Lord Oâ??Shaughnessy â?? Under Secretary of State for Health, UK

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Lord Oâ??Shaughnessy, parliamentary under secretary of state for health in the UK, discusses how stakeholders are interacting to ensure that the UK remains at the forefront of the global life sciences industry post-Brexit.

We have scrutinized the *Life Sciences Industrial Strategy* and found it to be a very optimistic and forward-looking document. However, when we interviewed captains of industry both within the UK and neighboring countries, they are noticeably more skeptical. How do you

respond to their doubts?

There is a certain amount of uncertainty that is inherent within the Brexit process and it is entirely logical that this might be unsettling for industry. That said, I am happy to be able to say that there is now much greater clarity about the direction in which Britain is heading and the goals that we are striving to attain.

I think one of the tremendous advantages we have in Britain is that we possess three world-leading assets: our National Health Service, a thriving life sciences sector, and a formidable academic research base. Each one is recognized as a world-beater in its own right. The real opportunity that we have as a nation, irrespective of the future regulatory or trading environment, is to bring those three stakeholders together in concert. So long as we can ensure harmonious interactions between this triad of actors, we can potentially establish a truly extraordinary and well-optimized public health scenario. Moreover, the lifeblood of this ecosystem should, of course, be data flows.

What is your assessment of the current interaction between that constellation of stakeholders?

They are already absolutely codependent on one another, but synergies are still not yet being leveraged in quite the systematic fashion that we would like. Promoting collaboration and combined focus lies right at the very heart of the governmentâ??s life sciences agenda. The whole purpose of this collaborative endeavor is to bring different entities together â?? regulators, purchasers, payers, private enterprise and so on â?? to identify and grasp win-win outcomes where everyone benefits.

Our priority is to develop a methodology for these win-wins. Part of the problem to date has been a rather transactional relationship whereby one entity tries to sell products to another, which, in turn, is mainly focused on trying to negotiate the price down. All players have eventually come round to the conclusion that this traditional style of business has to give way to something more akin to a partnership, which raises interesting questions about how risk can be more equitably shared.

Tangible progress is certainly being made in fostering a greater degree of collaboration around data sharing. Local health records have already been implemented in Greater Manchester, Oxford and Cambridge. A criticism in the past has, of course, been that the NHS hasnâ??t always played ball with the rest of the group. I detect quite the opposite attitude nowadays, which is that there is a great willingness and enthusiasm from within the healthcare apparatus to openly and proactively embrace innovation. The system just needs to be able to afford it. â??Accelerated Accessâ?? constitutes an excellent example of where the NHS is playing a fully engaged role. This represents a true partnership in the sense that it delivers up benefits to all sides: for the patients who get treated promptly, for the manufacturers and drug discovers who need to generate a return on their investments, and for payers who see their costs kept down when diseases are treated effectively at an early stage. Nevertheless, this still needs to be accomplished in a manner that is ultimately affordable within the NHSâ??s fiscal contract and prevailing budgetary constraints.

Other countries that perform the accelerated review pathway notice some subtle differences here in the UK. How would you describe the British way?

There are already multiple ways in which products can be fast-tracked to market. A good example would be the early access to medicine scheme, which affords pre-licensed medicines with transformative potential the opportunity to reach patients quickly. That means there are certain roots

in place that already exist. What we are aiming for is to reach a position where we can identify the most high-performance products of tomorrow, through horizon scanning, so that we can be taking steps to smooth their path to market and ensure a speedy and effective uptake. To do this effectively, we have to introduce an element of strategic foresight analysis.

Identification of therapies with genuinely transformative potential is merely the first stage of the process. Next, all parties need to agree about that potential: namely that a product does indeed provide value for money and offer a measurable improvement to patient lives. Itâ??s not just about getting an innovation into the health system in the first place, but also about subsequently navigating it through the system, via the NHS. It is this second phase where there is still a certain amount of room for improvement and optimization.

You mentioned a tendency towards risk sharing. Can you give some specific examples of this in action?

There are actually many workable examples of this in the medical devices domain. Johnson & Johnson have established a partnership with Bartâ??s Hospital to run their orthopedic department. Medtronic, meanwhile, have managed to strike similar deal in cardiology at Hammersmith Hospital. Under the agreed terms the company not only provides the kit but also actively participates in the provision of services and the risk burden is shared. This goes well beyond sales of devices and extends along the healthcare continuum so that the focus is ultimately centered on end outcomes and the patient experience.

