

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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Making patients voice matter: the role of Value added medicines (Minutes)

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

November 20th, 2018

Written by Manuela Amadori, Active Citizenship Network

Speakers: Mariano Votta (Active Citizenship Network); Adrian Van den Hoven (European Generic Medicines Association); Catarina Lopes Pereira (Medicines For Europe); Aurelio Arias (European Thought Leadership, IQVIA).

Facilitators: Kate O Regan (Medicine for Europe); Bianca Ferraiolo (Active Citizenship Network).

Secretariat: Manuela Amadori (Active Citizenship Network).

Participants:

Active Citizenship Network Constituency:

- SPAIN: Gloria Romanello, World Federation for Incontinence and Pelvic Pain (WFIP)
- HUNGARY: Gabor Pogany, Hungarian Patient Forum, president of HUFERDIS.
- MALTA: Gertrude Buttigieg, Malta Health Network
- CROATIA: Josip Peric, Croatian Patients' Rights Association
- BULGARIA: Penka Georgeva, Patients' Organization With You
- BELGIUM: Melina Raso, Health First Europe
- BELGIUM: Giuseppe Peretti, European Consumers Union. ECU
- BELGIUM: Philippe Müller, European League Against Rheumatism (EULAR)
- ROMANIA: Maria Lungu, EFFCA European Federation of Crohn's & Ulcerative colitis Associations
- UK: Jacqueline Bowman, SCIE Self-care Initiative Europe
- BELGIUM: Laura Cigolot, Health First Europe
- BELGIUM: Luisa Avedano, European Federation of Crohn's and Ulcerative Colitis Associations
- ITALIA: Manuela Amadori, Cittadinanzattiva/Active Citizenship Network
- IRELAND: Stephen Mac Mahon, Irish Patients Association (*In absentia*)
- MACEDONIA: Kiril Solesky, ADICD (*In absentia*)

Value Added Medicines Group:

- Csilla Juhasz, Egis Pharmaceuticals PLC
- Klára Marton, Egis Pharmaceuticals PLC
- Arun Narayan, Mylan
- Bernd Sundermann, Fresenius Kabi
- Tineke Vanlerberghe, Mylan
- Erick Tyssier, TEVA Pharmaceutical Industries
- Wojciech Nowak, Sandoz
- Julien Veys, Theranexus

[Welcome \(by Adrian Van den Hoven\)](#)

Adrian Van den Hoven welcomes all participants and underlines the importance of the event, which represents a starting point for a long-lasting relationship among Medicines For Europe, Active Citizenship Network, the present patients' organizations and the present companies. He then turns it over to Mariano Votta for a contextualization of the seminar.

[Introductory Speech \(by Mariano Votta\)](#)

- Today we are together to know more about the incremental innovation in drugs and new perspectives delivered by value added medicines.
- 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.
- Three concepts are particularly relevant to the issue of Value Added Medicines: sustainability, trust and involvement.
- SUSTAINABILITY: Value Added Medicines are particularly relevant to the sustainability of healthcare systems and to the current situation of restrictive national healthcare budgets. 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. 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.
- TRUST: Our role is to focus on and represent citizens and patients' needs and requests. Considering patients' needs and requests means also recognizing 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 personalized treatments, and so on. Basically, it means recognizing those famous principles established by the European Charter of Patients' Rights. 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 personalized treatments. Trust cannot be gained without proper guaranteed transparency, communication and especially involvement.
- INVOLVEMENT: Patients' involvement in the development of innovation is a key challenge throughout all phases of the process. 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 personalized treatments. As representatives of the civil society, we have put citizens at the heart of our organizations, 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 organizations.

Session 1: Why are value added medicines important for patients? (Presented by Aurelio Arias)

- There are strong forces driving changes in Healthcare:
 - On the demand side: ageing population; rising prevalence of chronic diseases; adherence/compliance.
 - On the supply side: rising cost of care – and technologies – and increasing scrutiny around value; increasing connectivity and healthcare consumerism; patient centricity (which refers to the fact that companies should never forget that their work is for the patient *in primis*).
- Significant unmet needs still exist in primary care:
 - Efficacy (forgotten uncontrolled patients subgroups; lack of effective treatment options);
 - Safety (long term safety, narrow therapeutic windows);
 - Tolerability (gastrointestinal side effects, drug-drug interactions);
 - Convenience.
- The opportunity for primary care presents itself in three segments:
 - Broadly satisfactory: there are available options generally effective across patient population;
 - Unsatisfactory: there are available options but they involve limited overall effectiveness or high treatment burden;
 - None: there is no disease specific/modifying medicine available. In this situation, value added medicines can become a real opportunity.
- Primary care innovators, including regulators, payers, providers, and patients, face several barriers.
- Compliance is undoubtedly the biggest source of inefficiency as it still remain a huge problem: generic products do not appeal to patients as much as branded products.
- Value added medicines sit somewhere between the generics side and the innovative side, providing benefits for both patients and other stakeholders through a change of the medicine pattern (repackaging, reformulation, combination, etc.).
- CNS (central nervous system) products have shown historical success.
- Value added medicines are truly global. Different geographies have different needs depending on their population and thus products vary from one country to another. Value added medicines fulfill individual country needs.
- Oral injectable solids make up over half of the market and represent the fastest growing sector.
- Combination products can take various forms, creating convenience and offering patients more options for using their medicines.
- Value added medicines products fall on a spectrum of innovation. Most of them belong to the “incremental innovation” category, while a few sit within the “high innovation” category , characterized by higher prices, cost and R&D.
 - Lower level innovation: combination, formulation, dermal patches;
 - Incremental innovation: inhalers, auto-injectors;
 - Novel delivery technologies: nanoparticles, microchips, minipumps.

