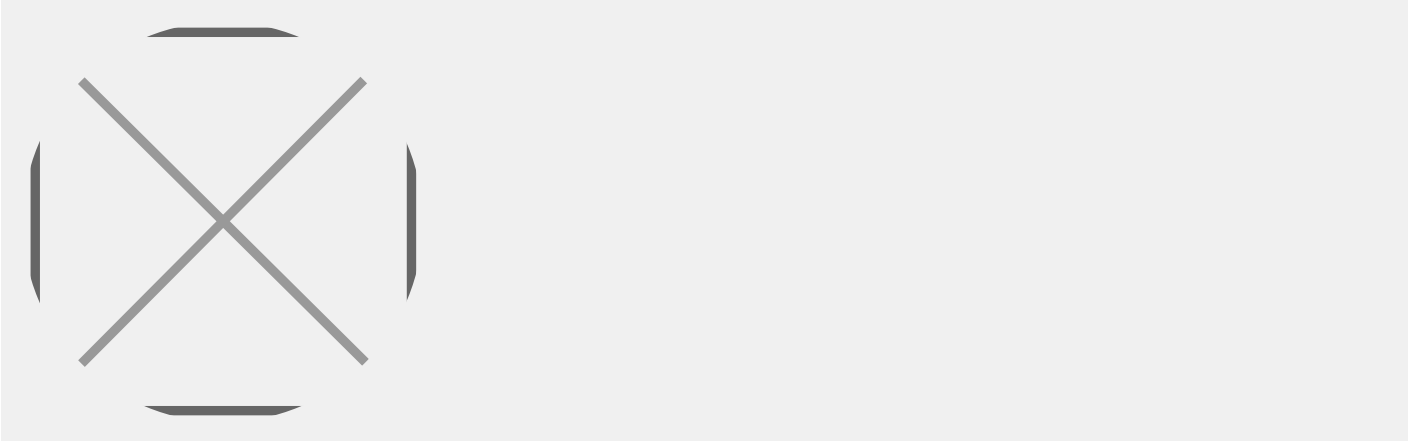
Interview: Donald Niesten, Partner, Deloitte Belgium



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Donald Niesten and Omer Saka discuss the current dynamics of the healthcare and pharmaceutical sectors in Belgium, the challenges of entering the market and the issue of effective communication with stakeholders, as well as offering opinions on the merits of 'clusterization'.

Deloitte is certainly renowned for its strong network of international expertise in the field of life sciences having teams in all of the crucial markets able to cater to their particularities. Having accumulated well over two decades of experience in the industry amongst yourselves, what in your opinion is it that your life sciences clients struggle with most in Belgium today?

Omer Saka (OS): I am active in an area which predominantly evaluates the value proposition of pharmaceutical and medical devices companies in addition to other life sciences organizations. As such, we are following the emerging trends in the market, especially over the past three or four years very closely and generate accurate responses to such trends with our clients.

From a pharmaceutical company's perspective, I believe the primary challenge facing the industry today relates to the perception and the communication of the value of pharmaceutical and healthcare products. Do we understand the value of our products? Are we able to estimate the value of the products for the different stakeholders? I think the industry has been struggling with these topics for over 10 years now, since a formalized pattern of hard technology assessment was introduced to the foray of market access.

More specifically, let us consider the challenges step by step. I will define those challenges as generating, illustrating, ascertaining and maintaining the value of life sciences products.

The first challenge, in my point of view, is, “Are companies, especially large pharmaceuticals, able to integrate an analytical, but also realistic, portfolio assessment program that would ensure they can have a good internal rate of return?”

Deloitte has recently published a report, which analyzed a dozen companies and their five-year return on investment rates and identified that there is indeed a clear decline. In relation to this fact, many of the top life sciences industry firms are struggling to maintain and further improve their profitability. Hence, this regression could be seen as an indication that there is space for improvement in bringing innovative products to the market.

The second challenge relates to the fact that once the decision is made to bring new products to the market, we must ask ourselves whether our teams with different tasks are properly integrated and coordinated in their efforts. Those efforts span from data collection to stakeholder management, from the setting up of clinical studies to matching clinical and economic messages with the requirements of market access strategies. Observing the approach of the industry first, we see that there are varying degrees to which life sciences companies institutionalize their value messages in a well aligned environment and synchronize it with the different functions that they have. The illustration of value in a synchronized fashion during the process leading to the market access stage of products in very crucial to be able to develop a complete set of arguments when finally faced patients, physicians and of course payers.

