Claudia Coscia â?? Southern Cluster Lead Nephrology & Country Manager Italy, Kyowa Kirin

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Claudia Coscia outlines how the geographic and portfolio transformation of Kyowa Kirin has played out in Italy in recent years. Coscia also touches on access challenges for rare disease therapies in the Italian pharma market, rising levels of rare disease awareness, and the digitalisation status of the countryâ??s healthcare system.

In October 2021, you returned to Kyowa Kirin as Cluster Lead Nephrology & Country Manager Italy after having left the company in May 2020. What brought you back?

I had previously worked with Kyowa Kirin for two years as Supportive Care Business Unit Director, and left during a significant reorganisation at global, regional, and national level. An opportunity arose at Recordati Rare Diseases, which was preparing to launch two new products in endocrinology here in Italy, and I took on the role of general manager for Italy and Greece. Although this position was at a relatively small affiliate, it represented a great opportunity to experience general management for the first time.

However, I always felt like I had unfinished business at Kyowa Kirin, which was undergoing an exciting transformation with a focus on rare diseases and people â?? both internally and externally. Therefore, when the company approached me to re-join in mid-2021 I jumped at the opportunity.

What were the most significant changes in Kyowa Kirin when you re-joined the company?

The Kyowa Kirin I joined in October 2021 was very different to that which I had left in May 2020. The firmâ??s focus was completely renewed with the creation of two main business units. The first, from which our future growth will predominantly derive, is rare diseases, mainly in onco-haematology and nephrology where two notable monoclonal antibodies based on Kyowa Kirin research are currently on the market. Very few companies of Kyowa Kirinâ??s size are today able to develop a molecule all the way from lab to market.

The second franchise is Kyowa Kirinâ??s historical and established product portfolio, which is mainly focused on supportive care, particularly in oncology.

In addition to this franchise reorganisation, Kyowa Kirin has also reshuffled its geographic organisation, with the Europe region organised into Northern, Southern, CEE, and GCE (also containing some middle Eastern countries) clusters. Italy was incorporated in the Southern cluster along with Spain and Portugal, with our Cluster General Manager sitting in Madrid, Spain.

What mandate were you given when taking on this new position?

My return had two main objectives. The first was to take care of the nephrology franchise â?? including burosumab indicated for X-linked hypophosphataemia (XLH) â?? across the entire Southern cluster, guaranteeing cross-functional collaboration. In parallel, my second role is as country manager for the Italian affiliate with the main objective of implementing key projects in Italy, represent the company in front of patients and institutions, and guaranteeing alignment and the cross-functional collaboration between all three countries in the cluster

Given that Kyowa Kirin is a relative newcomer to the Italian market, how would you characterise its reputation among stakeholders in the country?

In all of Kyowa Kirinâ??s daily activities we have a focus on people, both internal and external, and our aim is always to make people smile, whether physicians, rare disease patients and their families, or our own staff.

Italian institutions recognise Kyowa Kirinâ??s commitment to rare diseases in specific areas. Unlike some of the larger companies in rare diseases which have a broader focus, we have dialled in our efforts on a few specific areas and aim to succeed not only in terms of competition, but also in meeting the needs of rare disease patients and of physicians working directly on these complex and challenging diseases.

This also creates a need to increase awareness around rare diseases, where giving the disease more visibility can be difficult. This is particularly important for Kyowa Kirin, given the potentially life-altering impact of our innovative drugs for patients, and we are involved in several projects and services to increase awareness. Stakeholders â?? from the national health authorities to regional

and local payers, physicians, and patient associations â?? recognise this commitment and we will continue to work on it.

How much work is there really to be done on rare disease awareness raising in a developed European market such as Italy?

There is still significant room for improvement in the general level of awareness. The perception that developed European countries like Italy are better positioned than most in terms of diagnosis, patient identification, and disease awareness is probably fair but there is still much to do. Many initiatives still need to be put in place to facilitate better disease awareness and make the difficulties that these patients face in living a normal life more visible.

Even if not all rare diseases are life-threatening, most are chronic diseases that impact significantly on patientsâ?? daily lives and on the lives of their families. Additionally, many rare diseases are paediatric diseases, meaning that very young patients are suffering and need to be properly followed by their families and by the healthcare ecosystem around them.

