# New proposals to strengthen medical devices regulation and bolster UK life sciences sector

- New proposals published to strengthen the regulation of medical devices in the UK and support our life sciences sector to tackle future health challenges
- highlights opportunity for the UK to take advantage of its departure from the EU and create UK-specific regulation that puts patients first
- follows the government's new Life Sciences Vision, which outlined ambitions for the sector over the next decade, putting it at the heart of plans to build back better from the pandemic

A <u>new report published today</u> by the Regulatory Horizons Council (Thursday 19 August) sets out how the UK could strengthen the regulation of medical devices, learning lessons from the response to the coronavirus (COVID-19) pandemic while boosting the UK's world-class life sciences sector.

The Regulatory Horizons Council (RHC) is an independent expert committee which identifies the regulation needed to foster technological innovation and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction. Their new proposals set out how medical devices such as pacemakers or implantable defibrillators should be regulated to ensure we can tackle healthcare challenges effectively, now and in the future.

The report identifies the UK's departure from the European Union as an opportunity to build a UK-specific regulatory system that puts patients at the heart of decision-making processes — for example by increasing patient representation on expert groups for advice on medical research and devices, and by providing evaluations of medical devices that are easily understandable. It highlights the opportunities now available to the UK, not only to respond more quickly to new advances in technology, but to work with like-minded countries in shaping international regulation.

Life Sciences Minister Nadhim Zahawi said:

Our life sciences industry is at forefront of global, modern regulation, as demonstrated by the speed and flexibility of the UK's development and rollout of COVID vaccines.

Today's report supports our ambition to capitalise on the UK's departure from the European Union and put in place streamlined regulation that will ensure we can bring to market safe and effective medical devices quickly, benefitting patients across the country.

It calls for lessons to be learnt from the UK's COVID-19 response, including addressing delays in medical device approval so that equipment can be authorised effectively and at speed. It also recommends that pandemic preparedness should include fast-track evaluation of new in vitro diagnostics and that reporting of diagnostic tests be transparent and standardised.

The report also highlights opportunities for the UK to take a leading role in the development of international standards, notably in sectors of importance such as AI, while exploring membership of international programmes such as the Medical Device Single Audit Program (MDSAP).

Innovation Minister Lord Bethell said:

The UK's brilliant life sciences sector has excelled during the pandemic, pioneering important research and developing vaccines and treatments for COVID-19 which have saved countless lives across the globe.

Our regulator, the MHRA, was the first in the world to approve a COVID-19 vaccine and will soon be outlining proposals for a new regulatory framework for medical devices which will prioritise safety and help UK patients benefit from cutting-edge medical technology. This report is a welcome addition to help shape this area.

It suggests using medical devices as a template to help enable broader UK regulatory reform that improves patient safety and system efficiency by identifying areas where regulatory reform may attract inward investment and growth.

Today's publication follows the launch of the government's new <u>Life Sciences Vision</u>, published last month, which outlined ambitions for the sector over the next decade, including the Medicines and Healthcare products Regulatory Agency's (MHRA) forthcoming consultation on a new regulatory framework for medical devices.

Earlier this year the Medicines and Medical Devices Act 2021, which provides a framework for updating the UK life sciences regime, received Royal Assent. This Act is a milestone in ensuring that after leaving the EU, the UK remains a world-leading regulator by supporting the delivery of the Life Sciences Vision, but also by and ensuring the UK can continue to embrace new health innovations.

The Act allows us to maintain a regulatory system that does what is best for the UK supporting innovation and protecting patient safety. The UK government remains committed to working collaboratively with industry to deliver key ambitions for a future medical devices regime.

Today's report highlights the opportunity for the UK to show international leadership and become a global centre for medical device regulation.

The Business Secretary Kwasi Kwarteng has <u>written to the Regulatory Horizons</u> <u>Council</u> welcoming the report, and the Department of Health and Social Care will respond in detail to its recommendations following the response to the forthcoming MHRA consultation.

#### About the Regulatory Horizons Council (RHC)

The Regulatory Horizons Council (RHC) is an independent committee, sponsored by the Department of Business, Energy and Industrial Strategy (BEIS), that identifies the implications of technological innovation. It provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction of new technologies.

Establishing the RHC was one of the key recommendations from the government's white paper on Regulating for the Fourth Industrial Revolution. The RHC is currently undertaking deep dives with recommendations for government on regulatory reform on:

The Council has decided on its next programme of work for later this year including; principles for pro-innovation regulation, hydrogen, neurotechnology, and artificial intelligence in healthcare.

Learn more about the RHC.

# £20m to provide more early help for vulnerable families

Thousands of vulnerable or low-income families in England will benefit from a multi-million-pound investment to improve access to early education, health and care services.

