Value Added Medicines
Rethink, Reinvent & Optimize Medicines, Improving Patient Health & Access

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Study Objectives

To propose a harmonised typology for value added medicines
To describe potential contribution of value added medicines to health care systems
To understand current obstacles to adoption of value added medicines and their value recognition for P&R in Europe
To draw potential recommendations to overcome current barriers to fully capture potential value of value added medicines and incentivise their development for the benefit of the society
Study Methodology

1. Identification of health care system inefficiencies
2. Identification of existing definitions of value added medicines
3. Identification of examples of value added medicines
4. Definition of typology for value added medicines
5. P&R decision mapping & review of selected value added medicines
6. Consolidation of findings and key recommendations

Health care system efficiency is a key challenge for policy makers and efficiency should be improved in many countries.

Increasing demand to deliver better health

Several health care system inefficiencies related to medicines were identified and should be addressed whenever possible.
Health Care System Inefficiencies

- Non-availability of appropriate treatment options
- Irrational use of medicines
- Health Care System Inefficiencies related to Medicines
- Shortage of mature products
- Drug access and sustainability

Irrational use of medicines is considered wasteful and harmful for both the individual and the population by the World Health Organization. A key example: Irrational use of antibiotics is a large cause of antibiotic resistance and a major public health issue.

- Overuse of antibiotics, often unnecessarily prescribed for viral infections
- An overview of adherence to long-term therapies conducted by the World Health Organisation in 2003 found around 50% adherence as the average rate in developed countries.
- Poor adherence in Europe:
  - About €125 billion annually
  - Contributing to the premature deaths of nearly 200,000 Europeans annually

Poor treatment adherence is reported as a major barrier to achieve the potential benefit of available medicines.

Sources:
(1) WHO. The world medicines situation 2011, Rational use of medicines
(2) WHO. The evolving threat of antimicrobial resistance: options for action (2012)
(3) ECDC. Antimicrobial Resistance. (Access 2016)
Value Added Medicines
A Key Opportunity for the Society

Opportunity for the society to address a number of drug related health care inefficiencies but also an opportunity to delivering better health to patients, enhance health care system efficiency, as well as to contribute to the sustainability of the health care systems.

Value Added Medicines
Opportunity to Address Health Care System Inefficiencies

The World Health Organisation (WHO) recognises the importance of value added medicines to improve patient’s adherence and to contribute to fight against resistance to antimicrobials.

“Innovations in drug formulation can improve patients’ adherence to treatment or enhance the effectiveness of antimicrobials. For example, in patients with both tuberculosis and HIV infection, the use of fixed-dose formulations of multiple antimicrobial components facilitates compliance with the full course of treatment. Innovations to encourage patients’ compliance with treatment and optimizing treatment regimens can help to limit the risk of resistance.”

Source:
(1) WHO. The evolving threat of antimicrobial resistance, options for action (2012)
### Value Added Medicines

**Opportunity to Address Health Care System Inefficiencies**

<table>
<thead>
<tr>
<th>Non-availability of appropriate treatment options</th>
<th>Value added medicines could contribute to address the non-availability of appropriate treatment options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New tailored therapeutic alternatives</strong></td>
<td>• Represent an opportunity to tailor and expand access of well-known therapies to particular patient subgroups’ needs</td>
</tr>
</tbody>
</table>
| **New therapeutic options in areas of unmet medical needs** | • Could contribute to the faster development of new therapeutic options in areas of unmet medical needs benefiting from the knowledge gained from the previous drug development  
• It may also happen through the evolution of scientific knowledge |

<table>
<thead>
<tr>
<th><strong>Shortage of mature products</strong></th>
<th>Value added medicines could contribute to address the shortage of mature products</th>
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</thead>
<tbody>
<tr>
<td><strong>New market attractiveness of old medicines</strong></td>
<td>• Provide opportunity to create new market attractiveness of mature products which may avoid product shortage in some countries</td>
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</tbody>
</table>
Value Added Medicines
Opportunity to Address Health Care System Inefficiencies

Drug access & sustainability

Value added medicines could contribute to improve drug access and increase health care system sustainability

• Opportunity to create an intermediate step before switching to costly products, thus improving the affordability and limiting geographical access inequity
• Opportunity to provide new drug formulations for hospital-only medicines which could be used in out-patient settings, thus improving access in remote rural areas

Broader patient access to tailored treatment

Value Added Medicines
Opportunity to Create an Intermediate Step before Escalation to Expensive Products

<table>
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<tr>
<th>Current price setting of new innovative medicines</th>
<th>Intermediate step and potential price setting impact with value added medicines</th>
</tr>
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<tbody>
<tr>
<td><img src="image" alt="Graph showing price and responder rates" /></td>
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</table>
Value Added Medicines
Opportunity to Improve Health Care System Efficiencies

Opportunity to better address health care provision and organisation
- Value added medicines could contribute to a reduction and re-allocation in healthcare use

Improvement of usual therapies to meet patient needs
- Value added medicines could contribute to improve patient convenience of use and satisfaction with healthcare
- This might further participate to enhance patient compliance/adherence, especially for patients treated for chronic diseases

Regulators’ Recognition of Value Added Medicines

Regulatory initiatives
- STAMP “Repurposing of established medicines”
- Non-cumulative period of one year of data exclusivity granted for a new therapeutic indication for a well-established substance
- Period of data and market protection of 8+2 years covering indication(s) and appropriate formulation(s) for already authorised products developed for paediatric populations
- Market exclusivity of 10 years for repurposed medicines granted an orphan drug designation
- New partnerships have been established between public funders, the pharmaceutical industries and academic investigators in drug repurposing
- National initiatives regulate off-label use of marketed medicines
Current Obstacles for Adoption of Value Added Medicines

HTA obstacles
- **Existing stigma**: generic medicines, anti-generic medicines strategy, non-risky strategy
- **Budget silos**
- **Current HTA framework**

Pricing obstacles
- **Pricing policies pushing price down**: internal/external reference pricing, tender/procurement policies
- **Single pricing rule across all indications**

Lack of reward for manufacturers
- **Pharmaceutical business model**: time limited and under-resourced/dis-incentivised
- **Uncertainty about reward of investment to bring evidence requested by HTA bodies**
- **Price of value added medicines can be set by criteria other than added value** (investment risk)

Call for Policy Changes

HTA Pathways

- Eligibility for multi-HTA early dialogue and parallel scientific advice
- No legislative barriers preventing companies from pursuing HTA for selected value added medicines
- HTA decision making framework should take into account the special characteristics of value added medicines not currently captured (e.g., patients’ and health care providers’ preferences, more weight on quality of life and health economic benefit, accommodate for different time points at which evidence can be assessed)
# Call for Policy Changes

## Pricing Policies

- Tenders/procurement policies to allow differentiation from pure generic medicines
- Early entry agreement should be made available
- External & internal reference pricing should not apply systematically
- Not to be assimilated systematically to generic medicines because of the lack of new chemical entity status
- Make HTA requirements proportionate to potential reward
- Allow indication-specific pricing for drugs having multiple indications

# Industry Proactive Approach

- Validate surrogate endpoints
- Invest in patient registries and post-authorisation studies to collect real world data
- Raise acceptance of value added medicines through communication campaigns
- Engage patient’s groups and health care providers to identify their needs and ensure developed value added medicines address established and well-documented unmet needs
- Engage in early dialogues with HTA bodies/payers to best fit their expectations for value added medicines development and obtain recognition of additional value
Thank You

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