Our ambition is to apply the same sort of methodologies to the relationship with pharma companies and to shift the paradigm through which the national healthcare apparatus goes about procuring drugs in the first place. Meanwhile, the industry itself, is demanding a deeper level of interaction. Many drug companies are now striving to go beyond pushing pills. They are keen to get closer to the patient and to play a proactive part in ensuring the good adherence of the medications that they are supplying. Moreover, they understand that traditional ways of operating are no longer necessarily fit for purpose and, in many instances, are actually threatening the financial viability of health systems all around Europe and across the world. Enterprises now recognize that the time has come to band together and define practical solutions to unblocking bottlenecks.

This differs somewhat from the claw-back or pay-per-performance style of agreements common across some other parts of Europe, doesnâ??t it?

I do believe the Belgians have mechanism for that. Meanwhile, the Italians have very much gone for outcome-based contracts. We havenâ??t done that traditionally and indeed, our voluntary pricing processing scheme, the PPRS, doesnâ??t make it especially easy to do that. We are coming to the end of the current PPRS and weâ??re thinking about what needs to happen next. We certainly want to find different ways of partnering that reach beyond purely transactional interactions and are very open to applying fresh thinking and new ideas.

To what extent can the UK truly be regarded as a pioneer in rethinking drug development and public health provision?

Britain is noteworthy for having held the first-ever real-world evidence, late-stage clinical trial with the Salfordlung study. This has the potential to transform the way clinical trials are conducted, and, by virtue of the fact that itâ??s happening in the real world, to bring medicines in late-stage development to patients years earlier than they would be had they been going through the traditional licensing route.

A prerequisite of being able to do this is having a single payer, comprehensive health system that is available to all citizens from cradle to grave. This is where the UK already has a head start and advantage. So long as we can get the data infrastructure in place, to the point whereby a patientâ??s data is always readily accessible for the practitioners who need it, we can also potentially harness and deploy that same data in the drug development and clinical trials processes, to a standard to which the MHRA would readily accept. The upshot would be to positively reconfigure the way our health system receives state of the art medicines and, in the process, to reduce the costs of conducting clinical trials by as much as a third.

Will this be enough to encourage companies to come here in the aftermath of Brexit?

In terms of our relationship with Europe, our intention is to have an associate membership of the EMA, which would mean a continuity of the kind of relationships that we have now, albeit on a different legal basis. I believe the reasons that companies will want to come here are the reasons that they want to come here now. Key points of attraction are that we possess a terrific, high-performance life sciences ecosystem, and world-leading academic institutions combined with an ingrained attitude of wanting to drive uptake, plus the recognition that that is something that really does need to happen.

With regards to being imminently cut off from EU funding streams, where is the money going to come from in the future to support activities such as scientific research?

The Prime Minister was very clear about our desire to continue to be part of the EU research community and maintain linkages with Horizon 2020. The EU has already established analogous relationships with certain third countries outside of the EU such as Israel. Although the government has resolutely promised to underwrite any shortfall in future funding, our intention is actually even more ambitious. Our intention is to continue to contribute money and to play our part in those kinds of exercises. Our desire is certainly not to just go off and do our own thing. To do so would be wasteful because it would entail all manner of duplications.

The Chancellor set a target for us of 2.4 percent of GDP being spent on R&D. We are keen to provide additional financing for research and compatible immigration rules that, regardless of Brexit, will enable the best and brightest minds to continue to come to our great academic institutions.

From our side, we are very committed to remaining part of European research networks and we fully expect our European counterparts to be welcoming our stance. Every negotiation has at least two parties and it would be foolhardy to try to double guess the terms of the eventual Brexit deal. Nevertheless, I believe that the signs are positive that we can strike a very good arrangement for science, innovation and research. Itâ??s worth remembering that the EU negotiating position tends to be based on the concept of precedent and there is already a well-established precedent for arrangements with non-EU member states and third parties.

You have implied that perhaps Brexit represents an opportunity for the UK. Where do you see the opportunities ahead?

I am very optimistic about it. We want to continue to play that central role in the European regulatory department that the MHRA has always done. It does more work on licensing and pharma vigilance than any other agency in the Union. We understand that any negotiation is give-and-take process. While we want to continue to be part of the overall European licensing environment, the quid pro quo for that is the MHRA contributing its expertise to the safety of European citizens.

It is absolutely a two-way street. If that is the case, then we will align ourselves with the European regulatory environment. In order to play a full role, we would be contributing to the cost of its functions. The opportunity in that sense, is to continue to lead that work and improve the regulatory environment in the EU. If there isnâ??t a deal done, then that creates other opportunities to structure our regulatory environment in a way that is different to what is happening in Europe. Our guiding principle in that is, whatever happens, patients cannot be getting products and treatments later or more slowly, but ideally, would be getting them more quickly than they do now. Industry certainly mustnâ??t find it any more difficult to get their products to market here than they do currently. That is one of our top priorities.

