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.

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EU environment for value added innovation

- **Design fit for purpose regulatory framework that will enable clarity early in 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.