Tamás Demeter – Country Manager, AOP Orphan, Hungary

AOP Orphan is a highly specialized company that truly caters to a niche segment of rare diseases.

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Tamás Demeter, Country Manager for AOP Orphan shares his insights on the footprint of the company in Hungary, the areas of therapeutic need that AOP caters to, the performance of 2019 and its key achievements, the ecosystem of rare diseases in Hungary, and patient awareness while highlighting the role of the government.

Can you introduce yourself and AOP Orphan's operations in Hungary?

I have 20 years of experience in the pharmaceutical industry, where I held several positions in multinational companies such as Wyeth and Aventis. A decade ago, I joined AOP, which was at the time a relatively small company. Over the years, it has grown rapidly and focuses on orphan diseases.

We try to introduce innovative solutions and redound the access for the patients to these new treatments. AOP's area of focus is haemato-oncology, pulmonology, and metabolic disorders. The core products of the company focus on essential thrombocythemia, primary biliary cholangitis and pulmonary arterial hypertension, while future development will tackle polycythemia vera.

Currently, AOP is cooperating with another company on a joint product for this condition, which received approval from EMA and will be introduced to the market shortly.

AOP’s history in Hungary spans back 10 years and has remained a small operation to this day. There are only a few people on the team, as the company is manoeuvring in a highly focused territory. Nevertheless, it has contact with the relevant authorities to benefit from a successful market access pathway.

How is AOP’s entire portfolio reflected in Hungary?

We try to follow the global strategy and follow the same therapeutic areas as the one from headquarters, yet we need to adapt it to the local market to ensure maximum compatibility.

What were some key achievements for AOP in 2019?

Ropeginterferon alfa-2b, a new hemato-oncology product, has received European approval and is promising for the Hungarian market: it is much anticipated by hematologists. This product got early access to patients before EMA approval, and it received positive feedback during the clinical practice. Currently, the product is in the negotiation phase with the health insurance fund for the reimbursement.

What are important factors that constitute a strong market access strategy?

There is not a set strategy that fits every country, one must accept local constraints, possibilities and regulatory frameworks. In Hungary, success is driven by the discussion with the authorities, which means finding common ground on approval and pricing issues to help the patient segment.

What areas need to change to improve access to innovative treatments of rare diseases in Hungary?

Hopefully the approval process will change in the future and introduce new guidelines for products with orphan drugs designation that focus on small segments of the population. The model in place in Hungary caters to drugs meant for the general masses, which takes into consideration relevant

data. However, the sample size affected by these diseases is so small that it is difficult to provide comprehensive data for the evaluation process.

How would you assess patients' awareness of rare diseases?

Awareness is fostered through the relationships that patients build with their physicians and patient advocacy groups. They are the engine that generates movement and representation for key issues as well as developments. If the therapeutic area is not well-represented or is in a disarray, it will leave patients unaware of new treatments. Hence in some cases patients are unfortunately not as up to date as they ought to be.

Have you seen any impact from the seven-year national rare disease plan?

In light of the case of two children who were diagnosed with spinal muscular atrophy receiving a brand new and excessively expensive therapy through donations from citizens, as the reimbursing system refused to finance it, the government has passed a decision that greatly enhances access to orphan drugs and rare disease therapies. This decision would allow children under the age of 18 to have access to these therapies while the government would pay for them.

This example demonstrates how the social sensitivity as well the general governmental approach have changed owing to the implemented national rare disease plan.

There is still some ground to be covered, including removing administrative barriers and revising the approval procedure. This could reinvigorate innovation while giving Hungarian patients access to the therapies they need.

How is AOP in Hungary helping to raise awareness and education amongst the health stakeholders?

The collaboration with patient organisations and professional associations is intensive and tight. They are open and helpful to build a successful cooperation. As a result of these common efforts, even individualised educational and supportive programs could be implemented.

Nevertheless, there are still fields in the therapeutic area where no patient organisation exists for the rare diseases, which could protect affected patients' interest.

How would you see the care of rare disease in Hungary improving?

During the evaluation process the treatment of orphan diseases should be firmly separated from other diseases. Certain rules are currently not adequate or are not applicable to rare diseases. Clinical trials are not always applicable for technology assessment owing to the low number of involved patients.

What role does AOP have in improving these aspects?

AOP Orphan is a highly specialized company that truly caters to a niche segment of rare diseases. However, in the grand scheme of the ecosystem, it is still an important player that is always interested in collaboration.

What was your motivation to move from big pharma to a rare disease company?

In large companies the tasks are firmly divided and the decision-making is clear cut. However, in smaller entities you must fulfil different tasks and have a broader overview that requires more flexibility.

What are your objectives in the next five years?

I am convinced that the company will continue growing and will be able to broaden its portfolio in new therapeutic areas. Furthermore, a shortened approval process would be welcome for new orphan drugs. This would also require a stronger advocacy capability, which would go hand in hand with a larger therapeutic portfolio.

What is your final message to authorities?

The healthcare system, as well as new therapies, are changing the landscape for which governments and authorities have to adapt. As new opportunities arise for investments, I urge them to find innovative methods instead of sticking to used ones. Have the courage to find a new approach and lead Hungary into becoming a model to follow.

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