Giuseppe Maduri â?? Chairman, Managing Director, General Manager Italy, Greece, Cyprus, Malta, Astellas Pharma

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16.08.2022

Tags:

Italy, Europe, Astellas Pharma, Oncology, Market Access

Giuseppe Maduri, Chairman, Managing Director, General Manager Italy, Greece, Cyprus, Malta at Astellas Pharma explains the Japanese companyâ??s focus on unmet needs and how Italy, one of its top European markets, is working to ovecome market access challenges.

Could you begin by outlining your career up until now?

I started out in the industry with Menarini Group, an Italian company, as a Rep before moving to GSK in 2004. While at GSK, I worked in various roles, from marketing to sales and market access, as well as several different therapeutic areas, including oncology, vaccines, primary care and secondary care. I also had the opportunity to spend a year at GSKâ??s centre of excellence in France during my time at the company.

After 13 years at GSK, I felt it was the time for a new opportunity and moved to Astellas, initially as chairman and managing director for Italy, and â?? since 2021 â?? in an extended role that covers the following countries: Greece, Malta, and Cyprus.

What was the value proposition that attracted you to Astellas?

Several personal and professional aspects played a role in the decision. Having previously worked for Italian and British companies I was very curious about the culture of a Japanese company like Astellas and what it could offer. Additionally, the firm had set out a new global long-term vision, renovating its strategy and adopting a much more focused approach.

The intention of Astellas is clear: to add value in disease areas where no therapeutic option currently exists. Through our focus area approach, we combine the diseases with high-unmet needs and a deep understanding of their biology with innovative technology platforms and versatile treatment modalities. To do so, we invest about 20 percent of our turnover in R&D. From the outset, I found this to be a compelling strategy, and we are now seeing the fruits of it.

What are the most significant changes that you have been able to oversee at Astellas Italy in the past five years?

Internally, we transformed the affiliate in line with the change of strategy at a global level. This transformation required a cultural shift across affiliates and a reorganisation of our teams to face the new challenges and opportunities that came up.

We are focusing on external partnership and dialogue to open the scientific conversation with institutions, authorities and all the stakeholders involved in the product lifecycle and patient journey.

Has market access become a more critical function within your organisation?

Absolutely. We work in a sector where R&D moves extremely quickly, as seen in the number of new technologies being approved by regulatory bodies like the FDA and the EMA. However, this speed is not currently being reflected at a local level in countries like Italy, where national and regional bodies tend to react to innovation rather than anticipate it.

Greater anticipation would allow patientsâ?? faster access to innovation but requires a lot more collaborative work and dialogue between the industry, regulators, and payers than what we are seeing today. From the industry side, we need to provide more data to support a drugâ??s launch, especially in the context of a resource-constrained environment where a drugâ??s value needs to be proven in terms of both efficacy as well as its sustainability within the overall healthcare system.

Also, early access dialogue with authorities would mitigate the information asymmetry that most of the time causes delays and long processes. Through early engagement companies can provide more complete risk assessment (upon payersâ?? feedback) and payers can understand the place of a therapy and its value proposition (upon company feedback) with a more broad approach than a mere â??priceâ?• discussion like today.

Given the number of new drugs set to be launched in the next five years, this trend will only become more significant and will impact patientsâ?? quality of life

Market access delays are a common complaint among pharma country managers in Italy, but how would you propose to resolve some of these concerns?

What needs to be taken into account is the level of resources in our sector. A clear vision of the resources that exist, and that need to exist, is necessary to support the next wave of innovative

medicines being launched. In Italy â?? which spends one of the lowest percentages of its GDP on healthcare in the EU â?? this forward thinking is especially important and will allow companies like Astellas to better plan for the future.

The second consideration would be better use of the resources we currently have across the system, with greater priority being given to access. Following EMA approval of a product, Italian Authorities need to grant reimbursement of the medicine through a price negotiation with the company, and after that we must negotiate with the regions to gain access, all of which takes time. We need to make the process leading to access to new technologies even more effective through a more robust discussion of the overall value to the patient and to the system.

The third consideration should be bureaucracy and process speed. Patients should be placed higher in reform considerations because speed of access can make the difference, even between life and death. For example, leukaemia patients who have to wait six months for a treatment following EMAâ??s approval could potentially have passed away while waiting. Thus, lives can be saved with a more rapid process. Companies are ready to embrace this open and early dialogue.

Italy is poised to receive a EUR 140 billion cash injection from the EU for COVID recovery, 32 billion of which has been earmarked for healthcare. A lot of talk has centred around how this funding could boost digitalisation in Italian healthcare; what is your take on how this money should be allocated?

