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With over 30 years of experience in the life sciences industry, Angela McFarlane explains why the UK will not be removed from its position in the top 3 for new chemical entity launches, after USA and Germany, despite the uncertainty created by Brexit. Furthermore, she highlights the fact that the 'now' is real world evidence and how IQVIA is a global leader in that space.

Angela, your professional career has been an impressive one, spanning many years in the life sciences industry before you co-founded your own company, HGS Europe which you later sold to IMS Health and is how you come to work for IQVIA today. Can you tell us more about your path?

I have been in the life sciences business for 30 years. When I started at graduate entry level with MSD in 1982, there were very few women in the pharma sector, less than ten percent of the workforce were female. Having realised the second highest country level sales of a launch product in 1983, I was put on MSD's fast-track development programme. At the age of 25 I became their first field-based female sales manager and one of only a handful in the industry.

I went on to pursue a career in marketing with Squibb two years later, pre-merger with BMS. At that time there was only one other woman in head-office marketing. Post-merger, a new leadership team was built and as part of that leadership team we built the industry's first ever part-time sales force called PPP, consisting predominantly of women with families who wished to return to work

with school-time working hours. Having two children of my own at this time, BMS asked if I would be a role model in the HQ marketing team for PPP medical representatives to demonstrate that a family and a career could be combined.

Within eight months the part-time female sales team was out-performing their full-time male colleagues in what was then the all-important GP Call Rate and within a year they were doing the same in terms of product growth from new launch. 1989-92 marked a tipping point in the pharma industry as more companies went on to employ part- and full-time women; in some ways it feels strange even talking about it now!

In 1992 I left the relative comfort of the pharmaceutical industry to become marketing director at the UK's only managed care hospital, Surgicare. Being VC-funded and only in existence for three years meant that the organisational culture was radically different from anything I had experienced before. Within months of joining, it was obvious to me that a new strategy was needed if the VC backers were going to inject one final round of cash. I took a radical decision to completely change our customer base from privately insured or self-funded patients to the NHS patients of fund-holding GPs.

Through Varicare's unique diagnostic tool, our surgeons could accurately identify the weakness in the varicose vein (VV) and correct it. The recurrence rate in varicose veins at that time was 30 percent in the first year. I persuaded our surgeons to sign-up to an outcomes-guarantee, that if any of our VV surgery failed in the first year we would operate again free of charge. This was the first time GPs had ever heard of outcome-based surgery and the budget-savvy fundholding GPs loved it. They also loved the fact that we managed to treat most patients as day-case surgery through a lean operating model, avoiding unnecessary and costly overnight stays. Instead of closing the hospital, as was a very real threat, this strategy turned its fortunes around; within one year we went from operating on 125 patients per annum to 1,800 year on year and expanded the business to include hernias. Our business model was high-volume low-acuity surgery in which we could guarantee outcomes and patient experience. Quite revolutionary for the private hospital sector and the NHS in the mid-90s!

After Surgicare I took a one-year career break to have my third child, but mainly because my father had cancer at the same time and I needed to prioritise the family. In 1998, I started my own market access business (HealthGain Solutions-HGS). At that time there was only one other market access company in the world – this was very much pioneer country. We grew the business through a time when one had to persuade potential clients that the payer would have more decision-making power than the physician (1998-2003), and HGS became the dominant player in UK market access. In

2013, HGS was acquired by the then IMS Health (now IQVIA) and I found myself back in big corporate again, after 20 years leading small entrepreneurial organisations. I'm delighted to say that my entrepreneurial spirit and commercial vision has been allowed to flourish in IQVIA because of its values and commitment to finding new solutions to drive healthcare forward. Such that although I've finished my earn-out in 2016, I decided to stay with the newly merged company and contribute to its success story going forward.

What would you say defines the UK's position as a globally recognised healthcare system and market today?

Having been in market access since 1998 I appreciate that the UK is one of the toughest payer-dominated health systems in the world in which to successfully launch and grow a new medicine. Indeed, there has always been the unwritten rule that if you were to succeed in the UK, you could succeed anywhere. The UK invented HTA organisations and NICE has been a global pace-setter since its formation, rigorous standards and processes being part of its model function.

