

Observations of a market access expert



Reimbursement is the fourth hurdle of pharmaceutical development. Payers and Health Technology Assessment (HTA) bodies demand compelling evidence of how new interventions improve the standard of care and public health

By *Claes Buxfeldt*,
HTA Director,
NDA Group



Companies need to create — and persuasively deliver — a convincing value proposition in an increasingly challenging and budget-restricted environment

With over 30 years' of experience from the pharmaceutical industry, 20 of which are in the market access and health economic areas, Claes Buxfeldt, HTA Director at NDA Group, has extensive experience in developing the market access strategy/payer strategy/payer evidence generation for drug development programmes from pre-clinical to launch phase. Twelve months ago he decided to make the move from industry to consulting. Here he reflects on his experiences and what he sees as the key trends and drivers for change that are going to affect the Life Science industry in the HTA and market access space.

"It's been an intense and fast paced 12 months with a steep learning curve" says Claes. "Understanding the role, managing the time between working closely on client projects and reaching out to new potential clients, whilst helping to build and communicate our service internally has really been a challenge and has definitely tested my time management skills!"

What inspired the move to consulting?

"I have always enjoyed the feeling you get when you realise that the work you have done has had a positive impact and feeling that I have played a part in bringing a new medicine to patients in need. A couple of years ago I realised that I wasn't getting the same energy from my work and wanted a new challenge. At the same time I was approached by Thomas Lönngren, the former Chief Exec of the European Medicines Agency, who told me about an opportunity at NDA Group. After learning more about the role, I felt inspired that I could bring something new to the table and this would give me the opportunity to help a lot of different companies with their market access/payer strategies."

What is the biggest difference between working in industry and working in consulting?

"I was expecting there to be a lot of

differences between large pharma and consulting so I was very surprised when I realised how similar the work is.

"The challenges I face when pitching a proposal idea to a potential client and then providing the services within the given timeframe are very similar to when I worked in large pharma and had developed a strategy that I needed to present to internal stakeholders to get funding or secure an investment decision. I recognise the situation and the challenges and can utilise my previous experience in the new context."

This similarity is also reflected in networking activities. Instead of building an internal network, Claes has now had the chance to extend his external network and identify people and companies that NDA Group can collaborate with, to mutual benefit.

"I think the biggest difference for me is a very positive one. NDA is a much flatter organisation and it's easy for me to talk directly to any of my colleagues to move things forward, get buy-in and get decisions made. This allows for a quicker decision making process so we can respond to clients' needs quickly and efficiently."

You have had the opportunity to work with a lot of life science companies, big and small. Are they facing the same challenges?

"Over the last 12 months I've been involved in discussions with large pharma companies through to small biotechs. The challenges that they have to address and the mitigations needed are strikingly similar, but the view towards risk differ greatly.

"I've been surprised by the number of development projects that I've seen where they are planning to launch with a quite limited evidence-base, sometimes with only Phase 2 study data or with clinical data from small patient populations. Obviously if we are looking at an orphan designation product then the patient population is small, but sometimes it may also be subgroup of a larger patient population that the company is targeting driven by biomarkers/personalised medicine. This creates a very special and intriguing set of challenges that I've really enjoyed working with."

Another challenge Claes has been working with is to understand the scope of activities in the market access area that are acceptable for a smaller biotech company to start work on early.

"A small biotech has different constraints than a large pharma company.

They understand and accept the amount of work that needs to be done to de-risk their programmes to meet the regulatory requirements, but the understanding of the need for early market access thinking is radically different. An important message here is that regulatory approval no longer guarantees the success of a new drug; you must pass the payer requirements as well before you can get your product to the patient."

Working with companies with different exit strategies has also become second nature to Claes.

"Working with a company whose strategy is to sell their asset or partner with another company at a certain point in development is of course very different from working with one that wants to take the product to market themselves. If this is the case then due diligence and market access consideration is key. To be able to say and prove that you have taken into account and considered market access challenges and that you have talked to payers and to HTA bodies is extremely important and will help to optimise the value and the attractiveness of the asset to a potential buyer/partner."

When you look back at 2018 was there anything that stood out for you?

"There has been an important shift over the last couple of years in the way big pharma viewed investing in and developing products for orphan diseases. Historically, large companies were not working in the orphan disease space because the forecast revenue from these projects was quite small and therefore it was difficult to get internal backing for them. Today we see a different attitude and even the large companies have started to invest in research to combat orphan designation diseases. I think that the regulatory bodies have really helped push the companies into this space by stressing the urgency of developing medicines for smaller target patient groups and providing good pathways and incentives for those products."

Based on your experiences over the last 12 months what do you see as the key trends and drivers for change that are going to affect the life science industry in this space?

"The first trend I see is the special considerations needed when new technology creates challenges for the health care system to take onboard. The recent successes in the oncology space with the CAR-T treatments illustrate this well – how do we optimise

the way that the health care system takes new treatment options on-board? This is a complex challenge and requires a lot of changes in the system itself. If we're successful it will, as the treatments have demonstrated already, lead to significant improvements to the patients so it is a challenge we must take on."

The development in the scientific area with complex and novel mechanisms of actions leading to disease modifying treatments and even cures, is another key trend for the future that Claes is tracking with great interest.

"These novel treatments are challenging in many ways from a regulatory stand point, but even more so from a payer perspective, as there is little or no data to use as a reference point to base the decisions on. Many payers are struggling with this and it is a steep learning curve but we are starting to see the HTA bodies develop the methodologies needed to meet this challenge.

"Both of these trends also lead to the question of affordability. How much is society willing to pay to cure a patient from a disease? This is a topic which I believe will cause a lot of debate over the upcoming months and years."

A final key driver for change was introduced last year as the EU commission proposed a new HTA regulation in Europe.

"I believe the establishment of a central HTA office in the EU (with the ambition to administer a common review of clinical effectiveness for new medicines launched) and the provision of Scientific Advice through this office will change the dynamics in this space. At NDA, we are tracking this development with great interest and I hope it will result in more efficient and harmonised evaluation of medicines.

"As this is a work in progress we will however have to wait and see how it develops in the years to come before we can draw any broader conclusions of its impact on market access in the EU."

Do you have any recommendations to companies developing products seeking eventual market access in the EU?

"I always advise to seek early advice and input. At NDA we've supported many companies with data and development plan reviews with exactly that in mind, both as a complement to formal Scientific Advice and as a proxy for it when time is of the essence. Getting the input early optimises the development programme and that's what you want – to do the right things right, first time."