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Celltrion Healthcare Belgium's Nicolas Van Gelder introduces the concept of 'biobetters' and how they differ from standard biosimilars and originator biologics, the reception and uptake of these products so far in the Belgian market, and what he sees as Celltrion's role as driving savings and positive change in the country's healthcare system.

Could you start by outlining Celltrion's journey into the Belgian market and how you came to be involved with the company?

On a personal level, I have worked in the pharmaceutical industry for 25 years and started my career with large companies, working mainly with innovative products. I then moved to the post-patent sector with a switch to Mundipharma seven years ago. At the time, the company had the distribution license for the first three products from Celltrion which were significant milestones in the commercialization of biosimilars in Belgium.

This opened up a totally different environment for me, going from innovative medicines to post-patent products, where margins are tighter and volumes are larger. With the strains on healthcare budgets across the world, the reallocation, repurposing, and reuse of existing resources stand to have just as big an impact on healthcare as new innovations. The blockbuster biologics developed 25 years ago and which have driven industry growth over this period have all gone off-patent in the

last five to seven years, meaning that the time is now for a rethink of where healthcare budgets can best be used and how authorities, academics & industry can come together to ensure that innovative medicines are made available to patients.

A couple of years after I joined Mundipharma, Celltrion publicly announced they would start their own affiliates all over Europe. I felt mature enough to take on that challenge and play my part in building a sustainable global group, because Celltrion had already existed for 20 years in Korea, and was a standard in terms of production, and the research of monoclonal antibodies. But in terms of commercialization, it was still in the early days. I was chosen to start the affiliate in Belgium and the first three products that used to be distributed by Mundipharma are now distributed directly by Celltrion.

It has been a busy three years, because it was the start of a new story. It is all about access, commercializing, and making sure we redistribute the margins towards ones that will generate savings for a healthier healthcare budget. So, there is a governmental affairs perspective and a commercial aspect. We have a good footprint after three years, with six products launched and five more to come.

Celltrion is not just a standard generic and biosimilar company. We are not only replicating what already exists, and making sure that we make it affordable. But we also try to improve whatever we do and aim to make it at least as good or better than the originator by developing biobetter products.

How is ‘biobetter’ being defined and how do these products compare to biosimilars and originator biologics?

Whereas a biosimilar is a medicine that is similar to the reference biotherapy, a biobetter is a modification of a biotherapy that has already been approved, with the aim of improving its efficacy, safety or patient comfort.

For example, Infliximab IV was launched as a Subcutaneous formulation and has led to an improved version of the molecule that has been welcomed by healthcare professionals for its improved clinical features and by patients for its convenience.

Although biobetters require more resources for their development compared to traditional biosimilars, the research phase is significantly shorter than a new mechanism of action molecule.

This is one more example of how we can bring more value by further developing existing therapies or simply making better use of our standard-of-care medications.

Why did Celltrion decide to establish a Belgian affiliate so early in its European journey?

Celltrion decided to start in Europe and first considered the major markets (France, Italy, Germany, United Kingdom). However, the company established its first European hub in Hungary, because it was the country that hosted our marketing authorizations, so that was more from a regulatory perspective. After starting in Hungary, they went to the Netherlands, because the climate there to welcome new companies is advanced and open. So, for many years, they had an affiliate in the Netherlands, overlooking their partner Mundipharma.

Suddenly, in 2019, Celltrion announced that they would launch affiliates over almost all of Europe. They started with the big countries and were eager to expand the Dutch affiliate because the Netherlands is a very receptive country for biosimilars.

The adoption of biosimilars has always been extremely fast in Scandinavian countries, in English, Anglo-Saxon countries, and the Netherlands. The southern part of Europe, including Belgium, has had a more difficult adoption and fragmented market.

Despite this slow biosimilar adoption, our group quickly understood the importance and influence that Belgian scientists could have for our biobetters and new molecular entities.

How many people does the Belgian affiliate currently employ?

Over the Benelux region, we have 19 people with 12 in BeLux and seven in the Netherlands. We have almost all the functions required to do promotion and distribution but at this stage, we are currently outsourcing many of the copious regulatory functions. Looking forward, as we are going to launch five more products and grow even further, there will definitely be an opportunity to bring more talent on board.

How has biosimilar penetration evolved in the Belgian market?

Over the last 10 years, more and more biosimilars have come onto the market, but at one point Belgium had one of the lowest biosimilar penetration rates in the world. One of the reasons for that

was because there was not enough representation and no information. It all started in 2012 by the Kenniscentrum (KCE), who were mandated by the authorities to draft a report on that, to understand why there was such low penetration. Everyone was concerned that we might miss the opportunity to reduce the price, generate competition, and also miss the savings needed to invest in future innovations.

The adoption was around one percent, while the average uptake of biosimilars had a much higher penetration. The report said there was no trust or awareness of biosimilars. Also, the financing systems were inaccessible, and there was a reluctance to prescribe biosimilars because they are similar but not the same. Decision-making is also spread across many stakeholders. It is not those who prescribe biosimilars to patients that get the incentive out of it, but rather the government and institutions that are generating the savings through tendering legislation.

Over time, it has significantly improved thanks to lots of political initiatives. Especially when former Minister of Health Maggie de Block mandated a relaunch of biosimilars in Belgium.