Only recently, the Italian government has taken some positive steps, with the â??Testo Unico sulle Malattie Rareâ?• (Consolidated Act on Rare Diseases) published in the Official Gazette on 27 November 2021 and coming into force on 12 December 2021 (D.L. 175/2021, GU n. 283 del 27/11/21). The Consolidated Act was created to give greater visibility to these diseases and the creation of dedicated pathways to diagnose and treat patients correctly. Now, we are waiting to see how this will be implemented at regional level; Italy has a centralised government but in practice, there are 20 different regions where decisions in healthcare can be very different. The establishment of a common pathway in terms of early diagnosis, treatment and adequate social support would be an important step forward in ensuring a homogeneous approach to the care of this particularly fragile category of patients.

Are Kyowa Kirinâ??s medicines conditionally approved or fully approved in Italy? How well-received have they been?

Both of our drugs in RDBU (or for RD) have orphan designation and are conditionally approved in Italy, with the evidence being generated through registries and other programs supporting their continued use. Both have received Prix Galien awards, demonstrating the value that they represent for patients, and how a small, focused rare disease company like Kyowa Kirin can have a big impact in a country like Italy.

How digitalised was the Italian healthcare system pre-COVID, and what has changed since the onset of the pandemic? How has Kyowa Kirin upped its own digital footprint?

COVID significantly raised the need to digitalise healthcare activities at several different levels, from properly managing patient data, results, and diagnosis pathways at the hospital level to digitalising interactions between patients and physicians when hospital access was very limited.

Many hospitals and local health institutions attempted to rapidly implement alternative modes of communication and interaction between patients and physicians, including telemedicine and virtual consultation. On the private sector side, many pharma companies were already close to launching

digital transformations, but the COVID emergency accelerated their rollout. At Kyowa Kirin, we worked tirelessly to understand how to remain close to patients and all our stakeholders against such a backdrop and made rapid progress.

Italian healthcare could be more digitalised â?? it is now clear to all stakeholders just how important this is â?? but we must be careful not to lose the human element. Kyowa Kirin, with its people-focused culture, is therefore developing digital tools and services that provide information around rare diseases, how our drugs work, and what support services are available for patients, their families, pharmacists, and physicians. Additionally, we have launched our own Patient Support Program focused not only on access to medicines, but also facilitating access with physicians.

One of our key strategic pillars is to transform Kyowa Kirin into a digitalised company that is closer to our patients and key customers than ever before. We started this transformation two years ago, bringing in digital talent to support it, and are working on how we target and reach out to physicians, how we serve them through medical education, and how we can be more proactive in providing medical solutions for patients and physicians. Kyowa Kirin has a dedicated department within the Southern cluster, a digital expert and director, as well as a department at the regional level in London fully dedicated to supporting this transformation. Digital solutions will also come to support our disease awareness efforts.

The question of reimbursement for rare disease therapies that serve limited patient populations is a thorny one in the context of universal healthcare systems with limited budgets. How have you found the process in Italy?

The value of Kyowa Kirinâ??s drugs has always been self-evident, meaning that the reimbursement process has been broadly positive, especially compared to my past experiences at some other companies. The access scenario for orphan drugs is â?? on paper at least â?? well facilitated, with a general willingness across the healthcare system to make things simpler, faster, and more effective. Very often, patients suffering with rare diseases are isolated and have difficulties properly managing their health, meaning that faster access is crucial.

However, this willingness to be close to rare disease patients sometimes contrasts with reality given how long it takes some orphan drugs to reach patients after national and regional authorisation. We have experiences of regions which have granted access immediately and others which took months, creating discrepancies between what the health authorities or the central governments want to reach and the reality.

Kyowa Kirin has an overarching 2030 strategy to transition into a specialty pharma company; from the Italian perspective, what will the next three years look like?

Globally, Kyowa Kirin is transforming rapidly. The Italian affiliate, like all Kyowa Kirin Group companies, strives 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. Our vision for 2030, as KKG, is to successfully realize the creation and delivery of value that changes lives and ultimately makes people smile, as a global specialty pharmaceutical company based in Japan, built on a diverse team of experts with shared passion and innovation.

Is it challenging to find the right talent to execute this strategy?

Not particularly. Working in rare diseases, and at a company like Kyowa Kirin, requires a specific mindset, but if you really believe in what you do every day, this mindset is not difficult to reach. Once people understand the difference they can make for patients and their physicians, the motivation comes naturally. Our people have a great deal of focus and dedication.

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