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06.07.2022

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Kyowa Kirin's head of the South Europe cluster, Norberto Villarrasa, explains the Japanese company's presence in Spain, its focus on rare diseases and onco-haematology, and comments on the challenges around access to rare disease treatments. In addition, the executive provides the company's view on the potential and advantages of risk-sharing agreements in Spain, and underlines Kyowa's commitment to sustainability, diversity and inclusion.

Can you start by explaining your responsibilities within Kyowa Kirin as head of the South Europe cluster, as well as the company's presence in the three countries under your command?

I am responsible for managing the South Europe cluster of Kyowa Kirin, which includes Spain, Italy and Portugal. Since Italy is a big market, and we must defend its particularities, we named a country manager that represents the company to stakeholders. Mixing the three countries together makes sense if we take into account both their culture and the structure and management of the healthcare systems. We are also united by sharing the same mission, to make people smile, and by our core values – innovation, commitment to life, integrity and teamwork – which guide our actions and make us feel part of one Kyowa Kirin.

Kyowa Kirin does not have local production within the cluster. The manufacturing of global products is done in Japan, and some regionalized products from the legacy portfolio are either based in other countries or done by third parties. In Italy, we have partnered with Molteni Farmaceutici for one product, and with Recipharm in Spain for another.

What about Kyowa Kirin's portfolio in your region? What strategy is the company following here?

We are a global pharmaceutical company based in Japan, built on a diverse team of experts with shared passion and innovation. We strive daily to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies. Kyowa Kirin is rapidly transforming.

At the moment, Kyowa Kirin has two differentiated strategies in EMEA (Europe, Middle East and Africa). On one hand, we have mature products which are managed by our Established Medicines Business Unit; the marketing of those products is primarily done digitally because they are part of oncological treatments. On the other hand, we have an innovative portfolio, more targeted to rare diseases and onco-haematology. Within onco-haematology, for example, we have a product to treat acutaneous T-cell lymphoma, but since it is also a rare disease, it ticks the two boxes.

Looking at Kyowa Kirin's 2021 annual report, one can find a pipeline with many assets in the late stages of development. What can you share about the upcoming product launches in your cluster?

In all of Kyowa Kirin's daily activities we have an eye for all people, our goal is always to make them smile, whether they are doctors, rare disease patients and their families, or our staff. Spanish institutions have recognised Kyowa Kirin's commitment to rare diseases in specific areas. Thanks to shared efforts and commitments, our products have been very well received because they are prescribed for rare diseases with few or no alternative therapies and important unmet needs.

2021 was a year full of new launches for our rare disease and onco-haematology portfolio. That year we launched a treatment with a pediatric indication which is used to treat patients with x-linked hypophosphatemia (XLH), a rare, inherited form of rickets. In addition, in June of 2021, we launched the cutaneous T-cell lymphoma product. In the upcoming two years, we expect to launch new indications of burosumab for adults and tumour-induced osteomalacia (TIO).

The products were quite well received because they are prescribed for rare diseases with little to no alternative treatments. In Spain, we have treated a significant number of XLH pediatric patients. We are happy with the launches, especially considering the implications of the Covid-19 pandemic; it was not easy to launch two new products at a time when access to hospitals was limited. The organization has been forced to adopt digital solutions.

How did doctors react to the company's digital approach? Has the pandemic changed the way they perceive digital interactions with the industry?

I believe that they are open to new channels of participation. However, it is also true that HCPs are increasingly asking for more face-to-face, personal contact. But this does not render digital

interactions useless. We are implementing a hybrid approach, including all events. The company has conducted a study to analyze the preference of doctors and discovered mixed responses.

How do you evaluate the question of access in Spain for rare disease patients?

It is a controversial topic. It is true that Spain has been lagging in recent years regarding access to innovation; statistics are there for everyone to see. The country is getting closer to countries like Portugal in terms of time and conditions for approval when it used to be much higher in the rankings.

As representatives of the pharmaceutical industry, we understand that the sustainability of the healthcare system is an issue. It is true that innovative medicines are responsible for a large share of the budget, but they are also the ones that offer a solution for unmet medical needs.

