

# 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.

---

## **Press release: UN Security Council agrees UK-led resolution on Colombia**

The United Nations Security Council has unanimously adopted a resolution giving the mandate for a second UN mission to support the peace process in Colombia. The UK played a leading role in negotiating the resolution.

Sir Alan Duncan, Minister for Europe and the Americas, said:

I welcome the adoption of the new UN Security Council resolution, approving the continued presence of a UN Special Political Mission in Colombia.

The UK has played a privileged role leading negotiations toward agreement of this resolution, which will ensure continued UN support to Colombia's peace process. In its second phase, the UN mission will play a vital role in monitoring the transition of the new People's Alternative Revolutionary Forces (FARC) to civilian life.

This Mission will also help to monitor a crucial, temporary ceasefire between the Government and the National Liberation Army (ELN) announced by President Santos on 4 September.

The UK remains resolute in its support to peace and security in Colombia, and for efforts that ensure the safety of all Colombian citizens.

---

## **Press release: UK announces additional aid for victims of Burma violence**

Recognising the unprecedented scale of the crisis in Bangladesh and Burma, Britain is providing an additional £25million to meet the urgent needs in both countries of those affected by the violence.

In Bangladesh, where the majority of the funding will be spent, this will allow us to scale up the critical life-saving assistance that we are already providing – such as food, shelter, water and sanitation – to a greater number of those who have already fled.

In Burma, we stand ready to provide life-saving assistance to those affected in Rakhine State. Improvements in access are urgently needed to allow us to

reach those in desperate need.

International Development Secretary Priti Patel has strongly reiterated her call for the violence to stop. She said:

For the second time in a little under a year, the eyes of the world are once again fixed on Burma. I am appalled by the allegations of gross human rights violations against large numbers of Rohingya, including reports of the Burmese military and local militia forcing hundreds of thousands of men, women and children from their homes and villages being burnt.

Latest estimates are that a staggering 370,000 Rohingyas have fled Burma in just over two weeks to seek refuge in Bangladesh, carrying nothing more than a handful of possessions. Innocent people have drowned crossing the border. As each day goes by thousands more pour across the border having left behind their homes, livelihoods and loved ones, uncertain of what their futures hold.

Simply put, the Burmese military must put a stop to the attacks on the Rohingya. Urgently needed humanitarian assistance must be allowed to get to those in need at a far greater scale than has so far been permitted.

Unacceptable intimidation and restrictions on the movement of humanitarian workers must be ended. We also call on the Burmese Government to protect the rights and freedoms that must apply to all people in Burma.

The UK is at the forefront of responding to the plight of the Rohingya refugees in Bangladesh. As a world leader in humanitarian crises, this is what we do best. The issue is a complex one, but the UK has not shied away from its responsibility and we are working hard to provide thousands of displaced men, women and children with the basic essentials like food, shelter and water to stay alive.

## **Notes to editors**

- In a statement on 8 September, we announced an additional £5m to meet the humanitarian needs of vulnerable Rohingya who have fled into Bangladesh. This is in addition to £5.9m that we had programmed before the latest influx, reaching over 55,000 people. People now arriving in Bangladesh are hungry, injured and highly vulnerable – the majority are women and children. Monsoon rains are ongoing and many people are out in the open.
- UK assistance in Bangladesh will continue to focus on the critical needs of the most vulnerable among new arrivals, and among existing refugees

and host communities. We will work inside and outside camps providing lifesaving assistance, including emergency shelter, food and nutrition assistance and safe water and sanitation. Protection activities will be central. This will include safe spaces and support for children, care for survivors of sexual and gender-based violence and dignity kits for women and girls. We will be working closely with our partners on the ground to ensure the specific needs and vulnerabilities of children, women and girls, people living with disabilities and older persons are addressed in all the support we provide. We will continue to invest in strengthening coordination of the whole relief effort, not just our own assistance.

