value added medicines

a medicines for europe sector group

Creating a European ecosystem

for safe, timely and affordable patient-centric innovation

EU Pharmaceutical Strategy: a historic opportunity for R&D investment on off-patent medicines and better treatment of patients.

The Pharmaceutical strategy for Europe aims to address unmet health needs and the accessibility and affordability of medicines. **Value Added Medicines are defined as an accessible, affordable innovation to address health needs** that are especially important to larger patient populations in both, communicable and non-communicable disease management.

We recommend the establishment of a new, simplified regulatory pathway for VAMs. By **recognising VAMs as a category of innovation with a dedicated pathway and tailoring the system of incentives provided by the EU pharmaceuticals framework** to support innovation throughout a molecule's lifecycle, we can achieve a competitive and resource-efficient EU pharmaceutical industry while delivering medicines to satisfy the unmet need and improve the lives of patients in Europe.

How can Value added medicines make a difference to patients and healthcare systems during a pandemic and beyond?

REPOSITIONING - FINDING NEW INDICATIONS TO ADDRESS UNMET MEDICAL NEED

Dexamethasone, affordable steroid, repurposed for Covid-19 treatment, reduced deaths by 1/3 in hospitalised Covid-19 patients receiving mechanical ventilation.

REFORMULATION - FACILITATING PATIENT TREATMENT IN A HOME CARE SETTING

Covid-19 dramatically reduced accessibility of care and changed patients' needs in a number of ways. VAMs can support patient-centered reform of care with medicine reformulation and offer patients new ways to administer their own treatments at home and avoid in-person hospital visits.

COMPLEX COMBINATIONS - UTILISING DIFFERENT RESOURCES TO DELIVER THERAPY

Digital Value Added Medicines, combine medicines with innovative technological solutions and can support the patient-HCP relationship and improve treatment adherence in a remote care setting.

Design fit for purpose regulatory framework thatwill enable clarity earlyin the development

Establishment of a new legal provision that would result in a dedicated VAM regulatory pathway.

Recognise VAM as a category of innovation with proportionate incentives

Recognise innovation in form of granting a non cumulative period of 4 years of data exclusivity.

Recognise and define value for healthcare systems

Pricing and reimbursement rules should be shaped to adequately assess continuous innovation.

EU environment for value added innovation