

Tiziana Mele - Managing Director, Lundbeck Italia



At Lundbeck, we are wholly committed to restoring brain health and supporting people impacted by brain disorders.

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Tiziana Mele, managing director of Lundbeck Italia, explains the impact of COVID on mental health care from the perspective of a company dedicated to brain health, outlines the Italian operation that includes both commercial and production capacities and shares Lundbeck's support of independent clinical trials in the country.

You have been at Lundbeck since 2014. Can you give us an overview of your background and what brought you to the company?

Untypically for the pharma sector, my background is in business administration and management. I started my career at KPMG and went on to work at AstraZeneca, in pricing, market access, marketing and sales. I have had the opportunity to work in different areas and the opportunity to appreciate that the industry is working to provide and bring to market innovative drugs that can make a difference to patients.

When Lundbeck contacted me, I was in oncology at AstraZeneca. At that time the oncology pipeline was huge, but what attracted me to Lundbeck was the pure and genuine focus on the Central Nervous System (CNS), an area that is not necessarily an easy one. Working on CNS means focusing on Alzheimer's, Parkinson's, Major Depressive Disorder (MDD), Schizophrenia, post-traumatic stress disorder, and there are not many companies working on CNS due to the difficulties of developing innovative drugs. Thus, what really convinced me to move from a big company with different therapeutic areas to a company that is purely focused on CNS was the commitment and

the focus on this area.

I was hired in December 2014 when I was five months pregnant and in Italy, it is unusual to hire someone who is pregnant. I started as a marketing manager and then when I came back from maternity leave, I was promoted to marketing director. Two years later, I became commercial director, and after one year in that role I was promoted to managing director and became the first Italian woman to manage the Italian affiliate.

How important is Italy within the global Lundbeck organization?

Italy is one of the strategic markets for Lundbeck and is among the ten most strategic markets for the company. Apart from the commercial side, the importance of Italy is also because we have a production site here.

Lundbeck operates in Italy with 2 different entities: Lundbeck Italia, which I manage, and Lundbeck Pharmaceuticals Italy. Lundbeck Italia S.p.A. has been operating in Italy since 1994 and is the commercial affiliate located in Milan. Over the years Lundbeck Italia has marketed more than 10 molecules in Italy, including 4 antidepressants coming from Lundbeck Global research.

Our presence in Italy was further strengthened in 2000, when *VIS Farmaceutici (Istituto Scientifico delle Venezie)*, founded in 1929, was taken over by the Lundbeck Group, becoming Lundbeck Pharmaceuticals Italy (called LUPI, located in Padova), which represents a pole of excellence in chemical production. In fact, it produces active ingredients in Italy which are exported all over the world, providing research, development, industrial process safety, technical and regulatory support for the registration of new products in the chemical phase.

Naturally, having both the commercial and production sides in Italy is a clear testament to how important Italy is for Lundbeck at a global level.

Lundbeck is focused on CNS. How relevant would you say is the Italian scientific community in that area?

Italy is considered one of the leading countries in terms of scientific research on the brain, meaning the brain and not only mental health. Lundbeck is investing a lot in terms of phase three, phase two trials, which also involve Italian sites. Also, we are investing as a local affiliate in generating evidence locally and one of the things that makes me proud is that after the US, Lundbeck Italy is

the second country that has provided the most local evidence for MDD trials

In addition, it is also an honour to say that even if we have not yet launched our migraine drug, because we are still in the negotiation phase, we have already collected a number of local requests to understand the migraine pathway. Furthermore, we have full support from the global organization to run these kinds of projects. Another reason we are proud is that at the end of 2020- during the COVID 19 second wave, we launched, together with our partner Otsuka, an oral, anti-psychotic that is available in Italy, Switzerland, and the Nordics.

With respect to the MDD trials, were there issues with local bureaucracy and the fact that each region has its own protocol? What recommendations would you make in order to improve the situation?

The MDD trials I mentioned are independent trials that we decided to sponsor, but they are not Lundbeck trials. I am referring to trials that are run independently by hospitals, or the scientific community, and that we were asked to support and we supported. Of course, we know the difficulties in terms of ethical commissions and approvals, and this is the reason why many centres in Italy are not considered in very big international trials. However, with independent trials our experience has been very positive. It is also important to note that we have in many cases decided to support the scientific community in this way and not just through sponsored events. We prefer to generate scientific evidence and be considered as a partner to key Italian opinion leaders.

Apart from COVID-19 itself, the pandemic and its subsequent lockdowns have had an impact on mental health. Has the perception and practice of mental health care changed as a result of the pandemic?

COVID has been democratic with respect to mental health because it has impacted everyone, regardless of the age or status. The pandemic has changed the priorities of the general population, but it has also challenged the agenda of health professionals, including psychiatrists and other healthcare professionals. Everywhere in the world, psychiatric clinics are modifying their practice to guarantee care for people with mental health problems, but also to those who are not mentally ill and are suffering from the psychosocial consequences of the pandemic.

