just be based on a financial decision.

You colleagues around the world have told us what Takeda-ism means to them and how they implement it at the local level. What does Takeda-ism mean for you?

The longevity of Takeda stems from its deep cultural roots. Having worked for Takeda for almost ten years, I can say that the philosophy of Takeda-ism filters through the entire organization. It is not just a buzzword; we live it every single day. At the centre, Takeda-ism is about making decisions with integrity. We must sometimes make difficult decisions that are contrary to commercial wisdom in order to meet the needs of patients, enhance our reputation as an organization and build trust with society. I believe that if we act in this way, it will ultimately lead to positive business outcomes, maybe not immediately, but certainly in the medium to long term.

The first thing we ask ourselves when making decisions is: “Will it have a positive impact on patients?” If the answer is no, we generally stop it there. The last question is: “Is this a commercially viable decision?” Almost on a weekly basis, we make decisions that are not commercially viable, but enhance patient outcomes, improve trust with society, and improve the reputation of Takeda. This philosophy is something we talked about with our Shire colleagues from day one, so they understand what makes the organization tick.

What will your priorities be going forward to work towards Takeda’s Vision 2025?

My first priority is to continue and accelerate the cultural integration by engaging with people and bringing them along the transformative journey. For instance, every two weeks, we have a

company meeting update, even if there is nothing to say because silence is a killer.

The other challenge is completing the transformation of the organization as we still need to build several capabilities. However, in the Czech Republic, the unemployment rate is close to two percent, which makes procuring talent quite difficult. In order to attract talent, we need to project an exciting vision that people want to join. Our products will be a key part of the story. Our products coming onto the market will make a massive difference in patients' lives. We have treatments coming for ALK-positive lung cancer, hereditary angioedema and haemophilia, just to name a few. We also want to broaden access to our existing products, for instance, our treatment for perianal fistulas in Crohn's disease, a stem cell therapy already reimbursed for a few patients in the Czech Republic.

Overall, the goal is to bring the company together to ensure that the most vulnerable patients in the Czech Republic have access to these treatments. That means working in partnership with our colleagues in the Department of Health, payers, and patient advocacy groups. I think we are all singing the same tune. We would all love to see patients have access to innovative treatments, but we understand that it needs to be done in an affordable way, which requires a little bit of give and take.

What is your final message to executives in the pharmaceutical industry?

I think we are living through exciting times. The pharmaceutical industry has gone from being very stable ten years ago to a sector in major flux. Some people are fearful of this flux, but I say embrace it and see how you can shape the environment, rather than just accept the hand you are dealt with. We have the opportunity through partnership with providers, authorities, payers, and patients to shape what the future looks like. Therefore, for the sake of patients, constructive dialogue must be kept among all of us to make new medicinal technologies accessible.

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