



Addressing uncertainty - managed entry agreements for pharmaceuticals in the context of adaptive pathways in Europe

(Abstract - Manuscript in preparation)

September 2017

The work leading to these results was conducted as part of the ADAPT SMART consortium (Accelerated Development of Appropriate Patient Therapies: a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes). For further information please refer to www.adaptsmart.eu. This paper is the result of the collective input from working group D3.05 and D3.07 and only reflects the views of the authors.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115890. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.



Abstract

After adaptive pathways were first introduced in 2012 as a new scientific approach to the development of innovative medicines, the concept evolved considerably culminating in the adaptive pathways pilot that was successfully completed by the European Medicines Agency (EMA) in 2016. Adaptive pathways are a prospectively planned pathway for the development and introduction of a promising new pharmaceutical product to facilitate the earliest appropriate patient access to products addressing high unmet medical need. Yet, none of the products that have participated in the EMA adaptive pathways pilot have entered the market which makes the implications of adaptive pathways products for Europe's national healthcare systems and their pricing and reimbursement processes unclear. Although adaptive pathways involve HTA bodies in planning the managed introduction of a new medicine facilitated through early dialogue and scientific advice during the clinical development of the product, hesitation among HTA bodies and payer remains. Downstream stakeholders fear they might be confronted with products entering the market that will not have the evidence available suited for their decision-making processes. This review reports the findings of several activities undertaken by the ADAPT-SMART Consortium to explore the suitability and availability of managed entry agreements for adaptive pathways products in the European setting that might facilitate the managed introduction of adaptive pathways products.