Neil Dugdale – VP & GM, UK & RoI, Sobi

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Three years into his role as general manager of Sobi's UK and Republic of Ireland operations, Neil Dugdale introduces the scope of operations of the Swedish rare disease player to our audience, highlighting the company's unique positioning in working closely with patient groups to drive forward better understanding of unmet needs in rare diseases and life-altering conditions.

Can you please introduce Sobi UK and RoI, its scope of operations and the importance it holds for the group?

Today, Sobi has 40 employees in the UK and RoI. We recently moved our UK and RoI headquarters to a science park near Cambridge, partly to be closer to the science base available at the University of Cambridge. We are working intensively to find new ways to partner with academic organisations and are cooperating with the Milner's Institute as well as the Cambridge Academy of Therapeutic Sciences, which both try to connect industry and academia. Although this is still in the early stage, it is my goal as General Manager of the UK and RoI to leverage the great science we have readily available in this country.

Sobi UK and RoI employs approximately five percent of the total global Sobi workforce and contributes approximately ten percent of global revenues (UK together with the Republic of Ireland). I report directly to the EMENAR president who heads Europe, the Middle East, North Africa and Russia. However, although our products are used to treat a similar number of patients as in France or Germany, we contribute significantly less revenue because of the pricing situation in the UK. This worries me deeply for the future of access to innovation in the UK.

Why do you see this as so worrisome?

Prices in the UK market have been driven down significantly over the past years. While this is a good thing for taxpayers and should mean greater access to innovative medicines for patients, it has a sum of negative repercussions. First and foremost, we have to ask ourselves, how long is such a system with constant price cuts sustainable? The looming threat is that, at some point, companies will have to make the decision not to launch highly innovative products in the UK, because it does not make sense financially. I think we are not far from that point, and I am very concerned, even though I observe a strong will amongst my peers—especially in the rare disease space—to continuously bring innovation to the UK for the benefit of patients.

I see the NHS as an amazing organisation. It is the fifth largest employer globally, treating one million patients every day! It employs dedicated people. But we need to reconsider how we manage rare diseases in the UK and come up with a better solution.

What concretely do you think has to be reconsidered within the UK's public system when it comes to rare disease appraisal?

Within NICE, there is a 'one-size-fits-all' approach to treatment appraisal, as it was designed to analyse the cost-effectiveness of products treating thousands of patients. In rare diseases, however, we see patients gaining access to treatments – treatments that could either cure or extend their life substantially with a good quality of life – significantly later than in most other developed economies.

The issue is not limited to rare diseases: one reason the Cancer Drug Fund was established was to get innovative oncology medicines to patients faster because the NICE model did not work. In rare diseases we have to consider unique numbers: there are approximately 8,000 rare diseases, and only around 400 treatments available. With pharmaceutical companies now considering not launching new products in the UK, this number of treatments is not likely to raise significantly in the future potentially leaving some patients without access to life-changing new treatments.

There is now a special reimbursement pathway for treatment of rare diseases in the UK – the NICE highly specialised technology (HST) process. But even if you pass the first steps of the process and are recognised as cost-effective by NICE, if your product is to cost more than GBP 20 million over three years you are forced to pause the process to then engage in additional reimbursement

negotiations with NHS England. This is often the case with rare disease drugs that will only be used to treat small numbers of patients but still have the substantial research costs of other drugs with no extra patent protection.

In rare diseases, patients have to wait an average of five years to get a diagnosis and many of these patients are children. These families with sick children have been stressed and traumatised for an average of five years. Some are then told that there is either no diagnosis (SWAN: syndrome without a name), or that there is a diagnosis but that no treatment exists. The best case is a diagnosis and a treatment. However, with the current appraisal process, the treatment might be delayed significantly compared to other developed economies; my fear is that some may never reach the market if an agreement cannot be reached with the NHS. Furthermore, a company may decide to prioritise supply to countries that don't insist on the low prices demanded by the NHS. The UK is a tough market and it is getting tougher. The situation where a family has to go through the extreme stress of non-diagnosis, to the relief of a diagnosis and a suitable existing treatment, to then learn that it is not yet available in the UK, is just not acceptable for a top five global economy, considering its science base and global leadership.

What are some of the creative ways Sobi has found to demonstrate value of its treatments to the payer?