The third challenge involves actually entering the market. This is the point where the value of a product will be tested and ascertained by the users and more importantly by the payers. The biggest challenge at this point is the lack of standardized approaches both by the payers and the life sciences companies. Payers even though they state the analytics, data and assessment they require for a market access decisions (they group quite a few of the methods used for this purpose under the term Health Technology Assessment) they do not always apply the rules as they are expected to. For example a new technology with a very acceptable cost effectiveness profile may be refused market access via delaying the decision and or asking further price reduction.

In order to be ahead of the game with some of our clients, we involve decision makers/academics in product value preposition discussions and test their responses for quite a while before the products are launched.

Finally, the fourth challenge is being able to maintain and if possible improve the value preposition of the products already in the market. Given the amount of investment made on a medical technology, be it a medical device or a pharmaceutical drug, it is crucial to have a sustained commercial existence in the markets. Currently there is an increased emphasis given to real world

evidence studies which are crucial to establish the effectiveness of a product alongside proven level of efficacy. With some of our clients we evaluate methods for data collection and post market access so that additional evidence can be generated on the benefits of using new therapies as their use becomes standard of care in clinical practice.

Donald Niesten (DN): Typically, pharmaceutical companies have not excelled in articulating these issues. They have not, under all circumstances, been managing their broader stakeholders and they have not always been able to excel at managing their regulatory affairs when bringing new products to the market. Pharmaceutical companies have historically been trying to introduce new products to the market, hoping that they achieve blockbuster status. The latter introductions are too often done without communicating their value message to the broader community of stakeholders they have, with the exception of those directly using the drug. This is one of the issues that pharmaceutical companies have been struggling with for quite some time now. In that respect, big pharma can be compared to a big tanker vessel – if you try and turn the ship, it will take a while before it actually changes heading. On the other hand, we see that the relatively smaller organizations are able to respond to the changing environment more rapidly due to their increased flexibility compared to big pharma.

In this respect, is increased agility a part of the solution for the challenges of large pharmaceutical companies today?

DN: Indeed, enhanced agility is one aspect that pharmaceutical organizations are beginning to address. We now regularly see this with our clients that try to steer away from the rigid approach that is characteristic of bigger organizations, by addressing certain specialty areas where they can maneuver more rapidly and effortlessly. In essence, they do this by focusing on that specific area and then building the appropriate lean structure around that, all the while remaining to a certain extent under the umbrella of the larger organization.

OS: I believe this difficulty is certainly inherent in large pharmaceutical companies. On the other hand, with regards to the smaller pharmaceutical and medical devices organizations, it is the realization, or lack thereof, of value that is a cause for concern. For instance, some of the medical devices clients perceive value from an engineering point of view. As a result, they may try to gain market access with technologically improved products that they believe should be reimbursed or absorbed by the market relatively quickly. In practice however, this is not the case as they may not pay sufficient attention on the actual clinical and practical value of that improved technology for different stakeholders.

The value arguments have to be centered on the demands of the stakeholders such as payers, physicians and the patients. In particular, the value proposition has to be very clearly clustered around the economic and clinical value of the proposed product. The essence of what makes a

product achieve its financial potential and the expected rate of return is without a doubt entirely related to the value proposition being clearly targeted and communicated.

In sum, big pharma is challenged by the complexity of its organizational structures, while small pharma perhaps lacks the resources necessary to systematically analyze their value proposition and bring it forth to the stakeholders.

DN: In reaction to these challenges, one trend we have observed over the past few years, which we expect to grow exponentially with time, is that you see a lot of clustering between big and smaller pharma players in certain domains and niche areas. The overall aim here is to ensure that either the resources are there to carry out an adequate analysis or that there is an adequate level of flexibility in the various aspects of the entire value chain of the big pharma companies. As a result, we see that clustering is increasingly becoming a trend with companies engaging in a range of outsourcing or collaborative activities.

Considering that this trend towards clusterization can certainly serve to increase complexity, how should organization adapt from a governance point of view in order to tackle these challenges?

