Cumbersome, complex and unclear regulatory processes

Limited predictability of required evidence and development costs can be an obstacle in VAM development.

Absence of incentives that encourage continuous innovation

The further complexity, cost and duration of VAM development compared to standard follow-on products is not rewarded.

Lack of recognition of benefits, investments and added value in EU markets

Payers often categorise VAMs as standard generic medicines. P&R bodies require disproportionate amounts of evidence to assess and recognise the benefits of VAMs.

value added medicines