Other key differentiators such as the 100,000 Genome Programme, our universities and associated research facilities and our unique data-rich health ecosystem underpinned by a single patient NHS number makes the UK **the** go-to country for conducting Real-World Evidence studies-which are accelerating the molecule to market journey. That unique health data ecosystem is only going to improve with the Life Sciences Strategy and subsequent Government Sector Deal,¹ which will substantially open it up to commercial research and improve the integration of the health record systems with the advent of digital innovation hubs and new culture of collaboration from NHS England with the industry.

In the shadow of Brexit, the Department of Health seems to have really recognised the value of the investment that global pharma brings to the UK in terms of clinical trials, real world studies – and opting for the UK as an early launch reference country. The rapid approval of Kymriah (Car-T) for children in children and young adults aged up to 25 with refractory acute lymphoblastic leukaemia (ALL), within only 10 days of EMA approval is I believe an example of just how the UK now wants to be seen to be accelerating uptake of truly innovative medicines.

The western world as we know it has become a different place in the last five years, the only thing that is certain seems to be uncertainty. Pharma and life sciences are no exception and commercial success now depends on not doing things the way we always have; it really is adapt or die. The days of big blockbusters with massive trials and large patient numbers are confined to pharma history. The commercial need revolves around genomics, precision medicines and crucially much faster clinical trials to realise the value of the medicine both in patients and commercially. Both our

clients and the payer request earlier insights into how a product will perform in the real world, not in a randomised five-year Phase III trial. Real world evidence studies have the potential to accelerate drugs through the regulatory process and reduce payer risk in the post-license period. Again, the UK is pioneering the global challenge of new access arrangements by beginning to mainstream real world evidence into its managed access negotiations, as is the case with the cancer drugs fund and increasingly with access schemes for specialised medicines being underpinned by two to five-year real-world studies.

The UK is a great platform to see real world insights flourish. We are uniquely positioned with our joint health and social care data programmes. One is currently being deployed in Greater Manchester but many others are following. Our leadership position in that regard is further enhanced by the fact that NHS England seems willing to back up such initiatives. The UK has started the trend, developing new solutions for difficult medicines access decisions, other countries will follow.

The trend with CROs seems to be unexpected mergers between companies differing in nature. In Quintiles and IMS Health a CRO and data company merged, in Parexel, a clinical trials and a diagnostics company joined forces. How do these mergers make sense?

Mergers reflect customer need. **Pharma continues to innovate at a rapid pace**, however, innovation today looks different today than it did 20 years ago.

80 percent of new medicines launched between 2011–2017 were for people with complex specialty or rare diseases (eg Hepatitis C, Cystic Fibrosis, Duchennes) with patient populations either in the tens of millions or, in the case of rare disease, affecting less than five people in 10,000. This is very different from 20 years ago, when 80 percent of new medicines were developed for primary care disease areas (eg diabetes, asthma) with addressable patient populations in the 100s millions.

Today it costs around USD two billion (GBP 1.55 billion) to bring a drug to market, double the cost in 2013. If costs just grew at the rate of inflation, development costs should be only around USD 1.1 billion (GBP 0.85 billion) today.

From a pharmaceutical industry perspective, since 2007 global revenues have increased 1.4 times, but global R&D spend has increased 1.6 times. 80 percent of trials are delayed,¹ 60 percent of trials experience a protocol amendment,² and 48 percent of trials miss enrollment targets.³ Two thirds of trials fail to meet launch expectations.⁴

It is these client challenges that underpin the rationale for the merger of IMS Health and Quintiles. Our clients need to be able to bring medicines to market faster and realise the commercial value of

those medicines sooner. Through The Core that the merged company IQVIA has now created we are able to realise these goals through our domain expertise across diseases, scientific knowledge and geographies, our unparalleled data providing one of the world's largest curated healthcare data sources, transformative technology that is able to provide real time access to operations critical information and advanced analytics to support faster and more precise decision-making- better able to target the right patient populations.

At the end of the day, it is about the benefit we as solutions partners bring to customers, and, at the moment, I do not think there are many companies out there that bring together the kind of synergies we have at IQVIA. Moreover, it can be complicated for customers to deal with separate CROs, real-world evidence organisations, technology and pricing and market access agencies all at the same time. We simplify life for our customers, by providing access to all these capabilities in an integrated manner answering a genuine need.

IQVIA today defines itself as a Human Data Science Company. Can you describe to our readers what this implies?

It all revolves around the Core as described above of IQVIA: bringing all the benefits of human ingenuity through our domain expertise, analytics capabilities, our unique data and leveraging on healthcare informatics to our customers. Today, IQVIA employs over 5,000 clinicians, epidemiologists, real world evidence scientists and looks towards new tools such as artificial intelligence and predictive analytics to address the challenges industry is facing. By creating synergies, we establish our commercial value and differentiation.

