
# Towards more effective use of Innovative Models to facilitate the Negotiation Outcome

Renata Valsami

Health Policy & Government Affairs Manager, HealThink

Renata Valsami, Health Policy & Governmental Affairs manager at HealThink, gave a short presentation in a round table discussion focusing on the **effective use of innovative models to facilitate the medicines' negotiation outcome** during the 8th HTA Conference which took place on June 14th, 2023, in Athens Greece.

Renata through her extensive experience from the pharmaceutical industry and valuable insights from her participation in the first drug price negotiation committee in Greece has gained a holistic view of market access pathways for innovative medicines in our country. In her presentation she tried to capture the most important elements a that are required to move forward and prepare sustainable access paths for innovative technologies.

Starting from the definition and the classification of Managed Entry Agreements based on the objective they are called upon to support and the rationale that governs their design, she presented possible mechanisms that could, under certain conditions, be used **to implement personalized agreements for new innovative products.**

Agreements that take into consideration all the unique characteristics of a treatment and the accompanying uncertainties that the payer must respond each time, e.g., the impact on the budget or the proper use and adoption of the medicine, or the clinical uncertainty due to limited clinical data such as treatments for rare and serious diseases.

More specifically, she referred to the financial type of agreements, which are the most frequent, as they are easier to implement, and which have a very clear rationale: how the payer will manage the expense resulting from the introduction of technology in the reimbursement system. Financial agreements range from the simple discounts, which are the most common form of agreement in Greece, to more complex such as volume-price agreements, budget caps either at the drug level, or at the patient level, or at the therapeutic class level, and so on.

She also referred to the performance -based agreements, i.e., agreements that link reimbursement to the therapeutic outcomes of the technology. These are more complex, require more effort in their implementation

and may even be more costly. One of the most well-known examples is the "Performance Guarantee": the state covers the treatment only to patients who have the expected outcome while for the rest the treatment is covered by the pharma company either partially or entirely. There is also the "Coverage with Evidence Development" agreement: the principle is to reimburse the health technology, provided that data are collected through a clinical trial or through a register and after a certain period of time it is reassessed whether reimbursement will continue or not, or on what terms. In this case, there is a need to provide for additional procedures, such as an extensive clinical study, or a registry and several questions arise such as who will do the evaluation at the end of the predetermined period (HTA Committee?), who will bear the costs of the clinical trial or registry, or who will have access to the data and at what level.

Finally, there seems to be a lot of interest recently in service-based agreements, i.e., services offered by pharmaceutical companies that have as a rationale to support the proper use of medicine, whether it is patient support programs or screening programs, support for the development of a registry, funding diagnostic tests or biomarkers required, etc. These services are included in the overall agreement with the negotiating committee and are usually combined with a financial or performance -based agreement.

**The rapid development of new highly innovative therapies that radically change healthcare and/or save lives, requires the design of more complex and personalized Managed Entry Agreements that respond to the accompanying uncertainties and ensure unhindered patient access and long-term sustainability of the Pharma Industry in Greece.**

The key success factors for the implementation of these agreements include **a well-defined strategy** with objectives and expected outcomes, **an operational framework**, transparency of all processes that need to be integrated into the HTA and negotiation process e.g. Horizon scanning, a thorough **analysis of the existing data infrastructures** and possible adjustments that need to be made, the **organizational structures** that are required to support the whole process (a single HTA organization and negotiation possibly) and finally, the required **skills and capabilities** of people and organizations to support these agreements.

At Healthink, in 2022 we tried to capture in a systematic way **how Managed Entry agreements are implemented in Greece** from the beginning until today and to include in a research report possible obstacles, opportunities, and proposals for the future. Hopefully we will be able to update the report annually with all the latest developments and evolution of MEAs in Greece, shaping the future of sustainable access.

Finally she pointed out that after 5 years of experience as a country and in view of all the exciting innovations to come, we have a unique opportunity to open the dialogue on issues such as the generation and access to data necessary for the implementation of complex agreements, the design and use of drug registries, the design of innovative agreements adapted to the health system of our country, upgrading the technical skills of the organizations and people involved.

This dialogue should involve all stakeholders, not only the Negotiating Committee and the pharmaceutical industry, but also bodies such as EOPYY and EKAPY that implement these agreements, but mainly the leadership of the Ministry of Health, which is responsible for the political guidelines and decisions that will facilitate and support the work of the committees and other bodies.