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Arun Narayan is the Chairman of the Value Added Medicines Sector Group at Medicines for Europe, in addition to serving as Head of Global Portfolio Strategy and Head of European Business Operations at Mylan. Narayan introduces compelling reasons why payers in Europe should consider Value Added Medicines, including cost savings and improved rates of adherence, and underscores the importance of leveraging real-world evidence to demonstrate their value.

What are Value Added Medicines? What new benefits do they bring to the patients?

These are innovations that bring new and added value to known molecules. There are various ways through which we can achieve value addition like, repurposing, which means developing a new indication for an existing molecule; reformulation, which means changing the form in which a medicine is delivered; or creating a combination between a medicine and a device, or between two medicines.

The foundation of Value Added Medicines is patient-centric, and there are many reasons why we do these value additions. It may be as simple or as complex as reducing pain at the injection site, reducing side effects of an existing medicine or improving its efficacy by developing a new delivery

mode, reducing hospitalization time, and very significantly, improving adherence for a medicine that is on the market.

Can you explain why Value Added Medicines have been successful in the US, especially as generics & biosimilars have struggled to take off there, and why these medicines haven't yet gained traction in Europe?

In terms of the pharmaceutical market, the US and Europe are structured very differently. The regulatory process is different, and the pricing and reimbursement structure and mechanics differ. In the US, there is a well-defined regulatory pathway for developing Value Added Medicines, which is called the 505(b)(2) pathway and which is also linked with incentives. There is a clear process for scientific advice before the 505(b)(2) pathway is used.

From a pricing and a demand creation perspective, in the US, if the product satisfies an unmet need and if a physician is willing to prescribe the product, it can be sold. This is unlike the current situation in Europe, and this is why we want to borrow some of these elements from the US as we move forward with finding ways to make Value Added Medicines more accessible to patients in Europe.

Which of these elements do you think would be acceptable to European markets?

Today, there is a strong and compelling case for Value Added Medicines as the demand from patients, healthcare professionals and society already exists.

The challenges are in pricing and reimbursement as well as regulatory areas and that is what we are working on. We are working to create those appropriate pathways and a framework that supports and enables continuous innovation and allows us to bring Value -Added Medicines to the market and to make them accessible to patients.

What are the areas the Value Added Medicines group is focusing on to improve availability and access to Value Added Medicines?

We are working on five areas to help us create a suitable ecosystem and environment for Value Added Medicines and to allow them to be accessed by patients who need them.

The first is the regulatory aspect which is all about the timely approval of Value Added Medicines through streamlined scientific processes, acceptance of real-world data and a pragmatic approach to evidence requirements, which should culminate in an improved and fit-for-purpose regulatory process.

The second is tailor-made and appropriate regulatory and other incentives around such innovation; for example, we see the UK looking into tax credits for this type of innovation.

The third aspect is next-generation guidelines created by physicians and KOLs. Incorporation of these Value Added Medicines into the guidelines of the future will create the momentum to bridge the gap in unmet needs.

Fourth: pricing and reimbursement is a big topic we are addressing, and our objective is to achieve a pragmatic and real-world view, moving away from traditional HTA requirements, and focusing instead on specific benefits.

Finally, we are also working on disease management and the benefits that digital Value Added Medicines can bring to patients. This is a new area for all authorities and stakeholders: everyone sees it coming but nobody is prepared for it, so we must all work hard to ensure that we are prepared to measure the benefits of digital Value Added Medicines. We have already seen concrete steps in Germany, which has recently started reimbursing some apps.

You work to convince regulators and payers around Europe. Could you give us an estimate of the size of the market and the type of potential savings you could bring to the system?

We estimate savings on a case by case basis due to the benefits each Value Added Medicine provides. Some of these products provide direct benefits or savings to patients and to payers (for example, by reduction of pain or other side effects) and some provide indirect benefits or savings (for instance by reducing the need for hospitalization).

Already in 2017, the OECD stated that ‘a significant share of health spending in OECD countries is at best ineffective and at worst, wasteful. Overall, evidence suggests that up to one-fifth of health spending could be channelled towards better use.’

If we take the example of adherence, the OECD did a study in 2018 that showed that the lack of adherence alone costs European healthcare systems around 125 billion euros every year. There is

compelling evidence about the deficiencies in the current system, and Value Added Medicines are stepping in to bridge those gaps and make up for those deficiencies.

Talking about adherence, could you give an example of how Value Added Medicines can help?

Adherence can be supported in various ways. The simplest way is to reduce the number of pills a patient must take, which can be done in one of two ways: one way is by making medicines long acting, the other is by combining medicines. Other more sophisticated areas would include drug/device combinations. Thinking of inhalers, today we know that in COPD (Chronic Obstructive Pulmonary Disease), there is a very significant degree of non-adherence because either the medication is not taken on time, or is missed or not taken properly. Possible solutions include an inhaler which is linked with an app that has the capability to measure the inhalation and collect data which can be shared with the healthcare professional, to assess if the medication was taken properly or the position of the inhaler was correct. With this data, the patient's physician can see whether it's the medicine that is not working or if there is a problem of adherence. Adherence is a big issue across demography and disease areas. Aside from the monetary aspect, the OECD estimates that medication nonadherence leads to around 200,000 premature deaths every year. There is a lot of evidence on adherence alone which we can leverage to support the development of Value-Added Medicines and related measures.

Speaking about innovating with technologies and data, when taking into account limited R&D budgets, how competitive can generic and biosimilar companies be in the race to bring new technologies and drug/device combinations?

