

Value Added Medicines dialogue

Moving from a one-size-fits-all to a much more tailored and patient specific approach, value added medicines are one of the key components of the customization of healthcare.

EU workshop co-organized by Medicine for Europe and Active Citizenship Network

Tuesday 20th November 2018
from 13.30 to 16.00
Medicines for Europe Office
Rue d'Arlon 50, Brussels

save the date!

The participation is by invitation only

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Introduction by Mariano Votta Active Citizenship Network

Good afternoon and welcome to everyone. I am extremely proud and happy about this initiative. Recently we have felt the need to combine a public activity, in which we take into consideration the perspective of citizens in the process of policy making at the EU level, with a more reserved but necessary meeting to explore issues that are particularly significant to us. A few weeks ago we have organized a training initiative focused on vaccination, while today we are together to know more about the **incremental innovation in drugs** and new perspectives delivered by value added medicines. Actually, the request of this kind of meeting came directly from our constituency, which requested us to satisfy the need to be more up-to-date and prepared in front of such relevant phenomena.

I would like to thank Medicines for Europe very much for its support, not only for this specific EU workshop on Valued Added Medicines, but more in general for having gathered civic and patients' organisations to debate on a topic which is rarely considered by the public.

In fact, I am glad to remember that since 2017 Medicines for Europe, through its Value Added Medicines Group, and my organization Cittadinanzattiva Onlus, through its international branch Active Citizenship Network, have decided to cooperate for a better access to healthcare across Europe and for a better respect of patients' rights, starting from the patients' right of access to

healthcare, the patients' right to innovation and the patients' right to personalized treatment. In particular:

- Active Citizenship Network was officially involved in the Value Added Medicines Exhibition at the EU Parliament (21-24 of Nov 2017);
- Active Citizenship Network was included in the panel of the 1st Value Added Medicines Conference (22 of Nov 2017, Bruxelles);
- The Value Added Medicines Group was included in the panel of the XII European Patients' Rights Day at the EU Parliament (23 of May 2018);
- Medicine for Europe is one of the supporters of the social media awareness campaign across Europe on Therapeutic Adherence promoted by Active Citizenship Network as follow up of the XII European Patients' Rights Day (II° part of 2018/I° part of 2019);
- Active Citizenship Network was included in the panel of the 24th Medicines for Europe - 21st IGBA Annual Conference (13 - 15 of June 2018, Budapest);
- Active Citizenship Network was officially included as expert in the evaluation committee of the Value Added Medicines Award 2018. Also, tomorrow, in occasion of the 2nd Value Added Medicines conference in Brussels on November 21, 2018, I will take part to the ceremony award to deliver the awards to the winners.
- Today we co-organize this EU workshop, while tomorrow, Medicines for Europe is offering all patient participants a waived conference fee for the 2nd Value Added Medicines conference in order to learn more and to discuss the challenges and opportunities for value added medicines in Europe.

As you probably know, at the European level, ACN's action develops according to four well-defined strategic pillars: the protection of patients' rights; cross-border issues; empowerment; and sustainability. And of course, today's initiative is in line with each one of our pillars, in particular with empowerment and sustainability.

According to me, three concepts are particularly relevant to the issue of Value Added Medicines: sustainability, trust and involvement.

SUSTAINABILITY: Indeed, from our perspective, Value Added Medicines are particularly relevant to the sustainability of healthcare systems and to the current situation of restrictive national healthcare budgets. The sustainability of healthcare systems, especially with the introduction of increasingly innovative medicinal products, is a very sensitive issue. It is therefore 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-effect", such as having first-rate patients and second-rate ones.

Generics, biosimilars and Value Added Medicines all optimise efforts for better access to high quality medicines. Yet, they still represent options that are not sufficiently considered.

We are all aware that, if we enhance the cost-efficiency of our healthcare systems, sustainability would be achieved. Today, the experts will explain us that Value Added Medicines provide a responsible answer to some of the challenges that patients and payers are facing and that these medicines can actually improve budget efficiency, considering that their benefits apply to a large variety of therapeutic areas, including rare diseases.

