Speech: Lord O'Shaughnessy on medical technologies and Brexit

Introduction

Good morning, and thank you for giving me the opportunity to speak to you today.

I would like to use the next few minutes to outline the government's commitment to the medtech sector, and then to set out the opportunities and challenges we face together as the UK prepares to leave the European Union.

UK medtech sector

We all know the medtech sector plays a vital role in the operation of the NHS, and the health of our population more widely.

As a government, and as ministers, we are deeply committed to helping you – and the wider life sciences sector – to flourish. It's good for your businesses, it's good for UK plc, and most of all it's good for patients in the NHS. The medtech sector is incredibly diverse, with over over 500,000 different products on the EU market, from hip replacements, pacemakers and MRI scanners, to spectacles and plasters.

As I'm sure many of you were, I was at the NHS Expo this week and saw incredibly exciting new technologies, from a device being trialed through an Academic Health Science Network to regulate brain temperature following cardiac arrest to a very simple heart rate monitor that could be used in anywhere from a GP's surgery to your local pharmacy to look for heart beat irregularities as a precursor to stroke.

There are also exciting new frontiers around medical software, 3D printing and companion diagnostic devices – which have the potential to revolutionise the provision of healthcare in the coming decades.

The UK has a rich history in this area. For example, Professor John Charnley pioneered hip replacement surgery in the greater Manchester area, and this legacy is embodied by J&J, who have their orthopaedic R&D centre and European high-value custom manufacturing base in Leeds.

Or look at Siemens Magnets, part of what was Oxford Instruments in Eynsham near Oxford. The company produce most of Siemens' high-field magnets, and export over £400 million of high-value goods every year.

So I don't think our problem is innovation in this country. We're a creative bunch, with both public and private investment ready to help. The real challenge is taking innovation, getting it into the NHS and spreading it through the system. This often involves re-engineering clinical pathways, with all the complexities that involves.

That is one reason I was delighted to announce yesterday that Abbott's Freestyle Libre product will be available on the NHS, a really transformative product that will change the lives of many diabetics. And that's what the NHS should be about – bringing life-changing technologies to patients faster than anywhere in the world.

Encouraging access and uptake is a challenge that we are aiming address in the government's response to the Accelerated Access Review, which I plan to publish by the end of October.

Please be assured that medtech plays a central role in our plans, not least because it can offer genuine cost-savings while also transforming outcomes. We have already shown our commitment in a range of programmes that I announced in July to help companies like yours to change more patients' lives in the NHS.

In addition, with the launch of Professor Sir John Bell's Life Sciences Industrial Strategy, we are listening to what this global sector believes we need as we look to secure the best possible future for Britain's life sciences. Work now starts on a sector deal and I look forward to collaborating with you to come up with a proposal that contains some real game changing ideas.

Brexit and devices regulation

Brexit offers a major opportunity to build on our existing strengths – and we should look upon the challenge both pragmatically and with optimism. There is a collective determination and will in government to make a success of exit from the EU.

In July at the BIA/MHRA Annual Conference, I set out the core principles that will underpin the government's approach to medicines regulation, trade and support for the life sciences sector in the UK:

- First: patients, whether in the UK or the EU must not be put at a disadvantage
- Second: the UK will continue to play a leading role promoting and ensuring public health – both in Europe and around the world
- Third: industry must be able to get their products into the UK market as quickly and simply as they do now, with the UK and Europe remaining at the forefront of medical innovation

Devices regulation

Let me start with the regulation of medtech, which is of importance to everyone in the room.

To reiterate the principles above, our top priority for life sciences during the negotiations is to protect the safety of patients and ensure the integrity of cross-European public health systems.

I want to give this promise: no matter what the outcome of the negotiations –

on basic patient safety and public health issues – the UK will be, as it always has been, a willing and reliable partner for Europe.

This partnership is perhaps best illustrated by the leading role played by the UK in the recent negotiations of new EU regulations for medical devices and in-vitro diagnostic medical devices. The UK has already welcomed the new requirements of these regulations to protect patients while encouraging innovation.

Notified bodies

The UK has also played a leading role in European-wide joint actions, most significantly to raise the standards and consistency of notified bodies, which has seen the number of notified bodies designated to approve medical devices for the EU market fall from around 80 to close to 50 in just 4 years.

While this has undoubtedly created more reassurance in our de-centralised regulatory system, any loss in capacity of third-party assessments, at a time when the new EU regulations will significantly increase demand, is not to be under-estimated.

The 5 UK notified bodies assess a disproportionate number of medical devices. According to a recent independent assessment of the market, UK notified bodies make up the first, third and fourth largest share of assessors, with the British Standards Institution alone having a remarkable 30% share of the European market. Furthermore, we estimate UK notified bodies oversee between 50 and 60% of all the highest-risk devices on the EU market.