We are very focused on achieving a new relationship. And not just in this area but in other areas â?? like chemicals and aviation â?? where you have this particular issue about safety. They are not pure economic issues, and they are not security issues either. We do think that is in the interests of patients in the UK and the EU.

Do you agree with the premise that the NHS is underfunded?

The Chancellor of the Exchequer has just allocated an additional GBP 1.6 billion for the NHS at the last budget. So, from that point of view, there is already a political consensus aligned around the fact that the NHS needs additional money. If you look back, you will also find that the previous budget had freed up another GBP 9 billion over three years accumulatively for social care, because obviously that is a really important associated aspect when the country is faced with an elderly and aging population. My point is that nobody has been neglecting public health and starving the system of cash.

The government, and parliament in general, certainly recognize the growing seriousness of demographic pressures. There is a great willingness to come up with a long-term settlement that affords a strong sense of direction for a prolonged period of time. This is precisely one of the reasons why there is a major review going on around the issue of funding of social care. Whereas the NHS is completely state-funded, the money for social care actually derives from mixed sources. It is part funded by individuals with a means test, and part-funded by the state. This was a big point of contention at the last General Election so there is a need to forge consensus and address this issue comprehensively. A long-term funding solution has, unfortunately, evaded governments for the last 15 years, while all the time the grey population has been on the rise. The time is thus ripe for a breakthrough.

When you read the UK press, there are a lot of complaints about the state of public healthcare, and yet from a life sciences perspective, the NHS appears very forward-looking. What accounts for this discrepancy?

It is bit of a paradox. For the past eight years, the government has relentlessly continued to put more money into the NHS notwithstanding the fact that the system has been going through a massive fiscal consolidation. The reality is, the vast majority of peopleâ??s personal experiences of the NHS are very positive, and we also have very exacting standards on matters like waiting times in accidents and emergency. One of the purposes of the extra funding from the budget was to make sure we did actually hit that top target.

When considering a public health system of the magnitude, reach and scale of the NHS, there are always going to be instances when care levels dip below expectations and these receive much publicity and public outcry. The bottom line, however, is that we have very high standards that we set ourselves, and if we donâ??t always meet those standards then we get given a very hard time about it by the media and the opposition parties. From our perspective, that is absolutely fine as we are always striving to do better, and to improve patient safety.

I think with the life sciences, the contribution is perhaps slightly unseen because it would be delving into issues like particular courses of treatment and outcomes for various cancers. By most indicators, I can assure you that standards are clearly improving. Life sciences are making a big contribution to that, but itâ??s not always reflected in the headlines, which tend to gravitate around long waiting times and bed under-capacity. And yet, when you talk to the life sciences experts, youâ??ve also got this extraordinary culture and eco-system of innovation and discovery science, which has a direct impact on NHS performance.

One of the challenges we have is to make sure that the good work that our life sciences industry is engaged in generates more impact. We want the NHS to be embracing new technologies that come through the R&D base here, as in not just adopting innovation initially, but actually harnessing it in full and mainstreaming it. One of the steps we have taken is to instigate an internal review across the department and NHS England in which we track our performance in cultivating an innovation landscape. We have actually spent about three-quarters of a billion pounds supporting innovation in the NHS.

Where is that funding being channeled?

At the moment, funding is being allocated to some 38 programs and a lot of it is an upstream affect. Some of these are very effective. So weâ??ve got a Pathway Transformation Fund. But 38 programs is almost certainly too many. But one of the things we are trying to think about is are we spending it in the right places. At the moment, a lot of it is expended upstream on innovation and creation and early piloting. We need to do more on downstream with adoption and diffusion.

Thereâ??s something called the â??getting it right first timeâ?• program, called GIRFT. That is a really interesting methodology about how you set standards for best practice in surgery and then you hold surgeons and clinicians to account for their performance and outcomes.

What would be your message to companies to keep their European headquarters in the UK after Brexit?

First of all, as the life sciences industrial strategy shows, we continue to get major investments into the UK. That is because the UK is a leading place to do life sciences research work, discovery, product development and manufacturing. Our intention is that this environment will only improve regardless of what happens with Brexit.

Obviously, the relationship that we want to have with the EU is in everyoneâ??s interests in terms of patients here in the EU. It will mean that there will be no concern from a pharma company about having its headquarters here because they will still be able to access European markets as they do now. And that is absolutely what the government is committed to.

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