UK to strengthen regulation of medical devices to protect patients

- MHRA to reform medical devices regulation to improve patient health and encourage innovation
- The UK is seizing the opportunities provided by leaving the EU to bring forward new legislation that goes further to improve people's health
- To signify products have met these world-leading standards, they will carry the UKCA marking

New plans to strengthen the regulation of medical devices to improve patient safety and encourage innovation have been published.

Following the UK's exit from the European Union (EU), the Medicines and Healthcare products Regulatory Agency (MHRA) has a unique opportunity to improve how medical devices and in vitro diagnostic medical devices (IVDs) are regulated in the UK.

The package of reforms will apply to medical devices such as hearing aids, x-ray machines and insulin pumps; new technologies such as smartphone apps and Artificial Intelligence (AI); as well as certain cosmetic products like dermal fillers.

The new measures include:

- Strengthening the MHRA's powers to act to keep patients safe Giving the public and patients greater assurance on both the performance and safety of the highest-risk medical devices, such as those which need to be implanted.
- Increasing the scope and extent of regulation to respond to public need Enhancing systems that are already in place to better protect users of medical devices and certain cosmetic products, and providing greater assurance of their performance and safety.
- Addressing health disparities and mitigating identified inequities throughout medical devices development and use — Mitigating against inequities in medical devices, ensuring they function as intended for diverse populations. The government has launched a review into the potential equity issues in the design and use of medical devices to tackle health inequalities and will update in due course.
- Making the UK a focus for innovation, and the best place to develop and introduce innovative medical devices — Ensuring the new regulatory framework encourages responsible innovation so that patients in the UK are better able to access the most advanced medical devices to meet their needs.
- Setting world-leading standards and building the new UKCA mark —
 Transforming a new stamp of certification, replacing the CE mark, into a
 trusted brand that signifies global safety, health and environment
 protection standards have been met for medical device products. This
 will in turn boost the MHRA's global reputation and growing partnerships

Health and Social Care Secretary Sajid Javid says:

Now we have left the EU, these new changes will allow innovation to thrive and ensure UK patients are among the first to benefit from technological breakthroughs.

We are now able to introduce some of the most robust safety measures in the world for medical devices to ensure patients are protected.

Dr June Raine, Chief Executive of the MHRA, says:

As a regulator, our priority is to protect patients and the public and make it easier and quicker for patients to access the medical devices and treatments they need.

We would like to thank everyone who has shared their views as part of this consultation, including patients, industry and the healthcare sector.

We all know the importance of medical devices in our day to day lives and your input has been invaluable in helping us to shape the future regulations and ensuring continued patient safety and access.

The regulations will keep pace with new and emerging technologies, for example software and artificial intelligence (AI) which are increasingly being used in areas such as screening and diagnosis, as well as the management of chronic conditions and developing new treatments. The new measures will ensure innovations such as these are subjected to the same robust standards as medical devices, protecting patient safety while encouraging innovation to ensure UK patients are among the first to access cutting-edge healthcare.

Today's announcement follows a consultation on the future regulation of medical devices in which the MHRA asked for views on a broad range of regulatory issues — from requirements for running clinical investigations, to how devices are assessed before being placed on the market, through to importer and distributor obligations, and post-market safety monitoring to increase transparency and the role of patients.

This is an ambitious, transformational programme of reform and the MHRA will ensure that legislative changes to the system meet the needs of industry and the healthcare sector.

There will be continued work and engagement with industry and stakeholders

whilst refining legislation and implementing changes.

The MHRA will gradually phase in the new requirements with transitional arrangements, to give industry enough time to adapt to the change.

Notes to editors

- Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- 2. The MHRA is an executive agency of the Department of Health and Social Care.
- 3. The government has introduced a Bill to make changes to the Protocol to establish a dual-regulatory regime in Northern Ireland. Once the Bill becomes law, this would mean that businesses could choose between meeting UK or EU standards removing the barriers to goods made to UK standards from being sold in Northern Ireland and cutting the processes that drive up costs and disincentives businesses.
- 4. Under the current approach to the Northern Ireland Protocol, EU rules on medical devices and IVDs continue to apply in Northern Ireland. The EU Medical Devices Regulation (2017/745) (EU MDR) therefore took effect in Northern Ireland on 26 May 2021 and the in vitro Diagnostic Medical Devices Regulation (2017/746) (EU IVDR) took effect from 26 May 2022. The EU MDR and EU IVDR do not apply in Great Britain.
- 5. For further information on the government's review into potential bias in medical devices, visit: https://www.gov.uk/government/news/review-launched-into-the-health-impact-of-potential-bias-in-medical-devices