We are very happy that Italian healthcare is set to receive this funding, but we feel that the strategic thinking about how to allocate it should be improved. A long-term transformative vision is needed, focusing on three key areas.

Digitalisation and telemedicine are highly promising trends, and we are glad to see investment flowing towards them, but there also needs for investment in capabilities and literacy from both a medical and patient perspective. Without that, such investments will not be effective. Secondly, in order to implement new digital tools properly, there needs to be greater investment in infrastructure across the healthcare system. Spending heavily on such tools without investing in supporting infrastructure would not be smart. Thirdly, we need investment in capabilities. There needs to be enough well-trained nurses and physicians to roll out these tools properly.

How would you characterise the relationship between Italian authorities and private pharma companies like Astellas? Is the regulator well enough aware and prepared for new products in the pipeline?

The authorities know company pipelines very well, but that is only a starting baseline. There needs to be more dialogue that includes all actors â?? from regulators to payers, industry, HCPs, and patient associations â?? to collectively shape the next three to five years. In areas like oncology, for example, a cross-functional approach needs to be systemically implemented at a national level, because today there are myriad regional disparities in access to medicines for cancer patients.

Such a shift in the dialogue will require a cultural shift and the acceptance on the part of the authorities that the pharma industry itself, along with the other aforementioned actors, has knowledge and insight to be able to contribute to the system. Currently, there are too many silos and the lack of a long-term plan.

What significance does Italy hold for Astellas globally?

Italy is one of Astellasâ?? top five markets in Europe â?? along with Germany, France, the UK, and Spain â?? and one of its top seven globally with the US and our home market in Japan. From humble beginnings in Italy when I joined five years ago, we have grown significantly. Today, the level of innovation in Italy is well understood by global management, and a strong presence in the country is accepted as something of critical importance to bringing new products to patients here.

Clinical trials are an important piece of the market access puzzle; have you been able to bring some of Astellasâ?? global trials to Italy?

Italy has a strong presence in Astellasâ?? global clinical trials and all the drugs we have launched in Italy were involved in clinical trials here. Italian hospitals and doctors are of a high level, and I am always delighted to expose the ecosystem here to our innovations, giving to Italian healthcare organizations the opportunities to contribute to research by welcoming protocols for the trial of new medicines.

However, there is more work to be done. Italyâ??s stifling bureaucracy makes investing in R&D and clinical trials challenging, even with some of the fiscal benefits for doing so. This is especially true for decentralised clinical trials â?? an important global trend â?? but one which comes with a lot of bureaucracy in terms of implementation at the Italian level.

What are Astellasâ?? main growth drivers in Italy today, and how might that change in the future?

Our medicine, a nonsteroidal antiandrogen, for prostate cancer is one of our key drivers for growth. Additionally, Astellas is working in several area of oncology with high unmet clinical need.

The Italian economy is not growing, but Astellas is; what are your realistic hopes for the future of Astellas in Italy and of your countryâ??s economy and pharma industry more broadly?

I am very optimistic about the future of Astellas in Italy considering the new products that we are going to launch, the level of innovation in the company, our technological excellence, our capabilities, and our digital readiness.

However, I am not so optimistic regarding the external environment. Our economy is flatlining, and the war in Ukraine will only exacerbate the challenges that Italy is facing and further strain its economic resources, including those dedicated to healthcare and pharma. This means that open discussion on how to better use these resources is paramount. The risk is that without developing new collaborative solutions, patients will miss out on access to lifesaving drugs.

Last year you took on an expanded country portfolio including Greece, Malta, and Cyprus. From a management perspective, how have you adapted to these new responsibilities?

I feel that having strong teams composed of the best people is critical. As a leader, hiring people that are even better than you is a sure-fire path to success. I am proud of the team we have built in Italy and the new Greek team as well.

This experience has helped me understand the importance of different cultures and different external environments. My approach has been to give autonomy to the Greek affiliate, respecting the culture of the country, and not cutting and pasting everything that has previously worked in Italy. While I must ensure that Greece stays within the parameters of the global company, this respectful and inclusive approach has worked well so far. I trust the team there and they trust me, which creates a working environment with a good level of respect, accountability, and ultimately happiness.

In what is a competitive market for top talent, what helps Astellas stand out from the crowd?

Our first key asset is innovation. Our innovation levels are very high, as seen in our pipeline and products, but also our way of working. The second is our value base. We could have the best products, procedures, and organogram, but without the right value base it would all ultimately be fruitless. Our values of respect for each other run deep across the organisation. A third key point is happiness. I am happy when our employees are happy. When our people go home in the evening to spend time with their families, we want them to feel happy and relaxed; not stressed about ongoing work issues. While challenge is good, a strong work-life balance is crucial to maintaining happy people.

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