OS: One advantage of Deloitte is the fact that we represent the largest life sciences advisory firm in the world covering various domains and subject areas from supply chain to product launch, from pricing strategy to direct/indirect tax advice. Aside from the wide coverage we have exposure to a wide group of clients providing services to all of the top life sciences firms.

I, for example, function more in the market access strategy, which includes advisory services around pricing strategy, portfolio assessment as well as carrying out clinical and economic studies within the health technology assessment domain. Consequently, I look at how clinical trials should be set up and assess how the economic value should be derived from these products. This involves analyzing what the optimal market segmentation and what the technology assessment requirements will be, before finally detailing how the product will be introduced into the market.

In order for this process to function seamlessly, I need to have colleagues that can actually ensure that IT systems can cope with the way that I am proposing how this value should be brought to the market for instance. Similarly, I also rely on my associates in order to bring forth a clear and effective sales force strategy and others who understand enterprise risks involved in the process to be able to execute the market access strategy accurately. This way we do not focus on individual deliverables along the journey but are able to have an engagement with our clients to work towards improving their returns and eventually their profitability.

I suppose that any firm with the broadsheet experience of Deloitte would have this advantage. Indeed, there are many firms that are great at strategic thinking. There are others who can process

the analytics very well. However, because of our size and scope, I believe that our advantage is that we can combine these two together to provide our clients with comprehensive solutions. In that regard, we offer for example a global market access strategy proposition to life sciences companies, employing a one-stop-shop approach to market access.

DN: What we encounter in a number of large pharmaceutical companies is that they take a ‘silo’ approach to market access matters with some focusing on the regulatory aspects and others on market access and pricing. It would be beneficial to view this more holistically and that is why we take a more interconnected perspective. We can assist our clients in different domains with the aim of better integrating their internal organization and ensuring this is embedded in the governance process related to working with their partners or sub-contractors. In addition to this, we also advise our clients on what processes or tasks should be outsourced, depending on a range of considerations including the importance of maintaining internal control for instance.

OS: In addition to this, there is another advantage that we frequently bring to the table. If you look at the progression of the life sciences industry, up until about two years ago, the financial crisis represented a significant breaking point for the life sciences industry, just like for any other industry. As was the 1999 – 2000 period, especially for Europe and the Western world, because of the application of formalized technology assessment methods and their applications. Now what is happening is that pharmaceutical companies understand that the value proposition of a drug is not only found in the drug itself. In other words, they are being perceived as a company selling a pill, which is essentially a commodity, with very little to no differentiation among them. That is, pharma companies have not been traditionally making use of their clinical expertise to provide therapeutic solutions. To put it into perspective, why shouldn’t Sanofi for instance, until recently the producer of the biggest diabetes drug in the world – Lantus, partner with governments to tackle to global issue of diabetes and provide complete solutions to the problem?

So with regards to the advantage that a company like Deloitte brings to the table is that, as part of the strategy, we optimize the market access propositions and put forward therapeutic solutions. In addition to this, because we work together with other pharmaceutical companies, we know which companies could potentially be paired with others to take advantage of certain opportunities. Likewise, during the course of our work, we have also built up strong relationships with the authorities. We can utilize this network of contacts to contribute towards improving public healthcare by exposing them to the possible solutions we know our clients possess. For instance, Deloitte Belgium has recently been instrumental in merging the approach of a very large food company with a major pharmaceutical company to look into potential collaboration areas.

**Considering that R&amp
D based companies are under increased pressure to improve their innovativeness, how can**

they reinvent their R&D model to improve their productivity?

DN: Broadly speaking, what we see more and more is that rather than taking the drug from the initial discovery of the molecule to the end stages, companies are now outsourcing little bits and pieces of the process with some even contracting out extensive portions and in some cases even full externalization of certain molecules with milestone payments based on further development achievements. In other words, companies are trying to minimize their risks by shifting it third party providers. In doing so, they often either retain certain claw-back possibilities of getting the drug back in-house, collaborating in joint research projects with other organizations or completely outsourcing it. Others have also opted to form entirely new research entities with third parties while retaining the rights to repurchase the product if the development advanced far enough and developments are promising. We have seen in a couple of instances where the company indeed decided, after a certain time, to buy back the developing product from the outsourced company because they could identify the value potential of the new product.

