My Voice Matters!

Exhibition Space European Parliament

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Good evening everyone,

I am very pleased to be here, and I would like to thank Medicines For Europe for the invitation to my organisation - Active Citizenship Network - and so for having involved civic and patient organisations to debate on a topic which is still far from being considered from the wide public. For this reason, I can't thank enough the MEP Lieve Wierinck for hosting us today, because the Institutional attention, first and utmost at EU level, is indeed fundamental to raise these issues also at national and local level.

I just would like to develop here three main concepts, particularly relevant to the issue of Value Added Medicines. These concepts are: sustainability, trust and involvement.

SUSTAINABILITY: Indeed, from my perspective, Value Added Medicines directly implicate and are particularly relevant to sustainability of healthcare systems, and to the current situation of restrictive national healthcare budgets. Sustainability of healthcare systems, in light of the introduction of increasingly innovative medicinal products, is a very sensitive issue for which it is essential to strike a balance between a fair return on the substantial investments made by companies and the right of universal and equitable access to care, which inspires for instance the Italian National Health System. We should avoid any possible "side-effects", such as having first-rate patients and second-rate ones. Generics, biosimilars and Value Added Medicines: all of them optimise efforts for better patient access to high quality medicines. Yet, they still represent options which are not being considered sufficiently. The Council conclusions "on strengthening the balance in the pharmaceutical systems in the EU and its Member States", adopted last June ~~2017~~, have underlined the importance of timely availability of generics and biosimilar medicines to improve patient access. This acknowledgment- together with the development of Value Added Medicines - now needs to be followed by concrete actions, as suggested by the well-known case history of acetylsalicylic acid – known as aspirin – which is not just useful to treat the flu, but can reduce the risk of some tumours, such as colorectal cancer.
According to the Italian branch of Medicines For Europe Assogenerici, in the next three years 32 medicines will be off-patent, 16 of them by the end of this year. 16 pharmaceutical companies have already requested authorisation to produce generics for the medicines whose patents are expiring soon. Maybe - and I hope so - there are other companies thinking to innovate the molecules of these new off-patent medicines.
We are all aware that sustainability would be achieved if we enhance the cost-efficiency of our healthcare systems. Value added medicines provide a responsible answer to some of the challenges that patients and payers are facing and can improve budget efficiency, taking also into consideration that their benefits apply to a large variety of therapeutic areas, including rare diseases.

More than 50% of patients face challenges with medication adherence leading to a sub-optimal use of drugs, disease worsening, and therapeutic escalation. Value added medicines might work as an intermediate step, capturing those patients who are not responding to the first line treatment and who otherwise will need a more resource-intensive care. A more practical example of how these types of medicines can help non-adherent patients is by their long-acting formulation. Through reformulation, and taking into consideration patients' needs, it is now possible to 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.

TRUST: The second concept concerns trust, meaning that each of us has different responsibilities and roles. Civic and patient organisations' main role does not concern market authorisation of drugs or devices. We have national, European and international authorities dealing with that. Our role is to represent and focus on citizens and patients' needs and requests. If these patients' needs and requests are sufficiently considered, this enhances mutual trust among all the stakeholders. Considering patients' needs and requests means also recognising and respecting their rights, such as for instance the right to be informed, the right to access (including innovative therapies), the right of free choice, the right of personalised treatment, and so on. Basically, it means recognising those famous principles established by the European Charter of Patients' rights, drawn up in 2002 by my organisation, in collaboration with associations of 12 Member states and a milestone for other similar statements. This Charter has been repeatedly taken into consideration by the European Parliament in its official documents – and at least twice in the last year - to encourage the European Commission to make the European Charter of Patients' rights the official compass of its health policies as well as to promote the institutionalisation of the European Patients' Rights Day, as urged by hundreds of associations that celebrate it every year, throughout Europe and here at the European Parliament. 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 personalised treatments.

Trust cannot be gained without proper transparency, communication and involvement being guaranteed. Greater efforts need to be made in terms of transparency both on the side of the companies, which should publish even the negative outcomes of their clinical trials, and on the regulatory authorities, the latter still being too prone to consider the civic and patient point of view in their advisory committees. On the occasion of the last European Patients' Rights Day, we made a survey in 20 EU Member States on the involvement of patient representatives and associations in the decision-making process within their national medicine agencies. Results show that only 10 out of 20 are officially involved in the process. These data allow me to introduce the last point, which is about involvement.

INVOLVEMENT: Patient involvement in the development of innovation is a key challenge in all the faces of the process: clinical trials, evaluation, HTA, engagement to communicate efficiently each innovation useful for patients. But it is also fundamental to ensure the final product best meets patient's needs. The value-added medicines sector owns a great potential when it comes to answering patients' unmet needs or improving therapeutic adherence and new therapeutic uses, which help patients to better manage their health condition and to respect their right to personalised treatments.

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, empowering patients and delivering the most efficient care. As representatives of the civil society, we have put citizens at the heart of our organisation, meaning that our focus is not on a specific disease but on the rights that every one of us owns as EU citizens in first place, and then on the specific needs we may have as patients.

To ensure patient involvement, Medicines for Europe should guarantee continuity and not just spot initiatives on the topic and above all each company dealing with value added medicines should testify its long-term strategy to engage civic and patient organisations.

Today, we have only three civic and patient organisations endorsing this important initiative, meaning that we need to do more to engage all the relevant stakeholders. Change requires the cooperation of everyone – from policymakers to patients, civil society, healthcare providers, payers and industry, taking into account the whole of the patient's journey, not just the parts each of us affect. We believe to play a positive role to increase access to innovative therapies and new options for patients and we hope there will be room for cooperation and joint actions which will be essential to make value added medicines truly beneficial for the society as a whole.

Thank you.