Avicenna Alliance
Association for Predictive Medicine

AVICENNA ALLIANCE FEEDBACK ON THE REVISION OF THE EU GENERAL PHARMACEUTICALS LEGISLATION

The Avicenna Alliance supports the Commission's ambition to revise the EU's general pharmaceuticals legislation as it represents an ideal opportunity to update the regulatory framework to reflect the uptake of new technologies, including in silico technologies such as Computer Modelling and Simulation (CM&S), for medicinal products including combination products and Advanced therapy medicinal products (ATMPs).

1. Unmet medical needs

When considering a new definition for 'unmet medical needs', the Commission needs to consider the benefits offered by CM&S for regulators in assessing the benefit-risk of medicines. By generating additional data in a short period for regulators and HTA bodies, in silico technologies can enable a better characterisation of these unmet medical needs, accelerate products development and approval, and allow for better prioritisation when considering access aspects.

The Avicenna Alliance calls on the Commission to consider in silico technologies as a relevant source of data to refine, reduce and occasionally replace clinical trials, accepted by both regulators and HTA bodies/ payers, as evidence for approval and access to innovative therapies in unmet medical needs such the field of medicines for children and rare diseases.

2. System of incentives

When evaluating and revising the general pharma legislation, the Commission should maintain the spirit of incentivisation, by clarifying for researchers and industry, the regulators' requirements for acceptable in silico technologies application to demonstrate efficacy and safety of new treatments. The Avicenna Alliance stresses that academic and industry using in silico technologies, generating digital evidence of the efficacy and safety of treatments, should be incentivised and rewarded for doing so through the acceptance by regulators of this digital evidence.

3. Evidence generation tools for marketing authorisation of innovative medicines

In silico technologies allow us to leverage real-world evidence and generate digital evidence on the safety and efficacy of medicinal and combination products, leading to faster development overall. The performance of CM&S, including in silico trials, produces digital evidence, which is particularly interesting for paediatric and rare diseases, whereby evidence cannot be generated through in vitro, ex vivo or in vivo models, or is very challenging.

The Avicenna Alliance calls on the Commission to urge regulators and HTA bodies to accept evidence, particularly leveraging real-world evidence, as this encourages rapid and more efficient product development, as well as better post-marketing data collection that informs benefit-risk.

4. Support and accelerate product development and authorisation

In silico trials enable the rapid and safe development and testing of medicinal products by speeding up the development pipeline through the prediction of therapeutic failure without exposing real patients and minimising the undesired effects. They can dramatically reduce time and costs linked to the development process including the number of clinical trials, and even complement ongoing clinical trials by performing modelling and simulations on virtual patient cohorts.

The Avicenna Alliance calls on the Commission to equip the EU with a regulatory framework acknowledging the emergence of in silico technologies and to establish a clear regulatory pathway for the use and acceptability of in silico trials in the context of medicines and combination products development in the EU.

Besides, the Avicenna Alliance asks the Commission to streamline the regulatory assets to include guidance for academia and industry to perform reliable in silico trials of the highest quality. There is a need for the Commission to develop harmonised common EU standards on ‘Good Simulation Practice’ to ensure the robustness and the quality of computer models in medicinal and combination products development.