- In Burma, aid workers have been getting British-funded humanitarian assistance to more than 80,000 people in parts of Rakhine State. In the areas affected by the violence, DFID's partners are ready to provide emergency food to a further 30,000 people and to treat more than 3,000 severely malnourished children and pregnant women but have no access. We could provide significantly more assistance but have no current means of doing so.
- In a statement issued on 8 September, the Secretary of State condemned the appalling violence in and called upon the security forces to de-escalate the situation in Rakhine.
- It is important that the recommendations from the Rakhine Advisory Commission are implemented, and we welcome the Burmese Government's appointment of an Implementation Committee on 12 September.

---

## **[News story: Safer IT safer ship: cyber security code of practice for ships](#)**

The cyber security code of practice for ships was launched by [Lord Callanan at Inmarsat](#) yesterday as part of London International Shipping Week.

The MAIB assisted with the development of this guidance, which provides actionable advice on:

- developing a cyber security assessment and plan to manage risk
- handling security breaches and incidents
- highlighting national and international standards used
- the relationship to existing regulation

The code is to be used with organisation's:



- risk management systems
- subsequent business planning

[The code of practice can be downloaded from GOV.UK.](#)

---

## **Press release: Helping children learn through a proportionate primary assessment system**

Plans have been announced by Education Secretary Justine Greening for a primary assessment system which focuses on pupil progress, mastering literacy and numeracy, and scrapping unnecessary workload for teachers.

The plans to create a stable, long-term approach that ensures children are taught the essential knowledge and skills they need to succeed at secondary school and in later life were published today following a 12-week consultation with the teaching profession and other stakeholders. This is delivering on the commitments the government made at the election.

Education Secretary Justine Greening said:

A good primary education lays the foundations for success at secondary school and beyond. This year's key stage 2 results showed our curriculum reforms are starting to raise standards and it is vital we have an assessment system that supports that.

These changes will free up teachers to educate and inspire young children while holding schools to account in a proportionate and effective way.

The government confirmed that it will:

- Introduce a new teacher-mediated assessment in the reception year from 2020 to provide a baseline measure to better track pupils' progress during primary school. The check, which will be developed in conjunction with the teaching profession, will ensure schools are given credit for all the work they do throughout a child's time at primary school;
- Improve the early years foundation stage profile – a check on a child's school readiness at the end of their early years education. This includes reviewing supporting guidance, to reduce burdens for teachers;
- Make key stage 1 tests and assessments non-statutory from 2023 and remove the requirement for schools to submit teacher assessment data to the government for reading and maths at the end of key stage 2, as these

- subjects are already assessed through statutory tests, from 2018-19;
- Introduce a multiplication tables check to aid children's fluency in mathematics from 2019-20;
  - Improve teacher assessment of English writing by giving teachers greater scope to use their professional judgement when assessing pupils at the end of key stages 1 and 2 from the current academic year (2017-18).

Nick Brook, deputy general secretary of school leaders' union NAHT said:

Today the government have confirmed that, from this year, teachers will once again be able to apply professional judgement when assessing pupils' writing. Teachers and school leaders have argued strongly that sufficient flexibility to properly recognise pupils' achievements was needed. This move is a welcome step in the right direction.

The decision to make SATs for seven year olds non-statutory in favour of a new reception baseline assessment may well be met with trepidation by some, but it is absolutely the right thing to do. Under current accountability arrangements, the hard work and success of schools during those critical first years is largely ignored. If designed properly, these new assessments can provide useful information for schools to help inform teaching and learning whilst avoiding unnecessary burdens on teachers or anxiety for young children.

We intend to work with government to ensure that this is exactly where we end up. Taken together, these measures are a big step in the right direction.

The government has also set out how it will better support children who are not yet working at the standard of the national curriculum tests.

The changes, which follow a consultation on the findings of the independent Rochford Review, will ensure there are appropriate assessment arrangements in place and there will be a pilot of a new approach to assessing the attainment of children with the most complex special educational needs.

Introducing these measures will help schools support these children to progress on to mainstream forms of assessment during primary school, if and when they are ready, ensuring no child is left behind.