More than 50% of patients face challenges with medication adherence that lead to a sub-optimal use of drugs, disease worsening, and therapeutic escalation. Value Added Medicines may work as an intermediate step, capturing those patients that are not responding to the first line treatment and that would otherwise need a more resource-intensive care. A more practical example of how these types of medicines can help non-adherent patients is their long-acting formulation. Through reformulation, and taking into consideration patients' needs, it is now possible to develop a more suitable way for patients to take these long-acting medicines instead of standard oral tablets. In this way, patients no longer have to worry about taking their pills or treatments on a daily basis. This improves patients' quality of life as well as therapeutic adherence.

TRUST: The second concept concerns trust, meaning that each of us has different responsibilities and roles. The main role of civic and patient organisations' does not concern the authorisation of drugs or devices on the market, as we already have national, European and international authorities dealing with that. Our role is to focus on and represent citizens and patients' needs and requests. Indeed, when patients' needs and requests are sufficiently considered, mutual trust among all stakeholders increases. 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 to healthcare (including innovative therapies), the right to free choice, the right to personalised treatments, and so on. Basically, it means recognising those famous principles established by the European Charter of Patients' Rights, which was drawn up in 2002 by my organisation in collaboration with associations of 12 EU member states, and which represents a milestone for other similar statements. This Charter has been repeatedly taken into consideration by the European Parliament in its official documents – at least twice in the last year – in order 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 in Bruxelles at the European Parliament. We believe that, at a time when 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 guaranteed transparency, communication and especially involvement, which is the last point of my speech.

INVOLVEMENT: Patient involvement in the development of innovation is a key challenge throughout all phases of the process: clinical trials, evaluation, HTA, engagement to communicate efficiently each useful innovation, etc. However, involvement is also fundamental to ensure that the final product best meets patients' 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 conditions and to respect their right to personalised treatments.

If we aim to ensure patients better health conditions and better healthcare accessibility through Value Added Medicines, we need to move from curing illnesses to improving people's 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 organisations, meaning that our focus should not be on a specific disease but on the rights that every one of us owns as EU citizens and on the specific needs we may have as patients.

To ensure patients' involvement, each company dealing with Value Added Medicines should demonstrate its long-term strategy to engage civic and patient organisations. Medicines for Europe is leading this process and I am sure they can work as facilitator of this cultural change, as the title of today's initiative testifies: Value Added Medicines Dialogue. I am sure that this Dialogue will be reinforced more and more and that this initiative will become a regular appointment, useful to increase dialogue, mutual knowledge and trust.

Change requires everyone's cooperation, from policymakers to patients, civil society, healthcare providers, payers and industries. We believe to play a positive role in increasing access to innovative therapies and new options for patients and we hope that there will be room for cooperation and joint actions, which are essential to make Value Added Medicines truly beneficial for the society as a whole.

Well, it's time to start. I just want to remember that the purpose of today's initiative is to provide for a selected number of leaders of patients' organizations and advocacy groups across Europe an occasion to be empowered, an updated overview about the option of Value Added Medicines and an ease exchange of views on key policy developments related to Value Added Medicines.

So, to all my colleagues of patients' associations, thanks again for accepting our invitation. We have all travelled this far because we find this a valuable opportunity, and therefore I suggest you take advantage of this meeting to increase your knowledge on the topic and ask questions. What we are talking about? What is a Value Added Medicines? What type of improvements can they deliver?

What benefits will Value Added Medicines bring to patients and healthcare professionals? What are the benefits for the healthcare community? Why are Value Added Medicines important for patients?

Our experts will be happy to answer your questions. There will be two presentations and enough time for questions.

One last piece of information for our expert speakers: for this training seminar we have invited leaders of patients' associations. Each one of them is extremely committed to healthcare, but, for most of them, today is probably the first time they hear about Value Added Medicines. So, please let's not give anything for granted.

A special thanks to all the experts for their invaluable know-how, we appreciate a lot your availability to be here today!

Thanks again for the attention. I wish you a fruitful workshop.