The scope of Value Added Medicines, as we traditionally define it, is to look at off-patent medicines. Our objective is not to create more expensive new medicines, but to take existing medicines and innovate with them. We innovate outside the realm of New Chemical Entities (NCEs).

Originator companies are usually focused on developing NCEs and sometimes they do work with medicines that are still under patent.

However, there is a very large number of effective off-patent medicines and that's where our focus is: meeting unmet needs by innovating with these off-patent medicines.

We are advocating for fit-for-purpose evidence requirements and the opportunity to present real world evidence, in order to bring those medicines to market without having to go through an entire clinical program that may be required for an NCE. The benefit is that we aren't repeating clinical trials that are unnecessary and we can bring to market Value Added Medicines that truly benefit patients.

There are a few countries that already seem to be adopting regulations that are favourable to R&D as it relates to Value Added Medicines. In your dialogues with authorities across Europe, do you feel there is a proper understanding of what Value Added Medicines are and an interest in ways to adopt them?

Today, there isn't enough recognition of the value brought by Value Added Medicines. Belgium has used a fairly simple and logical way to amend regulations and to recognize the value that is brought by Value Added Medicines, and they have already reviewed a few products through this pathway. Belgium is a shining example that we are using to share best practices with other regulators and pricing authorities to explain that there is significant value offered by Value Added Medicines and that not only NCEs can bring value. We, all stakeholders, must be able to create the framework for recognising the real value in continuous innovation on existing molecules. There are other examples, such as Germany which has recently agreed to reimburse some digital apps, that are increasing visibility on the concept that there are non-traditional means to bring value to patients. It is our objective to accelerate these trends and to demonstrate the value to more and more regulators so that we move away from a traditional, siloed approach of assessing value and move toward using real world evidence and pragmatic means to determine value.

What you are asking authorities in a sense is a cultural revolution. For the companies who bring Value Added Medicines to market, how big is the cultural revolution?

It is a change of mindset, meaning we remove rigid siloes around value and quality of life assessments. It is great to see Belgium has already made that mindset change, meaning that it can be done. It requires a logical and pragmatic approach, and in this way, Value Added Medicines will slowly and steadily be accepted by more and more regulators in Europe.

Within the generic companies themselves, what is happening internally to help them embrace Value Added Medicines and bring them to market?

Every company is looking for opportunities to move up the value chain and Value Added Medicines offer a direct opportunity to do so. There are many companies that have the knowledge & capability, and that recognise that there is growing momentum around Value Added Medicines. It is true that the dialogue and interest around them is increasing, and more and more generic and specialty companies are thinking about Value Added Medicines – we see the momentum building further.

Furthermore, in companies, patients' groups, and in the minds of healthcare professionals, this mindset change around recognizing the need for and benefits of Value Added Medicines already exists. It is now up to us to enable and create pathways to bring those medicines to patients.

Speaking about your interactions with regulators, some countries are still facing very basic healthcare infrastructure challenges. Which do you think will be the first ones to adopt legislation around Value Added Medicines in Europe?

It's difficult to predict today. There is a budget crunch in nearly every country. Therefore, this dialogue is relevant because it is around bringing better value with existing products without having to jump to more expensive medications, while creating the framework for us to have a reasonable return for developing a Value Added Medicine.

Another element which I mentioned earlier is preventing the rising costs of lack of adherence: 125 billion euros in Europe alone. There is money already being spent that can be spent more effectively. This conversation is relevant to all regulators and payers, no matter the country: Bulgaria, Romania, Belgium or Germany – the numbers may be different, but the constraints are similar. The challenges and opportunities are similar across countries as well, as the population is ageing and has a different lifestyle and expectations from 30 years ago.

How can you avoid the pitfall in the generics industry of having to generate more and more savings, losing your return on investment?

We are looking for the best way to demonstrate the benefits of Value Added Medicines through pragmatic means. If we can identify inefficiencies such as lack of adherence or other challenges

that patients face and if we pragmatically demonstrate potential savings or other direct benefits to patients through the development of Value Added Medicines, we should not be considered a “me too”. The objective is to demonstrate true value which is over and above the current standard of care. Our dialogue focuses more on bringing benefits and real-world evidence to show payers the true value of these benefits.

What do you think will make the difference between failure and success in convincing payers?

Success is all about creating an environment that supports and encourages innovation, which, in turn, enables us to provide access to Value Added Medicines. As these enabling factors fall into place, pharma companies will invest more and more to bring a larger number of Value Added Medicines to the market. From a company perspective, it is important to understand and acknowledge unmet needs and the key factor for success would be to find solutions for those unmet needs.

Can you give an overview of how many companies have joined the Value Added Medicines Group so far?

Many companies have joined the Value Added Medicines Group such as 3M, Accord Healthcare, Alfred E. Tiefenbacher, Camargo, Consilient Health Ltd, DSM, EGIS, FRESENIUS KABI, medichem, Mylan, OJER Pharma, Oncomed, Polpharma, SANDOZ, TEVA, Theranexus and ZENTIVA. And today, we have a few others in various stages of the application process.

As we interview companies around Europe, many are talking about how artificial intelligence will revolutionize their approach to drug repurposing. What are your thoughts on this game-changer?

Digital health and related developments are the realities of today and incorporating digital technologies into Value Added Medicines is inevitable and should be welcomed. Therapeutic support as well as collection of real-world data are two areas where we are likely to see the biggest steps forward in digital health and these provide a fantastic opportunity for Value Added Medicines to improve outcomes for patients. There is a continuum between Value Added Medicines and

digital medicines.

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