# VALUE ADDED MEDICINES AS A NEW OPPORTUNITY FOR DRUG POSITIONING AT THE PHARMACEUTICAL MARKET

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Positioning in the market is of great importance among the marketing instruments of pharmaceutical companies. Its use provide flexibility and increase the efficiency of various types of marketing communications of pharmaceutical companies.

The purpose of this work is to describe the strategies of creating the value added medicines (VAMs) as well as the benefit of using VAMs.

VAMs are medicines based on known molecules that address medical needs and deliver relevant improvements for patients, health care specialists and payers. Their improvements include a better safety, efficacy and tolerability profile; a better way of administration and ease of use; new therapeutic uses (for instance, new indications or new group of patients).

The added value may be achieved through three main strategies: drug repositioning (finding a new indication), drug reformulation (finding a better formulation or dosage) or drug combination (developing a new combined drug regimen, adding a new device or providing a new service).

Drug repositioning (or repurposing) is the process of finding a new therapeutic use for an already known medicine which had at first been developed for another medical purpose. Sildenafil is a very famous and classical example of a repurposed medicine. Initially developed as an anti-hypertensive medicine, Sildenafil was later repositioned for the treatment of erectile dysfunction and pulmonary arterial hypertension. Other examples are Memantine (from Parkinson's to Alzheimer's disease); Propranolol (from cardiology to oncology); Plerixafor (from HIV infection to oncology), Bromocriptine (from Parkinson's disease to diabetes type 2).

Drug reformulation is the development of a different formulation for the same medicine. It means finding new ways of combining the different molecules of a medicine, including the active ingredient, in order to produce a final medicinal product. Examples of drug reformulation include: Bromocriptine (from standard release of the active pharmaceutical ingredient to quick release); Trastuzumab (from an intravenous injection to a subcutaneous one); Methotrexate (from an injectable solution to a ready-to-use prefilled syringe); Buprenorphine (from sublingual tablets to transdermal patches).

Different types of VAMs require different research and development efforts. Developing a new device requires considerable costs to optimize the administration of

the active substance. Certain changes to a medicine require a clinical development programme in order to collect new clinical data necessary to assess the safety and efficacy of the VAM.

The benefits of VAMs are expected to impact healthcare systems through increasing treatment options, preventing therapeutic escalation or increasing rational use of medicines. As a consequence, they will reduce the use of healthcare resources and improve cost-effectiveness ratio, and therefore contribute to the efficiencies of the healthcare system and better patient health and access to the treatment.

VAMs provide healthcare specialists with unprecedented flexibility in therapy to target better outcomes for patients, whose needs are unaddressed and unmet by existing therapies. Healthcare specialists will be able to select from a wider range of treatment options using well known active molecules, but allowing for a more patient centric approach, increasing patient and professional satisfaction.

VAMs offer a well-known safety and tolerability profile based on existing molecules, creating confidence in using alternatives which are more adapted to some patients' needs. Fewer side effects, better modes of administration, new dosage forms or easier to handle medicines are among the benefits that VAMs provide to healthcare specialists so that patients can be treated more effectively without resorting to expensive next line therapies.

Several healthcare inefficiencies are impacting the sustainability of healthcare budgets, such as suboptimal use of drugs. The WHO has notably estimated that more than 50% of all medicines globally are prescribed, dispensed or sold inappropriately and that 50% of all patients fail to take their medication as prescribed or dispensed. The cost of non-adherence in Europe is estimated to cost European governments €125 billion per year.

VAMs can benefit in different therapeutic areas. One of them is the treatment of respiratory diseases. 68 million people in the EU suffer from common respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). Due to known risks, the management of asthma and COPD is associated with high healthcare and societal costs. 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 and indirect costs amounts to €82 billion in total. Despite the availability of efficacious molecules to treat asthma and COPD, evidence shows that low adherence to treatments contributes to poor patient outcomes associated with an increased risk of hospitalisations, medical visits, and administration of antimicrobials or oral corticosteroids.

Thus, VAMs provide an opportunity to adapt treatment to specific patient segments and therefore to reduce misuse of medicines which can lead to therapeutic failure and which are unnecessarily consuming resources for payers.