Hence, to a lesser extent, we see companies exclusively covering the 10-12 year stretch between the discovery of the molecule and the final launch on the market. Not only is the risk associated with this increasingly becoming shared, but this also allows pharma companies to focus on their core competencies while outsourcing other activities to third party specialists.

OS: I would also add that the portfolio assessment companies have done in the past was focused superficially on financial assessments only.

In our approach, together with our colleagues in Financial Advisory Services, who have expertise in investment evaluation, we assess the sensitivity of investment decisions on conditions related to market access, such as evaluating how does the product actually address an unmet need, what would be its societal benefit, how easily it will be integrated into clinical practice, what will be the direct and indirect cost implications on the health care budgets at large in addition to hospital budgets in focus. Hence our methods involve considering these aspects in order to be able to make robust forecasts on investment portfolio options.

An important element of change which also has to be mentioned as an answer to your question are the major changes set to sweep the UK pharmaceutical market in 2014. The pricing system there is going to change from a PPRS (profit-based pricing scheme), to a system called value-based pricing. The new value based system will be based on four main pillars: unmet need, societal benefit, cost-effectiveness and innovation. Most interestingly, this represents the very first time that innovation and unmet need will be formally and quantitatively recognized as part of the reimbursement process, illustrating the growing importance of taking such factors into your portfolio and R&D decisions.

Is this why over the past five years, there have been no Class-1 drugs approved for full reimbursement in Belgium?

OS: I think Belgium is a very specific situation. Belgium is without a doubt a very attractive place for R&D activities. The available R&D patent and tax incentives are phenomenally good and the government is certainly continuing along this path. This is an area where the government is actively taking the measures they should be taking.

If you look at the market access points, on the other hand, and the way the authorities analyze products, then I think their attitudes are very detrimental for allowing market entry at an early stage. At the same time, pharmaceutical companies are not without blame since not all of the products they try to introduce to the market are ground-breaking innovations.

So for Belgium specifically, we have to look at both ends of the scale. On the on hand, there are attractive incentive packages and investment potential; however, whether this actually translates into increased value for the Belgian society is a separate matter. In practice, we see that with some of the drugs it does, while in other cases, the government is more reluctant.

Do you think companies should contract Deloitte at an earlier stage in the development process in order to avoid their products 'getting stuck'?

OS: Certainly. I think we can definitely help drug companies in various ways as we have already mentioned. However, a successful drug development and launch also requires the value-focused attitude of a company that we have been stressing. We have worked with a number of clients to support them to generate, ascertain and maintain the value of their products. Sometimes our support is in the shape of helping them design and set up clinical/economic data collection studies, or to build product or therapy area specific global value dossiers which form a comprehensive repository of information based on data and analytics.

In Europe, the success of a life sciences product in the market ultimately boils down to the national health systems (social security organizations, sickness funds or NHS type systems) agreeing to provide (or pay for) that product to the patients. Therefore, pharmaceutical companies in Europe must focus on conveying the value of their products clearly to payer agencies. In addition to this, they must also think and act like a partner to the authorities – not as an industrial partner that creates jobs – but rather a partner that actually provides healthcare solutions. We are observing trends where industry can work with the national health care systems to improve the care of the citizens rather than being the developer and manufacturer of drugs. Such collaborations are taking place in disease areas such as Diabetes. We are offering services where we assess the feasibility of such partnerships. We have also taken a role in enhancing communication between payers, providers and industry. We deploy detailed consensus generation tools such as Delphi surveys and/or multi criteria decision analysis in such activities. We also act as an objective evaluator of the

current situation. We have recently published a white paper on vaccine procurement methods and how to optimize the purchase of vaccines. We are currently working on another eminence project where we will be evaluating the patient views on the Value Based Pricing methodology which will be put to practice in the UK from 2014.

One point that needs to be mentioned is the improved use of technology to increase the chances of product uptake. For that purpose we work with entrepreneurial companies which are developing new diagnostic methods or new medical devices. In a program we call ‘Life Track’ we establish communication with start-up companies at a very early stage. We evaluate their business case and the viability of their technology. We then bring such companies to the attention of bigger industry firms.