We also host over 50% of the EU's authorised representatives for manufacturers based in third countries. We urge the EU to respond positively to the principles in our recent position paper on the availability of goods in the UK and EU markets – and prevent the risk of disruption that could negatively affect patients in the UK and across Europe.

It is also right to acknowledge that the UK's existing relationship with the EU is mutually beneficial. The MHRA plays a big role in this, but it is right too that we should acknowledge the benefits we have gained from the pan-EU burden sharing approach to medtech regulation.

This arrangement has allowed the UK and NHS patients to benefit from outstanding scientific expertise from across Europe.

Sharing this expertise across the EU has led to significant public health and safety improvements. Knowledge and innovation is not and cannot be exclusive to one country.

As the PM declared in her Lancaster House speech, and set out again in our recent position papers, ultimately, we want a deep and special partnership which allows the freest and most frictionless possible trade in goods. It is in the interests of both the UK and the EU that the UK's exit is as smooth and orderly as possible, with as little disruption and uncertainty as possible for UK and European business and patients.

Patients across the EU27 and the UK will be better served if together we continue the strong, effective technical collaboration that accelerates scientific advancement and ultimately benefits patient wellbeing.

And I know it is what industry wants too, which is why I am asking for your continued support in helping to achieve it. The recent letter from MedTech Europe, ABHI and COCIR to Michel Barnier and David Davis was an important step, and I thank you for it. Now we need you to lobby for your views on what success looks like for both the UK and the EU27.

No deal scenario

A future partnership between the UK and EU is in the interests of both sides.

However, as with other departments, we will be prepared for both a negotiated settlement but also for the unlikely scenario in which no mutually satisfactory agreement can be reached.

Both the UK and the EU would of course cope with a no deal scenario, in our case we would ensure a regulatory system in the UK that protects the best interests of patients, and supports industry. This is not the outcome we are seeking, but our successful past should give us confidence in achieving a prosperous future, whatever form it takes.

I understand the specific legal and operational issues around implementing the new EU regulations, in light of Brexit.

Elements of the new regulations have been applied directly in UK law since May, meaning devices can now be legally placed on the UK market if they are in conformity with the new regulations, invoking all relevant requirements. As it stands, the EU (Withdrawal) Bill would maintain this position beyond March 2019.

I think it is important to make this clear for everyone involved in the sector, as your preparations to meet the requirements of the new EU regulations are already well underway. I hope this provides some certainty.

Trade

Regulation isn’t our only consideration as we leave the EU.

The UK wants to see zero tariffs on trade in medtech and medicines, and to minimise the regulatory and market access barriers for medical research services.

We want to have a new customs agreement with the EU that supports these objectives, as set out in the paper on future customs arrangements, which was published in August. This is central to our principle of ensuring that UK companies have the maximum freedom to trade with and operate within European markets – and to let European businesses do the same in the UK.

The UK government wants such an arrangement to help make sure that devices and medicines reach patients when and where they need them and that product

integrity is ensured.

The UK and EU have a shared objective in the negotiations: to protect the health of patients, and to ensure safe and timely access to devices and medicines.

We will also be ambitious in pursuing new trading relationships globally, to ensure that medical devices developed and manufactured in the UK can be exported to all corners of the planet. We will support global initiatives like the Medical Devices Single Audit Programme, which aims to minimise duplicative regulatory inspections of individual manufacturers – which burden industry without providing any real additional value. Equally vital to global trade is the global movement of people. I greatly value the contribution of those from the EU and around the world who work in our NHS and in our life sciences industry.

We recognise that medical research and development is a mobile, global business – and we want the best and the brightest, wherever they are from – to be able to study, work and innovate in the UK. Whatever nationality – we want Britain to attract the best and the brightest.

I want to assure you that as the Brexit process progresses, we will continue to work closely with industry and trade bodies, including the ABHI, to plan our policy for a prosperous future as a great, global trading nation.

Conclusion

I hope that by setting out our domestic policy commitment to the medtech sector, as well as setting out clear principles for Brexit and explaining the expected regulatory requirements for medtech in the UK, even in the absence of a deal with the EU, I have been able to demonstrate our significant support for the life sciences sector.

We have challenging but exciting times ahead of us, and we have a superb opportunity to reinforce the UK’s position as a global centre of excellence for life sciences – collaborating and working closely with our partners in the EU and internationally.

I am proud that the government is able to work so closely with industry, and am pleased with the very positive level of engagement and debate that has occurred so far between us.

I am confident that the Life Science industry will be able to make the most of the opportunities offered by Brexit, and help reaffirm the UK’s position as a global leader in this sector.

Thank you very much.