



The secret to improve access to value added medicines

Catarina Lopes Pereira | [Follow](#)

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With Francis Arickx

Francis Arickx, Head of the Directorate Reimbursement of Medicines and Pharmaceutical Policy in RIZIV-INAMI Belgium, is here today to unveil the secret to improve access to value added medicines.

Value added medicines provide a wide range of different and important benefits to patients, healthcare professionals and healthcare systems. Since 2018, Belgium has been leading in recognising the benefits of these medicines in their Price & Reimbursement (P&R) process.

Catarina Lopes Pereira (CLP): Our conversation today will primarily focus on the so-called 'gold standard' legislation for value added medicines in Europe, making you a hero in policy-making...How important value added medicines are for healthcare systems and why you felt the need to recognise the benefits of value added medicines in the legislation?

Francis Arickx (FA): Everything that brings added value it's important for healthcare systems. Value added medicines, as well as new innovative medicines, are important because they bring additional health benefits to patients and healthcare systems. And, as our first goal is to serve patients, the additional benefits that value added medicines can offer are therefore relevant.

Since 2002 we had different P&R procedures for medicines, but we were confronted with several examples of value added medicines, such as sophisticated inhalation therapies, and had no possibility to valorise the benefits of these medicines which were not the classic new innovation. There were several examples, I remember, the injectable/soluble paracetamol,

innovation happening and that's why we felt this need.

CLP: Being creative with legislation most likely requires a wider support and determination, so that you can make things happen... Could you tell us a little bit more about this process of change?

FA: Changing legislation is indeed a process that requires will and persistence, but more important is our ultimate purpose of making sure that we are bringing value to patients and healthcare systems.

The first opportunity to start the process was the ambition from the new Minister of Health in 2013-2014 to focus on innovation, not any kind of innovation: innovation which is valuable for the patients. So, a whole process was started with the PACT for the future. This PACT aimed to bring valuable innovation to increase accessibility for patients and recognised immediately that innovation is broader than just breakthrough innovation. The additional value can be more than what we generally know from the breakthrough innovation, you do not only gain added value when you address new targets, you can also achieve more safety and more comfort with step-by-step benefits. Apart from providing specific procedures for the new innovative medicines we also created simplified and more transparent procedures for value added medicines.

CLP: The additional value of a medicine can indeed come from different corners of innovation and has a huge impact on patients, healthcare professionals or healthcare systems. So, we can go beyond rocket science breakthrough innovation and still call it innovation?

FA: The impact on patients or healthcare systems of these step-by-step benefits can sometimes be even more important than the breakthrough innovation. And one aspect that it's very important to highlight in this process to change legislation was the support and involvement of a multi-stakeholder dialogue - healthcare providers, academics, insurance agencies, authorities, healthcare professionals, industry representatives...- which helped to create a positive mindset. We discussed about innovation, what was considered value and as such we had the opportunity to change the decision-making process together.

CLP: And with regard to the change in the decision-making process, could you share with us your secret?

FA: First, as mentioned before, there was a large investment on stakeholder involvement in the decision-making process, to discuss the needs and to make choices. Regarding the legislation itself, we created a simple split between medicines that claim an additional value and medicines that are considered (bio)equivalent. We then created specific requirements for the claim of an additional value and a reimbursement procedure that enables a faster access to value added medicines. The result for value added medicines is that a premium became possible on top of a generic/me-too price. Obviously, the additional value has to be documented and demonstrated.

CLP: This is fantastic...and that's why it's called the 'gold standard' legislation in Europe! You also mentioned that the additional value has to be documented and demonstrated... What is your perspective on the evidence to demonstrate the value of these medicines?

important and the need to fit for purpose. You do not need the same level of evidence for pre-filled syringes vs a vial that you would need for a new indication. It is common sense what you are going to ask for the first example vs the second example. In many cases, common sense is useful – but it's challenging to put 'common sense' rules in legal terms. For instance, some of the benefits that are related with convenience for the patient or healthcare professional are difficult to demonstrate in the classical hard endpoints that we use in Health Technology Assessment (HTA): we feel generally more comfortable to analyse the evidence from clinical trials rather than real world evidence...

What is happening in HTA and what I see very often is that we have some difficulties with data, HTA is not an academic exercise - it fits a purpose, it aims to help the decision-makers with what to choose and how to decide; to help physicians on how to set their guidelines for a clinical practise. We need some pragmatism and we cannot have one set of standard criteria. We must differentiate between different types of innovation and different types of additional value that you want to defend or prove. If you look on how other medicines are treated, gene therapy, orphan drugs, small indications for oncology - in reality, we are already using different sets of evidence, so we should do the same for value added medicines...

CLP: The healthcare systems are definitely moving in the digital space, do you think that value added medicines have a role to play in this revolution in Europe?

FA: We don't have examples yet, but we see it coming...monitoring systems with a treatment (can be drug or not), apps that monitor compliance which can already provide a huge benefit and improve the outcomes of the patients... Then we also see the interaction of these digital systems with electronic health records – real world data floating into the electronic health records which is going to be a challenge to process this information, but worthwhile! In the end, it will come down to proof what is the added value and how to value this in financial terms, which might be challenging...I have the impression that citizens consider apps for free or at very low cost...Further, I believe that most healthcare systems are not ready yet to host digital innovation...

CLP: And are you optimistic on the future of digital innovation in healthcare?

FA: Yes! But I still bear in mind the long-term sustainability of the financing of this innovation...

CLP: And could you share with us, your thoughts, on the main enablers and hurdles to access innovation in the future?

FA: The answer will probably be expected: financing/pricing/budgeting will be both the enabler and the hurdle. Planning and prioritisation might probably help, so a horizon scanning system can definitely be an asset! I also recognise that probably not all the countries are considering all the types of innovation (such as value added medicines) in their system. But I see opportunities for value added medicines. Countries that struggle to access basic medicines face huge challenges to access new innovative expensive medicines. Possibly, value added medicines can be an opportunity in these countries that lack access to these new innovative medicines.

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Catarina Lopes Pereira
Market Access Senior Manager at M...

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