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Access to innovation remains the most pressing matter: how to create a fast, effective, and sustainable reimbursement system

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Dr Péter Holchacker, director of the Hungarian Association of Innovative Pharmaceutical Manufacturers (AIPM), shares his insights on the key activities of the organisation, the collaborations it fosters with authorities and multinational pharmaceutical companies, the attractiveness of the Hungarian market, and the AIPM's role in improving the country's regulatory and reimbursement system.

Can you introduce the Association of Innovative Pharmaceutical Manufacturers (AIPM)?

AIPM is classical national trade association with the specific role to cooperate with administrative and governmental incumbents, while representing the interests, findings and ideas of its members to decision-makers. It assists its members from the clinical trial stage to the marketing of finished products. AIPM does this by engaging stakeholders in open discussions and supporting the improvement of the regulatory framework and legal environment. However, it also forwards its own policy suggestions that are deemed favourable for both the industry and the regulatory bodies. The association is part of the Hungarian healthcare environment and its goal lies in the betterment of patient outcomes, collaborating with all parties in order to improve patients’ access, reimbursement, and portfolio of drugs.

AIPM recently conducted the First Innovative Pharmaceutical Overview to research the situation of innovative medicines in Hungary. What was the purpose of this survey?

The innovative pharmaceutical overview survey is an example of AIPM's efforts to bring complex healthcare issues to the attention of the general public and the government in a digestible fashion. The survey was an in-house poll, compiled by pharmaceutical executives and highlighted the expectations linked to therapeutic areas that are influenced the most by emerging innovations. Ultimately, the aim is making healthcare concerns visible and understood, to facilitate conversations around these topics.

What are the main issues and agenda of AIPM and its members?

Access to innovation remains the most pressing matter: how to create a fast, effective, and sustainable reimbursement system. Hungary has one of the most bureaucratic clad and complicated systems, as it takes two years until a new drug is approved. The approval process requires political decision, as the healthcare budget is not under the State Secretary of Health, but under the Minister of Finance; some decision even requires approval from Prime Minister Office moreover. Hence, reimbursement lists and additional funding require the approval of ministers that are far from the issues and industry. It creates difficulties and challenges for the entire healthcare ecosystem, as there is a lack of transparency regarding process guidelines. Furthermore, the higher proposals go up the hierarchical structure, the more condensed they must be and do not encapsulate the entire picture. In addition, there is no deadline for approval, and the AIPM is trying to improve that.

Beyond the regular and normative reimbursing methods, there is an individual and equity-based reimbursement system for patients to get access to innovative treatments that is applied in more comprehensive way recently (20k patient involved in annually). Each one of them needs to submit a lengthy proposal that stipulates why they should get access to these new treatments. No doubt that it is an option for filling the gaps of the regular reimbursement system, however, it is not designed for everyday application and it is far not a patient-friendly procedure.

What are the most important areas of change to create an improved reimbursement and regulatory system?

The bureaucratic burdens need to be minimized as there is a long administrative paper trail. Furthermore, there needs to be more transparency on the approval decisions so that regulatory bodies, pharmaceutical companies, and most importantly, patients, can have an overview when therapies are approved or rejected and why. From the legislative perspective, the Hungarian decision-making procedure is quite in line with the European requirements and transparency directives. However, the political influence in the decision-making process makes it hard to support improvement efforts, as it is unclear where the needs are. Another area of change would be to reconsider the allocation of the healthcare budget. There is a disproportionate distribution of funds between affordable and innovative therapies that reduces room for reimbursing or subsidizing innovative products that patients need. This is an utmost sensitive issue, however, this is put into question as in impedes the access of patients to vital therapies.

How open are the health authorities in communicating with the industry and engaging in these discussions?

AIPM has a good relationship with the government and is a reliable partner in these special issues. To have an open door for these types of discussions. However, overall there is some room to manoeuvre and to build more trust between the decision-makers and the business players.

What other opportunities do you see between the healthcare payers and the industry?

The industry has a long-standing relationship with the payers and the insurance authorities. It is a close and natural partnership. There are instances where payers and industry players are unified on the same issues, even if it means that they end up paying more. Better access and improving the system is the priority of every stakeholder in the healthcare system.

What makes Hungary attractive as a potential market to enter?

The current Hungarian administration is making serious efforts to provide business opportunities for newcomers by supporting them with favourable financial and regulatory policies. However, some of these incentives are focusing on regular business and investment. For instance, clinical trials initiated by multinational companies, represents EUR 300 million which the government is not fully taking advantage of. This is a considerable economic investment for the country but also in

the health sector, that is left untapped.

Do your members still see Hungary as an attractive destination for substantial investments like clinical trials?

Absolutely. Nevertheless, the regulatory framework needs preparation and maturing, if Hungary wants to continue to remain competitive in the region and Asia. There is tremendous competition between the European, Central Eastern, and Asian countries in this domain. The needs and requirements encompassing clinical trials are increasingly demanding, and a new European policy implementation is not enough to improve the attractiveness of the country. Rather, the entire ecosystem needs to be strengthened including healthcare providers and professionals to increase and improve the prospective of hosting clinical trials. Overall, Hungary is ranked number four in Europe for clinical trials per capita, which is evidence that the healthcare system is competitive and more than suited to host as well as conduct trials.

AIPM is cooperating with key investigators and opinion leader in this area, pharmaceutical partners, and authorities while taking over some of their duties. The national database of clinical trials is being developed under the auspice of the association, and the beta version will be released in the upcoming weeks.

How do you expect Hungary’s pharmaceutical market to evolve in the upcoming years?

We can be optimistic, but there are some basic requirements that need to be met to change it into real success. The Rx market faces challenges which requires the reimbursement system to be reconsidered: less than half of the approved EMA products have entered the Hungarian market. Those that do enter the market still need up to two years to be available. Nevertheless, there is a well-established market for OTC products and well experienced professionals in the environment. The potential is here and there will be growth, but we need to ensure that it is sustainable and can be adaptable for future challenges, i.e. shortages, price fluctuations, etc.

What your final message on behalf of AIPM?

The association is doing its best to help and support the Hungarian healthcare environment, with the goal to improve the system holistically for the benefit of patient outcome. Hungary has a

unique and delicate balance between the political sphere, national manufacturers, and multi-national companies who are all interdependent of each other.

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