Spain, unlike some other European countries, does not currently have a rare disease strategy or budget. This makes it harder for patients.

What can be done to improve access for rare disease patients?

Listening, collaboration and planning are Kyowa Kirin's main areas of intervention for people affected by rare diseases. The focus is, of course, on the development and research of innovative drugs, but we believe that to concretely help patients, we need not only a traditional and pharmacological commitment but also a social and educational one.

For our part, we are working to demonstrate the value of our products, doing risk-sharing agreements with health authorities, and introducing cost ceilings to reduce uncertainty around the impact of our medicines on the budget. We are willing to work with health authorities to limit clinical uncertainty of rare diseases – which is important because of the limited number of patients included in this type of clinical trial – and are betting on risk-sharing agreements to do it.

In addition, we stand by doctors, patient associations and caregivers in supporting activities and projects. Competences must be protected, shared and cultivated.

How receptive are the authorities in Spain to that type of risk-sharing agreement?

We negotiate risk-sharing agreements with the General Directorate of Pharmacy and Medical Products, which is in charge of setting reimbursement in Spain. They evaluate products through the so-called Therapeutic Positioning Reports (IPTs) which set the value of a medicine and its ability to be reimbursed.

If a product carries a high degree of clinical uncertainty, we try to propose outcome-based agreements. Those agreements stipulate that the system will pay more or less, depending on the value of the medicine. It is common to wait three months for a therapy to establish positive results, if it does not, the industry covers the total cost.

These agreements are increasingly common; there is one company that reached an agreement based on global survival rates, where the system pays 50 percent of the therapy if a patient reaches 12 months and the full cost when a patient survives for 24 months. Kyowa Kirin has not yet done a risk-sharing agreement for its oncological products, but it has done it with burosumab.

Outcome-based agreements are a great idea, but they entail a high level of bureaucracy in order to monitor patients. There are some autonomous communities that have asked the central government to slow down agreements citing a lack of funding to perform the monitoring of patients. For example, we proposed an outcome-based agreement for our cutaneous T-cell lymphoma product, but autonomous communities chose a price reduction instead. They alleged that it did not make sense to follow such a complex pathway for such a reduced number of patients.

Do you believe that having good brand recognition is key to Kyowa Kirin's success in Spain, or is there nuance to it?

Our strategy is not about Kyowa Kirin being recognized by the general public of healthcare professionals, but rather being well known in the therapeutic areas where our products have a presence. Those include rare diseases, nephrology, endocrinology and onco-haematology; and, in the future, in immunology. I can say that our impact in the last couple of years has been great in those areas.

Towards the authorities, our objective is to conduct certain projects that result in win-win scenarios with regional stakeholders. For example, we supported Galicia to perform a well-received project based on the development of a screening tool for identifying suspicions of patients with certain rare diseases.

As head of the South Europe cluster, what role do you believe that the healthcare systems of Spain and Italy play in both countries having two of the highest life expectancy rates in the world?

It is true that Spain and Italy have two of the highest life expectancy rates in the world. The Spanish healthcare system is recognized as one of the best in the world because it provides universal access to all patients. The Mediterranean diet helps, as well as having a less stressful worldview, more centred in the family. I believe that stress plays a big role in mortality rates.

What can a multinational pharma company that does not have local manufacturing do around sustainability? What can Kyowa Kirin Spain do to contribute to what the company deems a key priority? And what is the organization doing round diversity and inclusion?

There are several things we can do. First, we can always improve the impact that our distribution efforts have on the environment. Second, we have a project to have a zero carbon impact related to internal operations, which includes electric cars, recycling, paperless offices, and so on.

Moreover, we regard diversity, equity and inclusion as the foundation of our organizational culture at Kyowa Kirin, acting as a critical enabler of creation and delivery of life-changing values to all the patients around the world. We have internal groups intended to help the team get involved in several initiatives. In fact, 70 percent of the company's South Europe executive committee are women.

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