DN: In addition to this, there are other elements to be considered that are unique to the Belgium healthcare system. Although the local healthcare system is quite rich and provides enviable healthcare to its citizens, it is also very expensive. I believe the central issue is that there is little control being exercised across the system where people can freely choose to go to a physician or a specialist in a hospital and purchase relatively cheap treatment. In other words, there are insufficient incentives in place that promote the reduced use of treatments and drugs or select the drugs that offer a higher value added. Although this phenomenon has decreased, it still remains at sub-optimal levels.

OS: Another interesting point to consider in relation to the efficiency of healthcare provision is how the system can optimize its efficiency by generating a better hierarchy of decision making among clinical specialists. Should the physician be the only point of clinical decision making or can we also allow expert nurses, therapists and such like to take part in the decision making process? The healthcare system in the UK could be a good example on how such practices can be achieved. Belgium may also benefit from such a move.

Although it is important to advise the industry to be more value-focused, if the audience are not susceptible to that value proposition and do not understand what value means for their patients, then you have very little to work with. Hence it is the responsibility of the governments to create economic and evidence-driven guidelines and initiatives. These include pathways that are adapted from primary to tertiary care organizations, good referral mechanism and payment methods that pull away from a Fee-For-Service, to more an outcome driven financing system such as Diagnosis Related Groups (DRG) system.

DN: I firmly believe that the Fee-For-Service approach is something that drives the market in the wrong direction. After all, physicians earn more based on the number of treatments and often have a vested interest to prescribe more of certain drugs without self-correction in the system. They are not incentivized in any way to take a different or innovative approach and are often financially

penalized if they chose to do so. Looking at the Belgian healthcare system, it becomes apparent that this is where important savings can be realized.

How do you see the Belgium pharmaceutical market evolving over the next three years and where would you like to position Deloitte therein?

DN: Considering the established operations we have here, as well as the new projects that are being developed in Belgium, such as such a new bio plant development by one pharmaceutical company as well as the creation of a central Belgian warehousing facility by another pharmaceutical company, there are still quite a lot of activities going on and I would say we are still relatively well positioned in the market. Some of the most important pharma companies do have a very strong presence in Belgium, as do the third party specialized sub-contractors.

One area where I see lots of potential and a key element for future success can be found in the collaboration models between the industry and the academic world. However, I must admit I am somewhat suspicious of the likelihood of actually precipitating due to the highly fragmented decision making power in Belgium; sometimes it is at the federal level and sometimes at the regional level and there is at occasions too little upfront consultation of divers levels involved. Although there are such collaborative initiatives being taken, they are mostly initiated by the industry or academia itself. Unfortunately, however, there is no singular focused approach to this yet.

From the perspective of providing tax benefits and incentives, I think Belgium is doing a good job. However, if you consider the encompassing elements which probably hold the key to the industry moving forward, then we still have work to do. I believe that those links with academia can provide the missing pieces for an environment that nurtures this progression.

OS: If I was to refer more to the vision of the life sciences industry in Belgium, then I would say that, with the right policies and incentives in place, Belgium could very easily become the European leader in bio-pharmaceutical sector. I consider the biotech sector to be the jewel in the economic and financial crown of the country. In my opinion Belgium would benefit significantly by setting this as a major objective for her industrial policy. In addition to industrial policy there would be significant gains for Belgium in supporting this industry from a knowledge economy point of view. For example without the bio-pharmaceutical sector, the country would not be able to meet the EU's 2020 target of sustaining three percent investment of GDP in R&D activities.

The government therefore has to put the vision out there to be the leading country, not just in R&D, but also in manufacturing bio-pharmaceuticals. In my opinion it would also benefit from being at the forefront of allowing its citizens to have access to new medical technologies be it devices or pharmaceuticals. This would not only enhance Belgium's health care provision but also help build s robust life sciences industry which could be the backbone of a healthier and growing Belgian

economy.

In this regard, I believe that Deloitte is in favorable position because we possess the necessary expertise, systems and applications, all of which are prerequisite to achieving visionary strategic changes. We can also effectively provide these solutions because we work with the industry, hospitals and payers as well as other relevant government agencies.

DN: Building upon that, we have an important presence at the European Community and we maintain a large government affairs department which can be of help to connect our clients at various levels with the necessary decision makers – at the Belgian and European levels. Although large pharmaceutical companies typically have their ways into the key decision takers, this is v

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