Delivering on a manifesto commitment, the Government has today (Thursday 19 August) set out plans to elevate its Family Hubs programme, backed by £20 million of new funding, that will support councils to set up new Family Hubs in up to 10 new areas.

Family Hubs offer families, children and young people somewhere to access a range of support services, which can include early education and childcare, mental health support, meetings with health visitors or attending parenting classes, counselling or advice for victims of domestic abuse.

The hubs — delivered in person and supported virtually via online services — help families, children and young people more easily access the help they need, regardless of where in the country they live. They bring services together into one place, preventing parents and carers from having to search for different types of support that might otherwise be too hard to find,

especially for those on lower incomes, helping build connections between families, professionals and voluntary services.

Children and Families Minister Vicky Ford said:

It is absolutely vital that all families across England have access to the same high quality services in their local communities, no matter where they live. Services like these which offer early help and intervention can make a huge difference for parents and carers, levelling up opportunities for every child to fulfil their potential.

That is why we are championing Family Hubs, and this additional £20 million investment will drive forward this programme, helping to grow and expand hubs across the country so that even more parents and children can access the early health and education services we know can have a lifelong positive impact.

The £20 million announced today, awarded from the Treasury's Shared Outcomes Fund, will include:

- £10 million for the Family Hubs 'Transformation Fund', which will support local authorities to open family hubs in approximately 10 new areas of England. Family Hubs are already operating in several areas of England, providing vital support services to vulnerable families; and
- £10 million to expand the 'Growing Up Well' digital project, designed to level up outcomes for vulnerable and disadvantaged families. This involves improving how information is shared between professionals working with families and children in these Hubs.

This builds on the Government's manifesto commitment to champion Family Hubs so that they help provide families, including those who are more vulnerable, with intensive support for their children, not just in the early years but throughout their lives. The Government has already invested £14 million to deliver on this commitment, including the introduction of a national centre for family hubs earlier this year, led by the Anna Freud Centre to scale-up the number of Family Hubs and spread best practice on what works well to Hub providers across England.

Dr Camilla Rosan, Head of Early Years and Prevention at the Anna Freud Centre, said:

We welcome this £20 million investment from the Government into the work of Family Hubs across England. This additional funding is an opportunity to expand the Family Hub offer across local areas so that more families can access high quality support as soon as they need it.

The Anna Freud Centre is championing this work through our leadership of the newly founded National Centre for Family Hubs.

The evidence is clear that early help is what makes the most difference to the wellbeing of children and their families, and Family Hubs will sit at the heart of communities providing this support. We will continue to work closely with local areas to learn from and share existing expertise about what works best for families. That way, we move one step closer to providing every child with a positive start in life from the very youngest age.

Many councils have already started to open Family Hubs, benefitting families across the country. They often operate an 'open door' approach, with families able to have better access to vital services and receive support from a range of professionals, including midwives, health visitors, GPs, schools or social services.

Today's investment follows publication of the <u>Best Start for Life: A Vision</u> <u>for the 1,001 Critical Days</u>, led by the Rt Hon Andrea Leadsom and published by the Department for Health and Social Care in March 2021, which identified six action areas which will help to have a transformational impact for babies and their families.

One action area was to championing Family Hubs as a place where parents and carers can access Start for Life services. So the National Centre for Family Hubs will make sure councils understand how best to build a Family Hub network and to take steps at a national and local level to reduce the stigma some parents or carers experience when asking for help.

The Department for Education also recently launched a second round of recruitment for three more local area partners for the Family Hubs-Growing Up Well project.

Three additional local councils primarily based in disadvantaged areas will be recruited as part of the project to help develop data and digital products to support the practical implementation of Family Hubs. This will involve working with the Department to provide local insights to help develop digital solutions that reflect their community's local needs.

The project aims to improve how professionals collaborate and plan for families, with a particular focus on improving how information is shared and improving access and navigation of services for families and builds on work already being carried out by both Bristol City Council and Lancashire County Council who were recruited in the first round of the project.

# UKEF backs landmark £430 million green

### transition loan for Wood Plc

- First ever green transition loan backed by UK Export Finance (UKEF) helps Wood continue to transition to capitalise on opportunities linked to clean energy, hydrogen and decarbonisation
- Loan gives Wood the financial resource to take advantage of green trade opportunities
- Government aligns free trade agenda behind green exports ahead of COP26

LONDON — August 19th, 2021 — The first ever government-backed green transition loan has been awarded to engineering and consultancy firm Wood to seize new clean growth export opportunities, International Trade Secretary Liz Truss has announced today.

