Richard Barker – Founding Director, New Medicine Partners, UK

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British consultant, speaker and author, Richard Barker – a key opinion leader on UK healthcare – gives his take on the recently launched 'Life Sciences Industrial Strategy', the importance of facilitating accelerated access to medicines, and the potential fallout from Brexit to the UK's life sciences ecosystem.

Let's start with the recently released UK *Life Sciences Industrial Strategy*. Is that a cohesive document with a consensual opinion or is it just academic thinking of how things should be?

It's certainly not top-down academic thinking. Professor Sir John Bell has been the main author of the strategy and the sector deal, but a lot of work came in underneath it. I was most involved with the Accelerated Access Review, which aims to create a faster development path for transformative innovations in the NHS. A key element is the creation of the Accelerated Access Collaborative that we are currently setting up and which will be chaired by former GSK CEO Andrew Witty. What that will do is bring together different stakeholders at an early stage in the development of a transformative innovation, to figure out the requirements that the development program has to meet to satisfy not just the regulators but also NICE and significantly the NHS.

Traditionally, our system was based on dialogue through development with the regulators ie the EMA/MHRA. It was really only at a later stage that the HTA process was incorporated into the equation with the creation of NICE. Sometimes, companies find they don't have the data they should have to have a proper dialog with NICE, and even when they have a good dialogue with NICE, the NHS remains the main buyer of medicines, and they might take a different view. For example, in cancer, there is the cancer drugs fund, which has different criteria from the criteria applied by NICE.

So the initial goal of the AAC is to hold cross-stakeholder dialogue, involving also patients around five or six 'transformative innovations' a year – and they won't all be drugs, they might be a medical device or a digital health innovation. Then, the plan is to apply this approach over time to a much larger number. If we can successfully look at innovations whose value nobody doubts then maybe we can spread the practices elsewhere. A good example is CAR-T therapies. If you look at the clinical results of CAR-T therapies, people who have failed all other therapies for blood cancers are being cured in significant numbers. That's transformative, but it's expensive.

Which therapeutic areas – or unmet needs do you recognize are the best match for the Accelerated Access Review?

High unmet medical need. We will have a lot of discussions on what that means but a cure for hepatitis C would fit in that category, as well as a brand-new antibiotic for resistant infections and drugs for several currently untreated cancers. There was no definition of specific therapeutic areas, it was more the scale of the potential clinical impact, and if there were an innovation that saved the NHS a lot of money, that would be on the list too.

One of the industry's arguments when prices of medicines are being challenged by payers, is that approval processes are becoming longer and more demanding, hence they are having also an impact on the cost of the drugs to be put in the market. Taking this argument further, would Accelerate Access Review have an impact on R&D process and ultimately help to ease drugs cost and final pricing?

Yes. The whole idea of accelerating access is you can use the tools of precision medicine in many different ways. You can use them to identify patient populations most likely to benefit from an innovation. That's very common now in cancer and also rare inherited diseases. Many Phase 3

trials are very lengthy. But you can get some early feedback on the basis of either changes in biomarkers or progression-free survival, even if ultimately you want to measure overall survival. In other words, you can use some surrogate endpoints to say at an earlier stage, yes this looks genuinely transformative. There's therefore a possibility that the total cost of development can come down. Having said that, very small markets almost always lead to higher prices because you have to amortize a cost base over a small number of patients. We should not expect because we have produced a quicker and more focused development process that it automatically means lower prices. Even so, transformative innovations can significantly reduce NHS costs. Let's take the Hepatitis C example; NICE has stated that a drug that cures Hep C (although it is very expensive) saves over many years huge amounts of money to the NHS.

Although the UK has a track record for discovering and developing new medicines, as any nation that has a well-built R&D infrastructure, the issues of translational science and funding can be improved. Can you maybe comment further on what you believe are the challenges currently faced in the UK on the research front?

The biggest problem early on is the lack of alignment between academic research and industry requirements on a number of different axes. The first is academics tend to publish when they get a good result rather than confirm when its reproducible. So we have irreproducible research that is published. Also, the desire for academics is to get peer reviewed in high impact journal publications and secure future research funding, rather than having a commercialization mindset, but I feel this is changing. If you look at Oxford, we now have the Oxford Sciences Innovation (OSI) fund with GBP 550m, that will support spinning out technologies from the University of Oxford (which remains the best funded medical school in the country) into companies. They've already created several companies in life sciences, and we are slowly beginning to align the thinking in academia with the needs of industry. There are also increasingly companies reaching into industry research and partnering with them. For example, Celgene has a fellowship scheme with the University of Oxford, with a fellow spending six months in the Oxford labs and six months at Celgene. That is one way of companies getting a window in on what is happening at major universities. So you don't always have to create an SME 'middle man', if major companies can get access early on to the best research then maybe they can figure out how best to commercialize it.