By having it on the political agenda, and applying the tender legislation, significant action was taken by the hospital community. Biosimilar companies such as Mundipharma/Celltrion and other biopharmaceutical players contributed to building awareness and trust, making sure there is a face behind the products and therefore greater trust.

A game changer for biosimilars was the NOR-SWITCH study in 2016. When biosimilars came onto the market in Norway, the Norwegian authorities decided to switch all their patients to the Celltrion infliximab biosimilar, from the originator (Remicade), and proved the biosimilar was not inferior. The study received a lot of attention from the scientific community, reassuring healthcare professionals that biosimilars were not only equal in quality, efficacy and efficacy but also safe to switch patients from the reference product.

We are talking about monoclonal antibodies and medicines for potentially terminal cancer patients, and perhaps this is part of the reason healthcare providers (HCPs) can be reluctant to use biosimilars. How do you convince HCPs, and patients, to switch to biosimilars?

Indeed, from one area to another, the questions change, especially when we talk about lifesaving medications. For biosimilars, you need to have the trials performed and ultimately endorsed by the EMA. Once you have that indication, you can extrapolate it to all other indications. So, then we

have the data to persuade various HCPs and prove to them the effectiveness of biosimilars.

I am proud of Celltrion that every indication is being studied further, and we do far more than the agencies expect us to. So, delivering the science and data to clinicians is important.

Whenever we have products that are being delivered in hospitals, by law, the hospitals have to do public tendering. Whenever they do that, more than nine times out of 10, a biosimilar company wins the market, the originator either doesn't want to participate because the prices will be too low or are not competitive enough. In some cases, the originator companies have all the credit to have invested and generated innovation for important diseases. But in some cases, they tend to not continue to develop their own medication. They do have a clinical program at the beginning, but at some point, they may see that they will lose their patent in a couple of years, so stop developing that product and focus on other products.

I think that some biosimilars have the opportunity and duty to look at how they can improve the product further. Having improved features can help smooth the transition from originators to biosimilars.

Out of every product we distribute to hospitals, 90 to 95 percent of the market is allocated to biosimilars. The adoption rate, which was one percent, is now completely back on track and in line with the European averages.

Because hospitals have to perform tendering, clinicians no longer are the decision-makers. Instead, it is the hospital pharmacies and the procurement department who are there to perform tendering on behalf of several hospitals and take ownership of what needs to be allocated. It looks like it is great to have this penetration in hospital products. However, we have major problems with the leading products; the products prescribed by clinicians and delivered by local retail pharmacists. Their penetration is not at 90 percent, but around 20 to 25 percent. This is a major issue for the overall sustainability of the biosimilar sector

We have been discussing biosimilar adoption with the authorities for many years. The cabinet of the minister has appointed a full-time biosimilar coordinator to work on that. A report with 16 different propositions to support the Biosimilar relaunch in Belgium was published in April 2020. Since then, everything has remained on the table, but the current government has not taken disruptive actions yet.

One of the 16 conclusions is to suggest a quota of biosimilars that clinicians must prescribe. This should be the guidance moving forward.

Is Celltrion clinical data issued only in Korea, or does it include the European population?

Absolutely, our data is multicentric, international, and represents a very broad patient population. It is not solely and only in Korea. In the case of Infliximab Subcutaneous, the primary investigator of our global clinical program is Professor Westhovens from KU Leuven. Belgium may be a small country, we are recognized for the expertise of our academic hospitals everywhere in the world, including in Korea.

You are getting ready to launch five new products in the next 18 months. How are you planning for those launches? And in which therapeutic areas will they be?

This indeed represents an exciting opportunity & challenge for our growing organization. A new wave of monoclonal antibodies will lose their exclusivity next year and early 2025. Our R&D facilities have integrated this into their plans, and we have the internal production capacity to deliver on the demand.

Most of these products will be in therapeutic areas in which we already have an established reputation (gastroenterology, dermatology, and rheumatology) but for some others, it will require us to engage and build trust with new customers.

The first of the five products will be the Omalizumab biosimilar, which was recently submitted to the EMA for approval. Traditionally, head office will submit the application to EMA, and 210 days later you will get approval. One month before, we should receive a positive opinion from the Committee for Medical Products for Human Use (CHMP). That is what you need at the local level to submit your file for price & reimbursement. All of this has been facilitated by the reform and compressing of the reimbursement procedure from nine to three months. We will launch the first of these products in 15 months, and the others will follow.

The perception of Celltrion is perhaps that it is more of a manufacturer than a medicine solutions company. How do you change that perception?

Yes, Celltrion is a renowned company in Korea and has been particularly successful with our research and production facilities. However, what matters to patients, clinicians and the healthcare

system is not how big our factories are, but how reliable we are, what value we bring and how we engage with stakeholders.

In Europe, although we already achieved very good company reputation results within our area of expertise, it remains one of our priorities to ensure that we have increased visibility in the bio-pharmaceutical landscape.

Is there anything you would like to add to this interview that we have not covered?

A company like ours is contributing to generating savings that are essential for the healthcare budget. Replicating or rediscovering advanced therapeutics and making these affordable is what we do, and this is our legacy for the Belgian healthcare system.

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