value added medicines
better access. better health.

Press release

Now or never: Europe must seize the Pharma Legislation opportunity to ensure patient access to continuous innovation for existing medicines

Brussels, 07 November 2022

Medicines for Europe, representing the European value-added medicines industry, is calling for legislative reforms that will pave the way for patient access to safe, timely and affordable innovation for known medicines.

Medicines repurposing has emerged as an important strategy to address patients' needs. This kind of off-patent innovation can play a major role, particularly at a time when the affordability of health systems and patient access to treatments are significantly challenged, helping also to address treatment gaps where they currently exist. For example, as many as 27% of essential oral oncology medicines today lack safe, age-appropriate formulations for children; Value Added Medicines (VAMs) can provide paediatric patients with safer, more appropriate treatment.

The Chair of the Value Added Medicines Sector Group at Medicines for Europe, Arun Narayan (Viatris), commented *"The European pharmaceutical legislation review is an unprecedented opportunity to ensure sustained innovation for existing medicines, with significant benefits for patients, healthcare providers and healthcare systems. We are happy to support a dedicated article for medicines repurposing and we are resolutely committed to continuing our collaboration with policymakers at both European and national levels. It is equally important to find solutions for building the legislative pathways that are needed for value added medicines, as well as the incentives that will foster their development in Europe".*

Medicines for Europe is calling for:

1. **Streamlined regulations**: Value Added Medicines should be recognised as a separate group of medicines, having their own dedicated regulatory pathway to expedite patient access to VAMs.
2. **Incentives**: Proportionate data exclusivity for all Value Added Medicines that bring significant benefit to patients would support developers in ensuring affordable access to more treatments.
3. **National implementation**: Alignment of the means to recognise the value offered by VAMs to patients, healthcare professionals, and payers across Europe.

About Value Added Medicines

Value Added Medicines (VAMs), which result from repurposing existing therapies, present an opportunity to bring new treatments for indications or populations where no approved therapies exist. VAMs can also be derived from reformulating or combining existing therapies to fulfil patients' unmet needs and improve health outcomes.

For example:

- Over the past 5 years, a value added medicine aimed at epilepsy has helped to treat almost 7 million seizures in children[1]

[1] Based on IQVIA data

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- We know that over 50% of patients face challenges with adherence to their prescribed therapies. This often leads to exacerbation and therapeutic escalation – this alone is estimated to cost up to 125Bn Euros/year [2]
- In England alone, moving to 'ready to administer' formulations can free up the time of more than 4,000 nurses each year[3]

Resource hub

The future of value added medicines was discussed at the VAM23 conference in Brussels on 07 November.

Factsheet & White paper – Creating a European ecosystem for safe, timely and affordable patient centric innovation

Podcast - Value added medicines: a patient-centric approach to healthcare

[2] Toumi et al, 2016

[3] https://www.gov.uk/government/publications/transforming-nhs-pharmacy-aseptic-services-in-england/transforming-nhs-pharmacy-aseptic-services-in-england#:~:text=the%20UK%20economy.-,The%20case%20for%20change,-Transforming%20pharmacy%20aseptic