As the trend goes towards rare disease drugs and speciality medicine, we are as CROs facing the challenge to find the right patients for trials as we talk much smaller cohorts. Yet, it is essential those drugs reach the market as so many patients are just being treated for symptoms for decades before getting an exact diagnosis for their rare condition. In Hepatitis C for instance, it often happens that people are being treated for various liver diseases instead of their real illness. This is something we can address through the power of machine learning predictive analytics, leveraging our analytics capacities to accelerate diagnosis.

What are your thoughts on the Life Sciences Industrial Strategy (LSIS) and the resulting Sector Deal?

To me, there are three great components about the LSIS. The LSIS was the first sector strategy to be put forward in response to the Prime Minister's ask of 10 key UK sectors.

Then comes the fact that in it the NHS is directly called out to improve its collaboration with industry. First illustrations have already been birthed, such as partnerships in the Greater

Manchester area. The next one will revolve around the eradication of Hepatitis C and join efforts of the NHS, industry and IQVIA. For the first time in 20 years since industry has been talking about partnering with the NHS we are seeing ambition in action, and IQVIA is repeatedly being that bridge which brings the NHS and industry together to work on initiatives that address major NHS patient and financial challenges.

Finally, there is the importance the LSIS puts on a whole health ecosystem and building digital innovation hubs. We see how this is possible, again in collaboration of NHS and industry, as with the Salford Lung Study We now can capitalise on those learnings and expand this work, given we provide industry with a seat at the table.

What needs to be done to continue to secure the UK's position as a reference country for uptake of innovation?

I believe this is a trend that needs to come from the top of the NHS. When Simon Stevens the current head of the NHS took over his office, he promised to encourage innovation "but not at any price." Such statements do not simply ripple but tsunami through the system! We need new attitudes to the value that industry brings to UK PLC and patients right at the Executive Board level of NHS England. Since then his team have set up a commercial negotiations team, who really are working pragmatically with industry to find a way to overcome difficult affordability issues.

I expect us to witness the end of the NHS purchaser and provider split in the not so distant future. The split does not work and creates unhealthy competition between those working for the ultimate good of patients. In the current format, both sides do not truly consider their respective interests and the system creates perverse incentives and behaviours.

However, I see important steps taken as with the fact that the focus now seems to be as much on social care as it is on health, making the link between both visible under the auspices of the Integrated Care systems. All of this is good for the industry, because often the benefits of our drugs partially or largely consist of positive effect on the social side of people's lives. To date this social care benefit was not valued by the NHS as it didn't benefit its budget. Following the social-health care equation logic, Scotland has made important strides in countering and treating drug addictions for instance, something that has yet to happen in England.

How would you conclude on the UK's position to shape the healthcare of tomorrow?

The UK is in an unbeatable position to shape the healthcare of tomorrow, four unique features differentiate Britain in the globally competitive life sciences industry.

Firstly, the 100,000-genome programme: Having won the race to complete the genetic code of a human being – their genome – which led to the UK's 100,000 genome programme being established. Our global leadership in genome sequencing is akin to a new industrial revolution, but in healthcare of an importance not seen since Victorian times. The NHS can link a whole lifetime of medical records with a person's genome data and can do this at scale. The fact it can do this on a large scale is unique.⁵

Secondly, The Life Sciences Industrial Strategy⁶ which places an emphasis on putting the UK in a world-leading position to take advantage of the health technology trends of the next 20 years"¹ and sets the objective that, by 2023, the UK should be in the top quartile of comparator countries for the speed of adoption and overall uptake of innovative, cost-effective science.

Thirdly, the UK's vibrant biotech industry is booming as the 2017 BIA report ⁷ shows with record Private Equity Investment rising from GBP 665mn in 2016 in 67 UK companies to a record GBP 2.8bn in 2017 in the golden triangle of London, Oxford and Cambridge. IPOs doubled one-year post-Referendum to GBP 234 million – with cell and gene therapies attracting some of the biggest deals that year-building on the UK's leadership in genome sequencing.

Fourthly. global leadership in RWE: The Life Sciences Industrial Strategy will accelerate our existing global leadership in RWD to spread the use of this relatively new science into practice across global research and evaluation systems, building on the UK's rich health data ecosystem.

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