- Some examples of innovative solutions from MedTech companies include:
 - Lucideon's iCRT ceramic pills: opioids abuse deterrent against opioid abuse epidemic;
 - Microchips Biotech's microchip: implanted for precise automated dosing instead of daily injections;
 - Intarcia's Medici mini-pump: implanted for convenient dosing.
- Key takeaways:
 - Adherence is a real unmet need;
 - Value Added Medicines span a range of innovation which determines risk and reward;
 - Medtech is booming and will introduce novel technologies into this sector;
 - Real world evidences communicate benefits effectively.

Discussion with the audience:

- 1) C. Juhasz: Where did you first see this trend starting to happen? Who was driving and leading this change, the patients' community in need or the doctors?
 - A. Arias: It was initiated by companies wanting to do something about their old portfolio products. The trend probably started in the US but we are not entirely sure about what initiatives triggered the change. In general, there was a slowdown in growth and a big pricing pressure on generics companies, so companies started to wonder whether they could grow by volume and how. The rising of new technologies and research also plays a key role.

- 2) E. Tyssier: We see the interest of some companies that see the potential of value added medicines and new technologies. But what is the response of the authorities, the external community and the involved stakeholders towards these innovations?
 - A. Arias: In a situation of stall economic growth, authorities tend to approve these innovations and support new patterns of development. Currently there are more and more sophisticated discussions on value added medicines, but until a few years ago this topic was much less known.

- 3) Discussant: How does adherence take place and how do you increase people's adherence?
 - G. Pogany: In Hungary, we are promoting projects and long-term lasting campaigns involving pharmacist associations and universities in order to raise awareness.
 - G. Buttigieg: There are patients who look at the importance of their quality of life and are therefore open to try new medicines and pay for them to improve their well-being, while others simply complain. In Malta, most medicines that are given out by the government are generics. People are upset because they were used to branded products and find generics ineffective. We are trying to work together with pharmacists – who collect the most complains – to inform citizens on generics but the situation is rather complex.

- 4) M. Votta: Which is the level of confidence of general practitioners, healthcare professionals and other stakeholders about value added medicines? Should we include them in the dialogue as well?
 - A. Narayan: We need to include healthcare professional in the dialogue to understand their perspective because they do play a great role in deciding the proper treatment for their patients. Often it is the actual doctors and pharmacists that see the opportunity for and support the use of value added medicines.
 - A. Arias: At the end of the day, value added medicines make patients' life a lot easier. However, not all doctors are in control of prescribing these products even if they would love to (hospital policies),

and other times doctors are simply unaware of the existence of these medicines. Most physicians would love to have products that are beneficial for their patients.

- 5) M. Votta: What is the main difference between USA and Europe in regards of data? Most of the data come from the US, so in Europe there might be a problem with limited data.
- A. Arias: We constantly try to redefine what regions are more relevant on the market, but unluckily we do not have plenty of data coming from Europe (just 4/5 countries).
- 6) P. Georgeva: Have we given the right, comprehensive definition of “value added medicines”? Is there anything more connected to value added medicines that is not included in the definition but that could be considered as an added value? Would you consider other case studies to be presented or discussed?
- A. Arias: An example could be the technological devices for diabetics patients. In the US there are innovative glucose monitoring systems for people suffering from diabetics which are not provided in Europe, or which are very expensive and have limited eligibility. Recently, a patients’ organization has decided to create a device connected to an App through which diabetics patients in the UK could monitor and check their levels of glucose in a very cheap and easy way.
 - A. Narayan: We have started to think about how to include a digital delivery of disease management into the discussion on value added medicines, especially when thinking about patients’ compliance and adherence. There is a lot of technology out there but not within the traditional health systems.

[Session 2: Value Added Medicines and patient involvement - Improving patients quality of life through tailored medicines \(Presented by Catarina Lopes Pereira\)](#)

- What are valued added medicines?
 - Value added medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals, and/or payers.
 - Value added medicines lead to improvements such as new therapeutic uses, better efficacy, better safety, better tolerability, better ease of use, and better way of administration.
 - Value added medicines are categorized into 3 groups: drug repositioning (finding new indications); drug reformulation (new delivery systems); complex combination (new regimes or adding technology).
 - Impact on healthcare systems: finding new ways to deliver better health and access (quality and efficiency).
- Value added medicines provide a range of different and important benefits to patients and healthcare systems:
 - Superior efficacy;
 - Reduced side effects;
 - Improved patients experience ;
 - Additional therapeutic option.
- Patients seem to be secondary in the debate for value added medicines and their voice is not really heard by the authorities. We need to inverse this situation.
- What is our commitment?
 - Responsibility to look at the European healthcare systems and see how we can contribute with value to patients, healthcare professionals and society.
 - Engage in early dialogues and generate adequate and pragmatic evidence.