With less than three months before the UN climate change conference, COP26 in Glasgow, the UK continues to align its free trade agenda behind green exports to speed up the country's transition away from fossil fuels to low-carbon energy sources, which is expected to deliver <u>up to £170 billion</u> of export sales in goods and services for the UK by 2030.

Firms operating in the UK's industrial heartlands, like Aberdeenheadquartered Wood, will be backed by Government to drive forward this transition, whilst supporting thousands of green jobs.

This £430 million commercial loan will be supported by an 80% UKEF Transition Export Development Guarantee (<u>Transition EDG</u>) and will give Wood the financial resources to enhance its clean growth plans by:

- accelerating the speed at which Wood can organically grow its business by investing in future low carbon growth areas linked to the energy transition in the UK and abroad
- providing critical working capital for deployment in clean growth projects around the world
- providing additional funds for Wood's research and development in clean growth sectors

Under the agreement, Wood will commit to increasing its clean growth portfolio and significantly reducing its greenhouse gas emissions over the five-year tenure of the facility.

Wood employs nearly 7,000 people across the UK and generates nearly £400 million annually from its exports. The company expects its export revenue, related to low-carbon projects, to significantly increase as the energy transition gathers pace and the loan will help them capitalise on these opportunities, supporting green jobs at the firm.

#### International Trade Secretary, Liz Truss, said:

Green trade presents a major economic opportunity for Britain that will drive high-value jobs in every part of the nation. Wood has

already made great strides in repositioning its business for a low-carbon future. I am delighted it is the first company to energise its clean growth plans using UKEF's new Transition Export Development Guarantee, which will support thousands of green jobs.

#### UK Government Minister for Scotland David Duguid said:

It's fantastic to see the UK government's first Transition EDG going to a Scottish-based company, helping support low carbon jobs right across the whole UK.

As we prepare to host COP26 in Glasgow later this year, this announcement marks another important milestone in the UK's energy transition, showing how free trade will help deliver on our net zero targets.

#### Robin Watson, Chief Executive at Wood said:

We recognise the unstoppable momentum behind the energy transition and are committed to providing the practical solutions to help deliver a net-zero future. We are already well advanced with our own transition, deliberately broadening our portfolio across energy and supporting our clients to achieve their own carbon reduction goals.

UKEF's support will allow us to accelerate this journey and capitalise on the many opportunities emerging as we build the low-carbon energy systems of the future.

UKEF's Transition EDG was launched ahead of COP26 to enable UK exporting companies to access the financial resources they need to transition away from fossil fuels to clean energy alternatives.

The facility was co-ordinated jointly by Citi and BNP Paribas with Citi acting as Facility Agent while Rothschild & Co acted as advisers to Wood. The mandated lead arrangers were ABN Amro Bank, BNP Paribas, Citi, HSBC UK Bank, Lloyds Bank and The Royal Bank of Scotland.

Slaughter & May acted as legal counsel to Wood with Allen & Overy engaged jointly by UKEF and the banks. CRISIL, an S&P Global Company, acted as an independent consultant and was engaged to assess the credibility of Wood's clean growth plan and carbon reduction targets.

#### About UK Export Finance

<u>UK Export Finance</u> is the UK's export credit agency and a government department, working along-side the Department for International Trade as an integral part of its strategy and operations.

Established in 1919, it exists to ensure that no viable UK export should fail for a lack of finance from the private market. It provides finance and insurance to help exporters win, fulfil and get paid for export contracts.

#### **About Wood**

Wood is a global leader in consulting and engineering across energy and the built environment, helping to unlock solutions to some of the world's most critical challenges. We provide consulting, projects and operations solutions in more than 60 countries, employing around 40,000 people. <a href="www.woodplc.com">www.woodplc.com</a>

#### Contact

## Afghanistan: Foreign Secretary speech

NOTE — The last four paragraphs of the speech are as drafted, but were not delivered in the House due to time constraints.

Mr Speaker, in any crisis it is how you respond that is critical, and the government has two overriding priorities.

First, we must evacuate our own people, the British nationals, the dual nationals in Afghanistan who now want to leave, those who served our country so loyally.

And allied to this, we must live up to the best traditions of this country in playing our part in offering safe haven to those Afghans who are now fleeing persecution from the Taliban as refugees.

I want to pay tribute to those leading this work. I have already mentioned Sir Laurie Bristow, our Ambassador. There is a phenomenal cross-Whitehall team of military personnel — I pay tribute to the Defence Secretary — Home Office officials — I pay tribute to the Home Secretary — and they are working hand-in-glove, with gunfire overhead, to save others before they get out themselves.

And I want to pay tribute also to the Rapid Deployment Team that flew into Kabul last night to support that effort, and to the troops that went in to protect them and secure the airport so that we could prosecute this evacuation effort.

