

Amalia Mihai – Market Access Manager, Ipsen Romania



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Amalia Mihai, market access manager of Ipsen Romania explains that over the course of 26 years Ipsen has been increasingly helping Romanian patients in the field of oncology, neurodegenerative disorders, gastroenterology and endocrinology. She reveals that a successful market launch entails having a patient-centric approach, supporting patients not only with products, but also new devices that educate and enhance adherence to treatment. She highlights through the launch of innovative medicines, such as cabozantinib – a new targeted therapy in oncology – the challenges of access in the Romanian market, such as the pricing methodology, and delayed reimbursement for patients.

Can you introduce yourself and the activities of Ipsen in Romania?

I have 20 years of experience in the pharmaceutical industry and have taken the position of Market Access Manager in Ipsen in 2017. My work focuses on patients access to innovative therapies, which have been developed by the company during 90 years of heritage in the industry. Ipsen has organized the business in therapeutic divisions, hence I coordinate the local market access strategy for all divisions, speciality care and consumer healthcare.

Ipsen is a global biotechnology company focusing on innovative medicines addressing serious debilitating diseases, such as neuroendocrine tumours, prostate cancer and renal cell carcinoma in oncology. Additionally, it is active in neuroscience addressing cervical dystonia, spasticity in adults and post-vascular accidents by offering treatment and support in rehabilitation. Furthermore, it caters to children with lower limb spasticity. Ipsen is also active in the field of rare disease area with hormone therapy, addressing to individuals with acromegaly, a growth hormone disorder, or to children suffering from growth hormone deficiency. In the future, Ipsen plans to address and strengthen its rare disease portfolio.

Consumer healthcare medicines have a longer history, focused on gastrointestinal conditions with well-established medicines, such as Smecta, and on neurodegenerative diseases, with medicine from ginkgo extract.

Ipsen has been active in Romania since 1994 and over 26 years, it has continuously increased and facilitated treatment of patients. The importance of the Romanian market reflects also the fact that last year we established a full legal entity here.

What have been your main achievements since taking over this role with Ipsen?

The main achievement was enabling broader access to treatment for patients with neuroendocrine tumours, based on an update of local guidelines with latest clinical studies with lanreotide.

The second achievement was to ensure patient access to reimbursed treatment for spasticity for patients who suffered a stroke. We tried several years to convince the authorities about the need for such a treatment. Finally, this is part of the daycare service hospitalization and used in the rehabilitation phase.

Romania has the second-highest incidence in Europe for cardiovascular diseases, and one of the highest rates of strokes, following that patients remain with members spasticity. Consequently, about 60 percent of the patients that suffered a stroke are remaining in a condition that is not permitting them to lead a normal life. Hence, the reimbursement of this treatment makes it that much more impactful as there is a tremendous need in Romania.

How developed is the oncological division in Romania and has cabozantinib reached patients yet?

Oncology is Ipsen Romania's flagship therapeutic area, and this is where we perceive the highest patient's need coming from currently.

Lanreotide is Ipsen's first blockbuster, it is available to the Romanian patients and it is on its way to becoming the market leader in the treatment of neuroendocrine tumours and acromegaly. Ipsen has a patient support program for diagnostics and preventions tests because in many cases the disease has confusing symptoms and is discovered at a late stage.

Triptorelin, a reimbursed treatment in prostate cancer which is the fourth largest cancer in terms of incidence in Romania, is now considered already standard therapy in this pathology.

Cabozantinib is an innovative targeted therapy for renal cancer that has been available in Europe for the last two years, while in Romania was a long project to get it this far. Currently, the finalisation of

the reimbursement process is expected soon, while the reimbursement list update is under review by the authorities.

There are around 30 new molecules to be included on the reimbursement list, among them is cabozantinib. In Romania, ANMDDMR issued a Decision for the conditional inclusion of cabozantinib in the List of reimbursed medicines. Ipsen carried out all the legal procedures for negotiation and signing of a cost-volume contract with the National Insurance House (CNAS) in accordance with the applicable legislation. We are aware of the fact that patients urgently need the reimbursement status to come through. However, the reimbursement finalisation might be further delayed by the competent authorities due to the political turmoil and economic deficit in the country.

Where do you see growth coming from?

We assume that we will continuously grow in all segments of our portfolio, especially in neuroendocrine tumours as well as in neuroscience and also in Consumer Healthcare.