We have been relatively successful in gaining access for our products for all intended indications because we have always gathered as much 'real world evidence' as possible to support our products. Well before applying for an appraisal, we gather as much data as possible about the disease area, the disease evolution, cost to society, impact on the quality of life of patients and family, and cost of alternative treatments. In rare diseases, the cost of a new treatment will often be higher than that of the current alternative, which is often not as effective as the newer treatment and results in years of a poor quality of life or even death at a young age.

We have seen the survival rate for one rare disease in the UK change from 28 percent to a survival rate beyond four years of age of 89 percent. This speaks volumes and we are incredibly proud of the impact this has had on families and the patient community. We must, as an industry, gather as much data as possible in order to be able to show the value and benefits of novel treatments to policymakers.

The challenge we encounter in the UK is that often the focus is on cost reduction and not innovation and not a free choice for healthcare professionals to utilise all treatments for the benefit

of their patients.

Recently, in Ireland’s assessment of haemophilia treatments, a large proportion of the criteria considered for reimbursement were clinical outcomes. In the UK, 85 percent of criteria for the haemophilia A tender process were based on cost alone with no weighting at all for innovation or patient outcomes. Therefore, the majority of the people in the UK living with haemophilia A continue to be treated with conventional factor replacement products that have not changed significantly for 20 years. For people with haemophilia, a breakthrough bleed can be painful, damages joints and reduces quality of life. The difference between two and three infusions a week does not sound revolutionary, but for patients that require this as a life-long treatment, it is around 50 fewer injections per year.

We experienced a similar situation when NICE was reviewing options for management of Dupuytren’s contracture. We remain convinced that access to new medicines should be about innovation and improvements to patients and not only about cost.

You have several products in phase III showing some promising results. Which innovations from Sobi can we look forward to seeing introduced to the UK?

We have some really exciting developments with a number of products including a series of indication extensions such as a new indication in Still’s disease for one of our current products. Together with our partner in haemophilia, Bioverativ, a Sanofi company, we also have some very exciting future products in haemophilia.

We are actively looking to enhance our portfolio by further partnering with companies whose rare disease philosophy matches ours. Our CEO Guido Oelkers has appointed a new leadership team to lead us through the next phase of our exciting journey.

All pharmaceutical companies highlight their patient centricity, but it gains a new dimension in rare diseases. How is Sobi working closely with patients in the UK?

I am lucky as my philosophy and that of Sobi as a company are perfectly aligned. Every single person in our team in the UK cares about their actions and the consequences of our work. When working in rare diseases, you realise that small actions can actually produce a huge benefit for this patient group.

We work with a range of small patient groups, in areas matching our portfolio and other disease areas. Our goal is to support and understand as much as we can. Also, Sobi has a charity goal of reaching SEK 1 million (approximately GBP 100,000) over the next five years and we are very active in trying to reach that goal. Employees of Sobi UK have climbed Snowdon in Wales, Carrauntoohil in the Republic of Ireland and will be climbing Scafell Peak in England, the highest mountains of each respective country, to raise funds for a number of charities.

We worked with WellChild last year on a garden transformation for a family with a very sick daughter. That makes a massive difference to that family and we are all looking forward to our next WellChild garden project later this year.

Finally, we are very active in trying to raise awareness of the issues facing rare diseases in the UK and Ireland. We work closely with all the rare disease groups and I am proud to be asked to be involved in forming a new charity called the Rare Disease Nurse Network (RDNN) that aims to put in place a global nurse network to help provide additional assistance in areas that lack support for people affected by rare diseases.

We are all proud of the work we do to help the amazing people who are affected by rare disease and yet continue to strive for improvements so that eventually anyone with a rare disease will have a quick diagnosis and access to an effective sustainable treatment.

How would you like to conclude on the UK, Sobi and rare diseases?

From our perspective, the rare disease strategy—a work of Genetic Alliance and Rare Disease UK—is an important initiative. The UK was previously relying on the EU strategy and they have done a brilliant job in ensuring that we have a UK strategy and an all-party parliamentary group determined to ensure that the strategy is implemented effectively across the UK. We advocate to see it refreshed and renewed, and hope it remains at the top of mind of politicians so progress continues and doesn’t stall.

Hopefully, it will also mean access to innovative products for patients with rare diseases and a change from a focus on cost to a focus on patient outcomes, so that UK patients will have the same access to medicines that patients from many other developed economies have. Surely, UK patients deserve the same access to innovative treatments as patients in Germany, France, the Republic of Ireland and many other countries? We are very proud we have made a positive contribution to helping treat rare disease patients and we are committed to continuing this journey.

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