The pandemic and the related containment measures have had a detrimental impact on mental health. In particular, the increased loneliness and reduced social interactions are well-known risk

factors for several mental disorders, including schizophrenia and major depression. Concerns about one's own health and that of their loved ones, as well as uncertainty about the future, can generate or exacerbate fear, depression, and anxiety. If these concerns are prolonged, they may increase the risk of serious and disabling mental health conditions. A group at a particularly high risk is represented by infected people, physicians, and nurses working in emergency units and resuscitation departments. We may have a shortage of health professionals due to burnout and mental exhaustion.

Maybe now with the discussions that are happening in Italy about reorganizing the Ministry of Health, more emphasis will be placed on mental health. One of the general directions is to create a specific area dedicated to mental health and this shows how mental health is getting more and more attention from policymakers

In addition, it is clear that without mental health, you cannot think about productivity. Even if mental health can be invisible, the impact in terms of productivity is visible. You cannot be productive, if you are depressed or affected by anxiety and this is why we are launching several initiatives to promote mental health in workplaces.

What sort of patient engagement activities is Lundbeck involved in Italy?

At Lundbeck, we are wholly committed to restoring brain health and supporting people impacted by brain disorders. Our business activities, advocacy community engagement, and interactions with policymakers and NGOs are guided by the clarity of this purpose. Beyond developing transformative medical therapies, we strive to make a difference for people suffering from brain disorders, by working to increase support to affected families and engaging with communities to create broader social acceptance of people living with brain diseases.

That is why we collaborate with all main scientific societies, patient associations, institutions and organizations. We are carrying out many initiatives, among these I want to mention "People in mind" contest: an art competition to give hope to people living with mental illnesses and enhance the commitment of the associations that work with them. This year, with the third edition, we collected over 400 artworks from all over Italy and more than 40 projects from associations. We have also launched with *Biblioteca degli Alberi Milano* (BAM), a Riccardo Catella cultural Foundation project, "Art that heals, health starts from the brain": a cycle of artistic-cultural workshops focused on the importance of brain health.

On top of these activities, we have decided to reach out to young people and in July, presented the short film “Can you see me?”, part of the *adoleSCIENZE* project that stems from the need to raise awareness of mental illness in adolescence.

In addition, Lundbeck Italia, in collaboration with Giffoni Innovation Hub, acts as a spokesperson for this need to speak about depression directly to young people, as well as to their families, schools and to institutions, with responsibility and courage.

Do you see any changes in the near future with regulators in Italy?

With respect to drug approvals in Italy, we are in a changing environment more than ever, because with the new government that will come into effect in October. Submitting a dossier these days with this level of uncertainty is not easy. In addition, we need to consider that there is a public sector, but there is also a private sector and as Italians we are not used to considering the private sector. The scenario may change in five or ten years and perhaps we need to start thinking in a different way.

The possible change in Italy over the next 5 or 10 years that you mentioned, could it involve the introduction of co-paying? Could Italians be willing to pay more out-of-pocket fees or private medical providers for better care?

If you consider the level of funding of the system and the new drugs and services that will come into the system, the system is not sustainable. Thus, we need to find a different way to make services available to patients. And if it is not the public sector, maybe there will be another player in the private sector.

There is also an ethical issue. I have private insurance that pays 100 percent of my services and I do not use the public system. The public health system should not cover me when someone else is paying for my healthcare services. Thus, maybe the public path has to be considered only for people unable to afford private insurance because I cannot think that in five years we will have a public system that can cover 60 million Italians.

The number of women leaders in Italy is low compared to other regions. Would you say this is merely cultural or are there other factors involved?

It is cultural and I can easily say this because when the position for GM opened in Italy, I did not want to apply because I did not feel I was 100% ready and that I needed to prove myself more.

Yet, I applied and the process ran for three months with several assessments for the seven internal applicants from around the world. It was strange because I thought it was already decided, but it was not. Everything was based on the results of those assessments and on other KPIs.

I do not believe in quotas, but in skills and competencies regardless of gender, age, etc. However, I do believe in diversity, and I am referring to this while managing a leadership team made up almost entirely of women. I am where I am today also because I was encouraged by great mentors (all men) and I worked really hard on a job and for a company I admire.

Diversity is a mix. Inclusion is making the mix work. Equity is making sure we are fair and impartial in that process. Doing better business means empowering all team members by respecting and appreciating what makes us different. Diversity and Inclusion (D&I) allows us to accommodate differences that expand innovation and strengthen decision-making. An inclusive culture is essential.

Italy, along with other countries in the EU, has been granted an incredible funding line under the European recovery plan. Will these funds make an impact on healthcare?

In my view we cannot miss this opportunity to invest the recovery plan funds in the appropriate way. Of course, with Mr. Draghi [resigned Italian Prime Minister], we had more certainty about deliverables. However, as Italians, we are all aware of the unique opportunity that the recovery plan represents for the future of our country. We have to contribute to the evolution of Italy by leveraging the recovery plan. Of course, without Mr. Draghi, the challenge is more difficult than three months ago.

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