

Giving medicines a new life

Value Added Medicines (VAMs) present an opportunity to bring treatments for indications with no approved therapies and improve existing ones. They can reduce unmet medical need (repurposing/repositioning), optimise existing medicines to allow for patient-centric design or address healthcare inefficiencies (reformulation) and combine medicines or substances with digital services or devices to substantially improve treatment outcomes (complex combinations).

In Europe, there is significant untapped potential in innovation on existing therapies, providing an opportunity for patients, healthcare providers, payers, industry and healthcare systems. Re-evaluating the current innovation model should lead to greater focus on ways to stimulate innovation across the lifecycle of medicines and especially on off-patent molecules.

To promote an innovation ecosystem that focuses on relevant benefits to society, we need to consider some fundamental changes in the way innovation is currently fostered and evaluated. The pharmaceutical industry is transforming to continuously bring value to patients through sustained innovation in off-patent medicines.

- How can VAMs address some of the key healthcare challenges of today?
- ➤ How can the value of VAMs be captured for society?
- ➤ How are we advancing medicine repurposing in Europe?
- How could we shape an EU environment that supports continuous treatment improvements? How does continuous innovation fit into the broader EU agenda to bolster access to treatment and innovation?

The Value Added Medicines Conference will gather a wide range of experts in the healthcare community to share best practices and discuss patient access to continuous innovation. Come and join us to learn more about Value Added Medicines and to discuss the current environment, challenges, and opportunities in Europe.

Wednesday 30 November

08:00 09:00



Welcome coffee and registration

09:00 09:20



Opening addresses

- Arun Narayan, Head of Global Commercial Development, Viatris and Chair of the Value Added Medicines
 Sector Group, Medicines for Europe
- **Cristian-Silviu Buşoi**, Chair of the Committee on Industry, Research and Energy (ITRE), European Parliament and substitute member of the Committee on the Environment, Public Health and Food Safety



09:20 10:30



Healthcare needs of today: How can VAM address some of the key challenges?

What are the healthcare needs that are currently unaddressed? How could we tackle these by improving existing treatments or finding new ways to use them? In this session, we will aim to understand what the challenges for patients are when it comes to receiving the right treatment at the right time and explore the opportunities that VAMs can bring to healthcare.

Moderator: Kate O'Regan, Communications & Stakeholder Relations Senior Manager, Medicines for Europe

Views of the healthcare community:

- **Gilles Vassal**, Paediatric Oncologist, Gustave Roussy Cancer Center in France and Board Member of the European Society for Paediatric Oncology (SIOPE)
- Orla Galvin, Executive Director, European Federation of Neurological Associations (EFNA)
- Ber Oomen, Executive Director, European Specialist Nurses Organisation (ESNO)

10:30 11:00



Networking coffee break

11:00 12:30



Advancing Medicines Repurposing: A golden opportunity yet to come to fruition

Repurposing has been recognised as an important strategy to deliver safe, effective, and affordable medicines and tackle unmet medical need. Despite increased attention, systemic barriers remain. More is therefore needed to promote specific evidence generation efforts, address the issue of off-label use of repurposed medicines, and build a regulatory policy environment that facilitates and rewards continuous innovation on well-established molecules. This session will bring together different stakeholders to explore how to advance the European repurposing ecosystem.

Moderator: Anton Ussi, Operations & Finance Director, EATRIS

Presentations

- Christelle Bouygues, Regulatory Affairs Senior Officer, European Medicines Agency (EMA)
- Anton Ussi, Operations & Finance Director, EATRIS

Panellists

- James Burt, Vice-Chair of the Value Added Medicines Sector Group, Medicines for Europe and CEO, Pharmanovia
- Lydie Meheus, Managing Director, Anticancer Fund
- Dunja Huijbers, Senior Programme Manager Rational Pharmacotherapy, ZonMw





12:30 13:30



Networking buffet lunch

13:30 15:00



Value Added Medicines: How to capture their value for society?

There are some positive cases of recognising the benefits of VAMs across Europe, however we rarely see a dedicated, specific policy framework that would provide a clear signal and encourage more development in this space. Current assessment frameworks across Europe are not designed to fully capture the potential of VAMs. How could we design evaluation frameworks that better assess the benefits that VAMs bring? What is the current policy framework operated in different countries? Why do we need a tailored approach when it comes to off-patent innovation?

Moderator: Klára Marton, Vice-Chair of the Value Added Medicines Sector Group, Medicines for Europe and Business Development Director, Egis Pharmaceuticals PLC/Servier Group

Presentations

- Aurelio Arias, Director, EMEA Thought Leadership, IQVIA
- Zoltán Kaló, Professor of Health Economics, Center for Health Technology Assessment (HTA) of Semmelweis University in Budapest and Founder and Leader, Syreon Research Institute

Panellists

- María Álvarez Fernandez, Regulatory Affairs Coordinator, Spanish Generic Medicines Association
- Mariangela Rulli, Head of Public Affairs Area and autonomous groups IBG / VAM, Egualia
- James O'Mahony, Research Assistant Professor, Centre for Health Policy and Management, Trinity College Dublin, Ireland
- Guilherme Safioti, Senior Director Global Medical Affairs, Digital Respiratory, Teva

15:00 15:30



Networking coffee break

15:30 15:50



Nicolas Sireau, Chair of Trustees at the AKU society & Co-founder and Chairman, Beacon

www.medicinesforeurope.com



15:50 17:15



How VAMs can deliver more accessible off-patent innovation in Europe

The Pharmaceutical strategy for Europe presents a historic opportunity for R&D investment in off-patent medicines that can address unmet healthcare needs. In this session, we will look at what is needed to shape a sustainable European ecosystem to incentivise the development of Value Added Medicines. How could we shape an EU environment that supports the continuous improvement of existing treatments? How does continuous innovation fit into the broader EU agenda to support access to treatment and innovation?

Moderator: Adrian van den Hoven, Director General, Medicines for Europe

Presentations

- Florian Schmidt, Deputy-Head Unit D1, DG Sante European Commission
- Arun Narayan, Head of Global Commercial Development, Viatris and Chair of the Value Added Medicines Sector Group, Medicines for Europe

Panellists

- Momir Radulović, Executive Director, Slovenian Medicines and Medical Devices Agency, European Medicines Agency Management Board Member
- Kristof Roox, Partner, Crowell & Moring LLP

17:15 17:30



Conference closure - Maja Graf, Associate Director Policy & Market Access, Medicines for Europe

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