

# Factsheet | On Value Added Medicines



## What is a value added medicine?

**Value added medicines** are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers. The added value may be achieved through finding a **new indication** (drug repositioning), finding a **better formulation or dosage** (drug reformulation), or developing a **combined drug regimen, adding a new device or providing a new service** (drug combination).

### Improvements that they can deliver

- New therapeutic uses (indication/population)
- A better efficacy, safety and/or tolerability profile
- A better way of administration and/or ease of use

### Those improvements contribute to

- Better adherence, health outcomes or quality of life
- Improved safety and efficiency of healthcare professional resources
- Increased treatment options & preventing therapeutic escalation<sup>1</sup>
- Improved cost-effectiveness and ultimately access to healthcare

## Examples of Value Added Medicines

**Repositioning** (*new indication*): a very famous and classical example of a repurposed drug is Sildenafil. Originally developed as an antihypertensive, Sildenafil has been repositioned later on for the treatment of erectile dysfunction and pulmonary arterial hypertension.

**Reformulation** (*better dosage or mode of administration*): from standard release to quick release of the active substance; from an intravenous to a subcutaneous injection; from an injectable solution to a ready-to-use prefilled syringe; from a sublingual tablet to a transdermal patch.

**New combination**: a new treatment combining more than one molecule or the association of a molecule and a new device/service.

## What's in it for:

### Patients



**Value added medicines** can offer patients new healing opportunities. They can also help them to feel better with their treatment, offering more adapted medicines to those who need it.

### Healthcare professionals



**Value added medicines** provide healthcare professionals with unprecedented flexibility in therapy choices: new therapeutic uses, fewer side effects, new dosage forms, better ways of administration or easier to handle medicines are among the benefits that value added medicines offer to healthcare professionals so that patients can be treated more effectively without resorting to expensive next line therapies.

<sup>1</sup> Preventing therapeutic escalation: by offering new treatment options, patients will receive more tailored treatment preventing them from moving to more expensive treatments (e.g. more expensive medicines, surgery, etc.)

## Payers



**Value added medicines** provide an opportunity to tailor treatments to specific patient subgroup needs and therefore to reduce misuse of medicines which can lead to therapeutic failure and escalation, which are unnecessarily consuming healthcare resources. This will allow a more efficient use of current budgets.

## Research Community



**Value added medicines** R&D merge a pharmacological approach of known molecules with a well-known safety and tolerability profile together with more patients and/or healthcare professional insights, also leveraging new technologies to transform existing molecules to address specific needs that could not have been tackled 20 years ago. They bring **innovation throughout a molecule's lifecycle**, particularly those molecules no longer protected by patent, **without impacting patient access**.

## Example of Therapeutic Areas: Respiratory Diseases

- **68 million people in the EU** suffer from common respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD).
- Despite the availability of efficacious molecules to treat **asthma and COPD**, evidence shows that low adherence to treatments contributes to poor patient outcomes<sup>2</sup> associated with an increased risk of hospitalisation, medical visits, and administration of antimicrobials or oral corticosteroids<sup>3</sup>.
- Asthma and COPD are respectively responsible for 250,000 and 1.1 million annual hospital admissions and their estimated annual economic burden, in terms of direct (healthcare) and indirect (lost production) costs, amounts to €82 billion in total<sup>4</sup>.
- There are convincing health benefits in investing more time and resources to understand and address this situation. **Value added medicines** can enable known and efficacious active substances to deliver on their promises to patients who need them, averting or reducing complications and exacerbations as well as associated costs.



## About the Value Added Medicines Group

The **Value Added Medicines Group**, a sector group of **Medicines for Europe**, aims to rethink, reinvent and optimise medicines based on known molecules by bringing untapped innovation to improve care delivery. The **Value Added Medicines Group** adopts a complementary perspective compared to other **Medicines for Europe** sector groups by tackling the targeted portion of patient needs that remain unmet to this day, delivering additional improvements to the healthcare community as whole.

**Medicines for Europe** represent the European generic, biosimilar and value added medicines industries, which provide access to high-quality cost-competitive medicines to millions of patients in Europe and worldwide. The vision of **Medicines for Europe** is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

<sup>2</sup> National Institute for Health & Care Excellence. Medicines Adherence. NICE Clinical guideline 2009. Available from: <http://publications.nice.org.uk/medicinesadherence-cg76> accessed: Nov 2013

<sup>3</sup> Melani, AS, et al. Respir Med. 2011;105(6):930-8

<sup>4</sup> European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

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