A majority in the UK has voted to leave the EU. In your view, what has been the scientific community's reaction and concerns vis à vis of Brexit?

There is almost no one I have met in the life sciences community that supports Brexit or would have voted for it. However, it is vital that we continue to attract leading researchers from around the world. Someone told me that 60 percent of people working at the Crick Institute are from somewhere else, which is unsurprising. Many of the Nobel prizes won at the MRC lab in Cambridge were from people from abroad. So any restriction on that movement of talent or any appearance that Britain gives that these people are not welcome would be a bad thing. Also, any misalignment between the MHRA and the EMA will make it difficult for companies to approach Europe as a unified market and they will therefore need to approach the UK market separately – but the UK is less than three percent of the world market, which I think is a figure that speaks for itself. Companies don't plan on doing anything special for the British market. Hence Brexit poses a substantial challenge in pharmaceuticals and life sciences in a way that the British electorate have yet to understand.

I regularly travel to the US and for example recently attended the annual J.P. Morgan Healthcare Conference. It is clear that for a US-based pharma company, the UK is a tough market and it has actually always been. While our high point is science and discovery of new medicines, adoption of these new drugs is not our key strength. Europe overall has been a challenging market and therefore the UK has been part of what a US-based pharma company would regard as a challenging market. It's a market where prices only go down, whereas in the US they can go up.

On the positive side, UK-based biotech companies are raising considerable venture capital and two or three international companies have recently announced they are making new investments in the UK. So it's not insuperable. It is a problem I prefer we didn't have and I hope that we have the chance to think again.

One aspect of Brexit, is the future of pan EU funding for science, that has historically led to joint research projects. How do you think the UK should go on about leveraging some research funding losses in the European budget?

In the Life Sciences Industrial Strategy, there is a new infusion of money for R&D from the government. In the White Paper, they announced a further increase in R&D investment of £2.3bn in 2021/22, raising total public investment in R&D from around £9.5bn in 2016/17 to £12.5bn in 2021/22. There will therefore be more additional funding for the more blue-sky research.

The charities are also focused on investing more money in research and they are getting more and more focused on translational research which I think is extremely positive. I believe that the industry in general has failed to develop relationships with the third sector, meaning charities and ultimately patients, and that's a pity as patients are the most obvious and legitimate advocates for what they need. I believe there should be a recognition of the fact that if patients advocate for something, it is much more effective towards politicians.

Would initiatives such as the above mentioned Accelerated Access Review help to increase the appeal of the UK as a market for launching innovation or would still be treated as satellite place after Brexit?

This is the problem we have yet to crack. The Accelerated Access Collaborative is a significant first step for these transformative drugs, devices and innovations. It actually follows on the PRIME scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need. There is a comparable process in the UK, called the Early Access to Medicines Scheme. But companies don't want to have to think separately about the UK from a regulatory standpoint. They want to think about Europe. They know they then have to think about the UK, France, Germany or Austria separately from the reimbursement point of view, but from a regulatory stand point, there needs to be a common framework. The EMA can then be focused on how to create a common comparative effectiveness database that the national HTA bodies can use in their assessments.

Unfortunately, some pieces of this will be left to trade deals, if there are trade barriers and tariffs…

We had a meeting of trustees of a charity that I chair which moves donated medicines around the world and we were asking what the impact would be if we were no longer members of the single market, of the customs union, if there wasn't any mutual recognition between the MHRA and EMA. They would all be negatives for us.

Going beyond the UK, what do you think are the most pressing issues that life sciences executives need to have at the top of the mind today.?

How can we take full advantage of these accelerated routes and programmes? By working hand in hand with patient organizations, regulators and others, how can we halve the current idea-to-approval time of 10-15 years? In other words, how can we bring down the time and cost of development? That will be the focus because it is getting easier and easier to replicate new therapeutic approaches. If you think about cell therapy or gene therapy, there will be some patent estates, but basically, there are going to be 20 or 30 companies from around the world (including China) that will be bringing forward therapies for some of these key conditions. It will be more important to be fast than to tick every box methodically over many years, as long as you can ensure quality. So speed to market will become even more important. As part of that whole phenomenon, being able to anticipate the needs of payers and demonstrate the value of products and to build that thinking in right from the beginning of the development process.

There are, of course, several others: novel partnerships with academia, creative reimbursement approaches, greater partnering with health systems on the challenges they face. The next few years will be full of both challenges and opportunities.

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