Mr Speaker, we are straining every sinew on that evacuation effort and it is supported by the crisis team in King Charles Street, with Home Office experts, military planners, and they are working around the clock. I pay tribute to them, having visited them yesterday.

The evacuation effort has three strands. And by the way, it's been, Mr

Speaker, in place for four months.

First, it is worth recalling that we advised all UK nationals to leave Afghanistan back in April and many hundreds did so on commercial flights, with the benefit of consular support and advice from our team.

Since the security situation deteriorated last weekend, we switched to chartered flights to get nationals out, as well as those under the ARAP scheme.

The first flight left Kabul on Sunday with around 150 UK nationals and their dependents on board. They have arrived back in this country safe and sound.

In the last 24 hours, 646 people have been evacuated, a combination of nationals, Afghans who worked for us and UK allies, and there will be eight flights following today.

The crucial point was that in order to secure the airport, we had to inject 600 British forces, we had thousands come in from the Americans. Without that we wouldn't be able to get any of those to the airport, indeed out of them, or process them in the way we need to.

The second strand of the evacuation, beyond British nationals, is the ARAP programme, also set up by the Defence Secretary back in April, to help those who worked for us, and who now face the risk of retribution precisely because of the loyalty that they showed to our country.

And to date, Mr Speaker, we have settled over 3,300 Afghan staff and their families. That includes 2,000 since April, the most generous scheme of its kind offered anywhere in the world, and rightly so.

The third strand of the evacuation scheme is, as my Right Honourable Friend the Prime Minister and the Home Secretary announced today, our plan to provide a bespoke asylum offer to settle 20,000 Afghan refugees over five years.

And like the Home Secretary herself, let me just say as the son of a refugee I am deeply proud that this government is continuing the big-hearted tradition of the British people in offering safe haven to those fleeing persecution.

So we are getting our nationals out, those that work for us out, and we are providing a lifeline to the most vulnerable.

I can also tell the House today that we have contacted all of the Chevening Scholars in Afghanistan, not just to tell them that they can come, but to actively make arrangements for the upcoming flights to the UK.

Mr Speaker, at a time of crisis we also need to look to the longer term, and there are four areas that need particular focus.

Counter terrorism: we must never again allow Afghanistan to be a haven for terrorists, we will work very closely with all of our partners within the

parameters that the current situation allows.

Secondly, the international community must be prepared to respond to the humanitarian plight caused by the Taliban's campaign.

The UK is already using our convening power, our aid budget to galvanise the global response.

Thirdly, we must work to safeguard regional stability, and that will require us to work with different partners and it will require engagement with key regional players, including India, China, Russia, Pakistan, the Central Asian states, however difficult or complex that may prove and outside of our comfort zone.

And we will be fully supporting the efforts of the Secretary General of the UN's Special Envoy for Afghanistan, Jean Arnault.

The fourth area is human rights and accountability. We will hold both through our domestic sanctions regime, but also working with the Indians who chair the UN sanctions regime for Afghanistan, to make sure we can exercise a moderating influence on the Taliban regime.

We will pursue each of these areas with vigour. As the Prime Minister has already made clear, we will be convening a special meeting of G7 leaders to consider a concerted and co-ordinated response.

We will be looking at the question of a contact group of international partners on Afghanistan and we plan an event at the UN General Assembly next month to focus minds and raise funds for the humanitarian response.

We are raising our aid budget in response to the crisis, channelling it via third parties on the ground.

And we will no longer provide funding to Afghan security institutions, redirecting this to humanitarian efforts which benefit the Afghan people.

Mr Speaker, we will get our people out of Afghanistan, we will provide a lifeline for the most vulnerable, and, with our partners, we will forge a new international strategy for Afghanistan.

We will not allow the hard-won gains of the last 20 years to be lost.

And we will continue to stand with the Afghan people, and support their aspiration for a better life.

# PM call with Prime Minister Draghi of

# Italy: 18 August 2021

Press release

Prime Minister Boris Johnson spoke to Italian Prime Minister Mario Draghi this evening.



The Prime Minister spoke to Italian Prime Minister Mario Draghi this evening about the situation in Afghanistan.

The leaders shared their understanding of the current situation on the ground and agreed to work together to help the urgent evacuation of our nationals and others.

The Prime Minister outlined his five-point proposal for the international community to support the people of Afghanistan and to contribute to regional stability.

The Prime Minister and Prime Minister Draghi agreed to work together to prevent a humanitarian emergency in Afghanistan and the surrounding region, and to discuss next steps at a virtual meeting of G7 leaders in the coming days.

The leaders also talked about the upcoming COP26 Summit, which is being cohosted by the UK and Italy. They discussed ways to boost global ambition and innovation on addressing climate change, including through economic levers.

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