Currently, the new topics are prostate cancer and tumour treatment in oncology. The future focus for oncology, for Europe as well as in Romania, is in renal carcinoma for the patients, that were previously treated, with a progression on the disease.

How has 2019 been for the affiliate?

This year has been successful, as we have reached our targets and fully achieved what we had forecasted for this year.

How do you go about to patients having access to Ipsen's latest innovations?

In Europe as well as Romania, the governments have cost-containment measures. Increasingly, medicines are putting pressure on public funds, that is why companies must contribute to facilitating patient access to treatment in accordance with the applicable legislation (e.g. claw-back tax, contribution based on cost-volume/cost-volume-result agreements).

Unfortunately, Romania is particular, as there is a long waiting period until new drugs are approved and available on the market. The bureaucratic gridlock and the unpredictability are the biggest challenges for market access of innovative medicines. The lack of continuity of health authority's leadership roles is a major hurdle.

According to a 2018 IQVIA study on access to innovative medicines, Romanian patients have to wait on average 2.4 years to have access to the same medicines as in Europe, and during this time Western Europeans can be treated and have a chance at improving quality of their lives.

Are you planning on bringing new products to the market this year?

The global vision of Ipsen is to launch each year a new product or a meaningful new indication. In Romania, the affiliate tries to keep the same rhythm, even though it is difficult, by being proactive and anticipate changes in the market.

Indeed, this year we hope to officially launch cabozantinib for renal cell carcinoma as well as a new indication for hepatocellular carcinoma. Furthermore, there is a new indication for botulinic toxin for lower limb spasticity in adults, as well as breast cancer indication for triptorelin molecule.

Ipsen tries to make the vision possible in the benefit of the patients and to cooperate with the competent authorities in this respect.

How has the environment impacted Ipsen's portfolio?

Ipsen is in a good position and so far, it was not forced to take any business decisions to withdraw products from the market. However, as the market changes constantly in an unpredictable way, we cannot exclude any changes in the future.

The minimum pricing methodology, as well as clawback tax, make for a brutal combination. Last quarter of 2019 the tax jumped up to 27.65 percent, and the estimates predict that it will grow to 30 percent. Additionally, each delay in the reimbursement process forces price adjustments, and this drives down the top line. Hence, with no predictability, implementing a strategy and a long-term forecast is a challenge.

What is the significance of the affiliate for Ipsen's regional presence?

Ipsen Romania is a significant player of Ipsen Central European Cluster and a strong player in the consumer healthcare business. The tradition and the interest of the patients in medicine have been kept and maintained. Nevertheless, we hope to grow further in speciality care.

There is great potential for Romania and for Romanian patients. The environment remains still a difficult challenge.

What makes a good market access strategy for Ipsen?

The focus on the patients' needs is paramount to the success of a medicine. It does not matter whether it is related to medicine itself or providing education if it benefits the quality of life for patients, and caregivers can support them.

This year Ipsen will launch a new device of lanreotide for patients who suffer from neuroendocrine tumours. It will allow patients to inject themselves, or have a relative do it, and it curbs the cost of travelling and consulting a doctor. This ensures patients' adherence to the therapy. It is not a new product in terms of treatment, but it supports existing assets in the market by facilitating access and understanding.

What are the objectives and priorities that you have set for the affiliate and yourself?

For the affiliate and for myself, it is to ensure access to medicines and to improve the quality of life here in Romania. There are a lot of things that need to be done, and we need to be open to the life stories of the patients, in the hopes to save as many lives as possible.

What are your goals for 2020?

There are many things, but on the top of the list is to make cabozantinib available and reimbursed for the Romanian patients. The wait has been long, and I wish that we can shorten the gap between Romania and other European countries in the benefit of the patients.

In Romania, funding and allocating the budget efficiently remains a challenge and has severe ramifications on the healthcare ecosystem. Ipsen is a supporter of the EU initiative for a cancer masterplan. This is an initiative to elevate oncological care in the country through enhanced prevention, screening, rehabilitation of the patient, and reintegration of a cancer patient in society.

What has been your proudest moment with Ipsen?

My proudest moment and achievement since joining Ipsen was working to extend the reimbursement for more patients with neuroendocrine tumours and working to the approval of reimbursement for patients with spasticity which needed botulinic toxin treatment in rehabilitation after a stroke. The greatest achievement is yet to come from bringing to patients with renal cell carcinoma the new oncology drug in Romania.

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