- o Engage with patients to discuss and develop innovative ways to enable access to value added medicines.

Discussion with the audience:

- 1) C. L. Pereira: What is your experience with valued added medicines?
 - P. Georgeva: We will translate these presentations in our own language and disseminate all information across the country to raise awareness and facilitate access to value added medicines.
 - E. Tyssier: When does the dialogue between patients and doctor take place? It is in this moment that patients should be informed of the existence of these innovative options.
 - J. Bowman: How are individuals able to stop the progression of their disease when they do not have enough time to speak with their doctors? Do medical professionals have enough time and enough training to know how to have this discussion with their patients? How can we make sure that ,when doctors and patients have those 10/20 minutes to talk, medical professionals know how to talk with their patients and what they need to discuss with them?
 - C. L. Pereira: We are also tackling directly the issue of physicians. For examples we are working on valued added medicines that reduce the steps and activities that doctors have to take to reconstruct the medicine or even to decrease the time that is sued to administered the medicine to the patient. We are tackling this inefficiency of the system so that healthcare professionals can actually use their time to have a dialogue with their patients and explain them the disease.
 - M. Votta: There is not much health literacy about value added medicines. Can we translate people’s experiences into a “narrative medicine” to spread our message?
 - G. Romanello: Value added medicines seem to improve people’s quality of life; yet, there is a great lack of knowledge about these medicines among people. Why are authorities not allowed to spread information about it?
 - o G. Pogany: it is not just authorities’ fault. People don’t know what value added medicines are even when they are using them; we need to educate them about it.
 - E. Tyssier: the concept of value added medicines is relatively new – Medicines For Europe has been working on it for the past 3 years – and the message hasn’t been properly spread yet. Is the definition clear enough? Can we translate the definition in different languages? We need to work all together to raise awareness among patients.
- 2) C. L. Pereira: What are your views on patients’ voice in decision making processes?
 - J. Bowman: The most important moment is the initial patient-doctor discussion when they need to decide what the best option for them would be. We need to take a step back into the actual development of the therapy and start from what patients’ preferences and expected results are. More patients’ integration and participation is necessary since the beginning of the cure: look at patients’ preferences, need, expected results, etc. from the beginning.
 - M. Votta: We need a change of perspective. What is the role of European institutions in the field? There are different ways in which patients’ voice can be heard and different stakeholders ready to hear them, but we need a good strategy to combine them. It is essential to include the voice of patients’ in the decision-making process.
 - A. Narayan: Patients’ ideas, and especially the patient’s perspective, should be taken into account throughout the whole process. There is a lot of push back based on theory and not on what is actually needed in practice.
 - J. Bowman: We need to look at the recipient of the intervention, not at the intervention itself. What is the impact of the intervention on the patient’s life? What will be the consequences of the

cure in 5 years? Since value added medicines represent an innovation, we have to stop looking back to the old way and start looking at innovative structures to provide a value-based healthcare.

- L. Cigolot: We also need to take into consideration the internet perspective, as we live in a digitalized society and the digitalization of the healthcare system is happening very fast. There are many websites selling medications in an illegal, non-compliant way with national legislations. We really need to have a comprehensive picture of what is happening around us and, in order to make a change, we need to create space for innovative projects and medicines and we need to face existing issues together, such as the one of fake or illegal medications.

More questions to reflect on (C. L. Pereira):

- 3) What can we do to ensure more participation from patients in these processes?
- 4) How can we find solutions together to make sure that this happens?

Concluding remarks and next steps:

By Catarina Lopes Pereira:

- To sum up, during today's seminar we have analyzed the environment in which value added medicines exist, the benefits and results of some examples of value added medicines, and the importance of the dialogue between doctors and patients. Above all, we have highlighted the importance of hearing patients' voice. Once back in our countries, our first commitment will be to evaluate if the definition of "value added medicines" is heard and understood in our country, and possibly translate it into our language. Then, we need to cooperate and decide the best ways in which can we raise awareness about these innovations, tell people when they are using value added medicines and, above all, make sure patients are present throughout the whole intervention and that their voice is heard.

By Mariano Votta:

- Dialogue is the key of today's initiative, which should represent just a starting point in the discussion on value added medicines.
- We would like to identify how we can assess the next steps in a practical way, putting together innovation and patients' needs (different perspectives).
- We could have a focus group for each healthcare area.
- A narrative medicine translating what we are talking about into concrete experiences could be very helpful.
- We can do advocacy only if we are empowered and we cannot do it alone.
- We need to know more about the innovations, as we are not those who lead them, and then share our experiences.
- We need to harmonize terminology, considering the importance of the media.
- We need to publish articles and documents on the topic, as there is no health literacy in national languages.