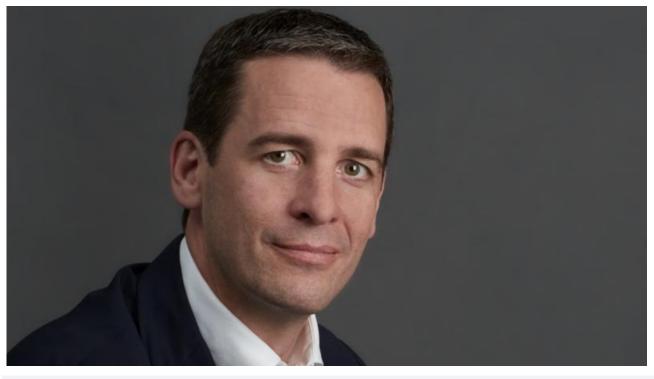


Pharma expert: new 'value added medicines' offer cheaper, customised treatment

By Sarantis Michalopoulos | EurActiv.com 6:37 (updated: 10:04)



Christoph Stoller Print Comments 3 1

A new breed of drugs, called "value added medicines", could help patients improve their everyday life while in treatment, without increasing healthcare budgets, Christoph Stoller said in an interview with EurActiv.com Christoph Stoller is Chair of the Value Added Medicines Sector Group at Medicines for Europe, an association which represents the European generic, biosimilar and valued added pharmaceutical industries.

He spoke to EurActiv's Sarantis Michalopoulos.

Let me start with a general question. What is the definition of 'value added medicines'?

Many believe that addressing patient needs is only about generating new molecules. But innovation can also come from other areas such as focusing on improving those molecules no longer protected by patent. Unpatented molecules were discovered more than 20 years ago. Since then, new scientific knowledge and new technologies have emerged, opening new research and development opportunities to address specific situations that could not be tackled 20 years ago. Value added medicines are based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals, and/or payers.

It is said that value added medicines can improve patients' everyday life. Could you explain in what way?

By rethinking, reinventing and optimising existing medicines, we aim to move from a onesize-fits-all to much more tailored and customised treatments. While the majority of existing treatments deliver on their promises to a large number of patients, some may need to be adapted to match specific patient needs. They represent a new horizon for those who are currently looking forward to a better quality of life with their treatment. Value added medicines can indeed provide a better efficacy, safety, and/or tolerability profile; a better way of administration and/or ease of use; and new therapeutic uses. So value added medicines are designed to help patients to better manage their health condition and ultimately lead to better adherence, health outcomes and quality of life.

Do you have practical examples of therapeutic areas where value added medicines could actually have an "added value"?

Yes, the benefit of value added medicines applies to a large variety of therapeutic areas. Asthma and chronic obstructive pulmonary disease (COPD) are, for example, two conditions where value added medicines can deliver relevant improvements. In Europe, 68 million people suffer from these two common respiratory diseases. 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 (health care) and indirect (lost production) costs amounts to \in 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.

Schizophrenia is another area where value added medicines could deliver additional benefits to patients, healthcare professionals and payers. Schizophrenia affects 24 million people. Antipsychotics are generally effective for the treatment of schizophrenia; however there is a

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critical unmet need: 75% of patients are non-adherent to treatment within two years and the relapse rate is 2-5 times higher in non-adherent patients. These are examples of healthcare needs we aim to tackle.

A more practical example of how these types of medicines can help patients is by their longacting formulation. Through reformulation, pharmaceutical companies can develop a more adapted way for patients to take these long-acting medicines instead of standard oral tablets. Patients no longer have to worry about taking their pills or treatments on a daily basis. This improves the quality of life for patients and also improves adherence, as long acting formulations ensure a continuous steady blood concentration of the medicine over a longer period.

Excessive pricing of medicines is a huge challenge for the EU pharmaceutical sector. What is the average cost of such medicines and how can you ensure they will be affordable?

The Value Added Medicines Group is fully aware of the current healthcare budget constraints faced by the health authorities and payers. More than 50% of patients face challenges with medication adherence leading to a sub-optimal use of drugs, disease worsening, and therapeutic escalation. We believe that value added medicines provide a responsible answer to some of the challenges that patients and payers are facing and can improve budget efficiency. We see value added medicines as an intermediate step in the therapeutic regimen, capturing those patients who are not responding to the first line treatment and who otherwise will have to jump to a more resource-intensive care. Our aim is to provide better results without increasing healthcare budgets, notably by capturing healthcare inefficiencies. We believe that, at a time where the concept of universal access to quality care and innovation is under pressure, value added medicines enable the healthcare system to reap the benefits of innovation without compromising equitable access to tailored treatments.

Value added medicines are still not present in the pharmaceutical market. What are the main challenges you are facing?

The recent study commissioned to Professor Toumi has identified several obstacles to the uptake of value-added medicines: pricing, HTA and lack of reward for manufacturers innovating in that space. The report clearly shows that we have to have a shift of mindset, a sea-change, from cost focus to outcomes focus. According to the study, most stakeholders already recognise the benefits that value added medicines bring. However, to make sure that all stakeholders concerned have access and can take advantage of these medicines, we need clear market access pathways that allow the recognition of the benefits that these medicines are providing, which is not the case in all European countries.

How does the pharmaceutical industry see the outlook for this type of medicine? Have you already launched partnerships?

If we aim to ensure better health and better access for patients through value added medicines, we need to move from curing illness to improving well-being, keeping people healthy and delivering the most efficient care. We must seek different approaches, not only looking at the costs of treatment but also how the system can better recognise improved outcomes, including the ones coming from known molecules. What is clear to me is that it can't be done alone, by any single player. We need changes that will require the cooperation of everyone – from policymakers to patients, healthcare providers, payers and industry. The value added medicines group is currently engaging with the different stakeholders as it will require each of us to look at the problems that we've just described, taking into account the whole of the patient's journey, not just the parts each of us affect.

How can this new type of medicine help address the orphan medicines challenge? Do you also deal with rare diseases?

Value added medicines aim to address healthcare needs and deliver relevant improvements for patients, healthcare professionals, and/or payers. They can cover all types of conditions including rare diseases.

You focus a lot on research. There is a certain view suggesting that if a drug is funded by public money, then it should have an impact on the drug's price, meaning lower drug prices for patients. EU member states recently decided that instead of less expensive medicines, this money should be earmarked for further research. Do you agree with that approach?

We refer here to public-private partnerships that enable pre-competitive collaboration. This type of multi-stakeholder collaboration focuses on stimulating basic research and its uptake for industrial research and development. It aims at aggregating, accessing, and sharing data that are essential to innovation and that benefit the entire ecosystem, not just the industry.

Without such collaboration, which is far from being free for the pharmaceutical industry, some innovation could not take place and the competitiveness of the EU in medical research would be at stake. I strongly believe in the value of these partnerships and what they deliver to society as a whole. For me, drug pricing is a different debate. I believe that sustainability would be achieved if more could be done to enhance the cost-efficiency of our healthcare systems. Some solutions already exist such as value added medicines, but also greater uptake of generic and biosimilar medicines represent options which are not being considered sufficiently. The Council, in its conclusion, has recently underlined the importance of the timely availability of generics and biosimilar medicines to be followed by actions and I'm looking forward to further engagement between our industry and Ministers of Health in reaching this objective.