Obstacles for Adoption of Value Added Medicines: Call for Policy Changes for Value Recognition of Repurposed Medicines

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BACKGROUND

- Value added medicines encompass existing medicines which are re-positioned in another indication(s), re-formulated or combined with other medicine(s), medical device(s) or service(s).
  - These medicines are defined as "*medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers*" [1].
- This concept is known for many years, however, current obstacles to their value recognition from health technology assessment (HTA) and pricing and reimbursement (P&R) perspective in Europe continue to exist creating a disincentive for further development.

OBJECTIVES

- The objectives of this study were:
  - To identify key obstacles for adoption of value added medicines.
  - To elaborate on policy recommendations to overcome current hurdles to fully capture potential value of value added medicines.

METHODS

- A primary research was conducted to get perspective of various stakeholders on value added medicines as follows:
  - Twenty European stakeholders among healthcare professionals, regulatory authorities and HTA bodies/payers *(Country scope: Austria, Belgium, France, Germany, Italy, Poland, Spain, The Netherlands, Scotland, Sweden)* were interviewed using a standardised discussion guide.
  - Patient's perspective was also collected during the first European Patient's Forum – Medicines for Europe Dialogue that took place on 31st May 2016 following presentation of key examples of value added medicines.
  - A written survey complemented by a focus group were conducted among representatives of pharmaceutical industry developing medicines in this field.
- Ad hoc literature review was conducted to illustrate, when appropriate, statements of the various stakeholders, especially targeting healthcare inefficiencies related to HTA and P&R rules.

RESULTS

- Various obstacles have been identified through P&R pathways for a full benefit recognition of value added medicines :
  - HTA and medicine coverage related issues.
  - Medicine pricing rules related issues.
  - Stigma surrounding these products impacting further P&R decisions:
    - ✓ Value added medicines may be alternatively perceived like generic medicines, or as an anti-generic medicines strategy preventing from capturing any savings from medicine falling off patent.
- HTA and medicine coverage related issues included:
  - The current HTA decision-making framework not tailored for assessment of value added medicines (Figure 1).
  - Budget silos, when some European Union Member States (EU MS) tend to consider pharmaceutical assessments and reimbursement decisions in a silo, preventing from capturing any benefits such as transfer of cost-savings outside of the pharmaceutical expenditure budget (e.g. cost-savings achieved across a hospital healthcare organisation).

Figure 1. Current issues with HTA decision-making framework for value added medicines

Complexity to evidence the benefit of some value added medicines

- In some cases, benefit of value added medicines may be complex to evidence when it relies on improvement of patient's preference, compliance, convenience of use, surrogate endpoints, etc.
- Such benefits are poorly or not captured by Quality-Adjusted Life Year (QALY) which is the reference measure of medicine value in several countries, and require substantial investments to be proven through study designs acceptable by HTA agencies.
- Level of requested evidence generally disconnected from relevant reward from HTA bodies/payers.

Separate HTA of medicines and devices/procedures in some EU MS

- It prevents HTA bodies from fully capturing the benefit of some value added medicines using a medicine and device or procedure combined and can lead to patient access delays or even inconsistent decisions when processes are not coordinated.

Different HTA and medicine coverage procedures between medicine classes, e.g.

- Orphan or end of life medicines can enjoy privileged assessments (*e.g., in 2009, the National Institute for Health and Care Excellence (NICE) introduced end of life criteria to improve access to end of life treatments which could potentially be recommended at a higher cost-effectiveness threshold than "standard" medicines).*
- Conditional reimbursement can be restricted to specific categories of medicines (*e.g., expensive hospital-only medicines in the Netherlands*).
- Some medicines not eligible for HTA, e.g. categorised as generics or for hospital-only medicines.

- Medicine pricing rules related issues included:
  - Pricing policies pushing price down (Figure 2).
  - Single price rule across all indications which may either restrict access to the most cost-effective indications, or disincentive companies from launching the medicine in indications with the lowest value, thus depriving society of the treatment needed to address an unmet need.

Figure 2. Pricing policies pushing price down for value added medicines

Internal reference pricing	• Systematic positioning as generic medicine and inclusion of value added medicines in internal reference pricing (IRP) groups based on active substance.
Tenders/ Procurement policies	• Tenders/procurement policies with award criteria based exclusively on economic criteria for active substance (lowest price).
External reference pricing	• External reference pricing (ERP), especially when value added medicines are considered differently from a pricing and reimbursement perspective (e.g. internal reference pricing, tendering, etc.).

DISCUSSION

- The lack of reward for value added medicines might negatively impact investment in such products, or lead to launch strategies in the most favourable countries (*inequities in patient access across countries*).
- This situation calls for policy changes in HTA pathways and pricing rules (Figure 3).
  - Value added medicines should not be assimilated systematically to generic medicines because of the lack of new chemical entity status.

Figure 3. Policy recommendations for value added medicines

HTA Pathways	Pricing policies
• No legislative barriers preventing companies from pursuing HTA for selected value added medicines. • Eligibility for multi-HTA early dialogue and parallel scientific advice. • HTA decision making framework should take into account the special characteristics of value added medicines not currently captured*.	• IRP/ERP should not apply systematically. • Tenders/procurement policies to allow differentiation from pure generic medicines. • Early entry agreement should be made available. • Make HTA requirements proportionate to potential reward. • Allow indication-specific pricing for medicines having multiple indications.

*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)

CONCLUSIONS

- Current HTA frameworks and P&R rules in place in some countries prevent full recognition of value added medicines benefits and calls for policy changes to foster appropriate incentives to enhance their value recognition and encourage manufacturers from bringing such products to the market.

References

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