



# **Enablers of decision making in an adaptive environment: managing uncertainties and disengagement strategies**

**(Executive summary – document under review by consortium)**

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## **Executive summary**

The development, evolution and availability of the Medicines Adaptive Pathway to Patients (MAPPs) concept as a mechanism of appropriate early access of innovative medicines to patients with a high unmet medical need, centres on the application of this concept within the existing regulatory and legal frameworks. MAPPs addresses the evidence vs access conundrum through a progressive reduction in uncertainty as more evidence is generated through iterative multi-stakeholder dialogue and assessment. For a product to utilize MAPPs it must fulfil criteria (engagement criteria), before entering the pathway. During iterative cycles of development, multi-stakeholder consensus is sought at key engagement points. Under MAPPs each stakeholder and decision maker retains their remit and responsibility - the regulators and payers as decision-makers will retain full ownership for granting/ withdrawing marketing authorization or granting/withdrawing reimbursement based on their assessment.

However, MAPPs also requires stakeholders to engage in a common dialogue during the development process to define which evidentiary uncertainties to address. The early and continued dialogues create a moral obligation for stakeholders to complete the process and to inform each other from the decisions taken. This collective engagement whether formalized or not raised discussions amongst stakeholders on their ability to disengage or exit from MAPPs and how to manage the impact of a negative opinion and potential product withdrawal.

We have found that the terminology surrounding disengagement from MAPPs needs further clarification as interchangeable terminology such as, 'exit strategy', 'withdrawal', or 'disinvestment' holds different meanings and different implications to different stakeholders.

It is not possible to map all the potential scenarios under MAPPs where disengagement may occur, as many will be specific to a product or a therapeutic area. We have sought to consolidate an understanding, but not seek consensus, across various ADAPTSMAART deliverables on the rationale why disengagement from MAPPs might occur, how it may impact stakeholders and where gaps exist for stakeholders. We identified two important gaps ; i) the lack of established best practices to manage price adjustments based on the level of evidence (mainly for pricing and reimbursement authorities) and ii) the lack of an established detailed process of how to concretely disengage from MAPPs and how to effectively manage the impact such decision has on other stakeholders. The later could be specified in an overarching agreement that would accompany the development process and covers topics such as the binding or non-binding nature of dialogues, stakeholder duties and expectations, a mechanism for conflict resolution or arbitration, and best communication practices. We provide a summary of discussions around these topics to stimulate further exploration on how best to manage disengagement from MAPPs as the concept matures.