PM to say to G7 leaders: We must keep up our resolve on Ukraine

- PM will tell major summit of democratic leaders that President Zelenskyy needs western backing more than ever
- Meeting in Germany an opportunity for Western leaders to demonstrate to Ukraine, Russia and the world that we will support Ukraine for as long as it takes
- UK is ready to guarantee another half a billion dollars in loans to the Ukrainian Government, bringing total UK economic and humanitarian support to over £1.5bn

Any sign of fatigue or wavering in Western support for Ukraine will play directly into President Putin's hands, the Prime Minister will tell world

leaders this week at the first in-person gathering of G7 leaders since Putin's full-scale invasion of Ukraine.

The first few weeks and months of the Ukrainian resistance have been characterised by overwhelming global unity and a huge surge of support for the Ukrainian people. It is essential that this is sustained for the long term. Russia's behaviour and the atrocities Putin is committing must not become normalised in the eyes of the world.

During his second visit to Kyiv since the outbreak of war last week, the Prime Minister spoke to President Zelenskyy about the urgent needs of the Ukrainian Government. This includes military support, opening up the routes out of the country blockaded by the Russian military and urgent financial support to allow the Ukrainian state to function.

The Ukrainian Government fears it could run out of funding by the autumn unless it is given urgent financial help. To help with this pressing need the UK stands ready to provide another \$525 million (or £429 million) in guarantees for World Bank lending later this year.

The new support announced today brings the total amount of fiscal support including UK loan guarantees to £1.3 billion (\$1.5 billion) and the combined UK economic and humanitarian support to Ukraine to £1.5 billion (\$1.8 billion) this year.

President Zelenskyy will virtually address the G7 Summit today. Following his address, the Prime Minister will use an intervention at the Summit to rally support for Ukraine. He will encourage all G7 countries to back Ukraine in the long-term, building on the significant pledges already made since February.

The Prime Minister said:

Future generations will be awed and inspired by the truly heroic Ukrainian resistance in the face of Putin's barbarism.

Ukraine can win and it will win. But they need our backing to do so. Now is not the time to give up on Ukraine.

The UK will continue to back Ukraine every step of the way, because we know that their security is our security, and their freedom is our freedom.

UK loan guarantees are playing an important role in closing Ukraine's financing gap, enabling Multilateral Development Banks like the World Bank to lend far more than they otherwise could to the Ukrainian Government. This lending is covering costs like Ukrainian public sector wages, and the running of schools and hospitals.

These investments will help preserve the Ukrainian state. The UK only covers the cost of the loan if the Ukrainian Government is unable to pay. They are

therefore both an investment in Ukraine's strategic resilience and an expression of confidence in the country's future.

Without international support, the Ukrainian Government would be forced to pursue paths which compromise their macro-economic stability and long-term economic security, including running down reserves and printing money. Policies like these would directly lead to mass inflation and humanitarian catastrophe in the country.

Joint Statement on the Establishment of the Partners in the Blue Pacific (PBP)

A new initiative for more effective and efficient cooperation in support of Pacific Island priorities

The Pacific Islands region is home to nearly a fifth of the Earth's surface and many of its most urgent challenges, from the climate crisis to the COVID-19 pandemic to growing pressure on the rules-based free and open international order. It was in this context that the Pacific Islands Forum, the premier driver of regional action, <u>committed</u> to organize its members "as one collective if we are to address our increasingly common challenges."

As our countries—Australia, Japan, New Zealand, the United Kingdom, and the United States—continue to support prosperity, resilience, and security in the Pacific, we too must harness our collective strength through closer cooperation. To that end, our governments dispatched high-level officials to Washington, D.C. on June 23 and 24 for consultations with Pacific Heads of Mission and other partners, including France, as well as the European Union in its observing capacity. These meetings followed discussions with Pacific partners, including with the Pacific Islands Forum Secretariat; they remain ongoing, including with other partners engaged in the region. Today, our five countries launched an inclusive, informal mechanism to support Pacific priorities more effectively and efficiently: the Partners in the Blue Pacific (PBP).

This new initiative builds on our longstanding commitment to the region. Australia and New Zealand are of the region and members of the Pacific Islands Forum; Japan, the United Kingdom, and the United States are founding Dialogue Partners. Our countries maintain close people-to-people ties to and are longstanding development partners with the Pacific Islands, reflected in our combined \$2.1 billion in development assistance for the region. We are united in our shared determination to support a region that benefits the peoples of the Pacific. We are also united in how we realize this vision—according to principles of Pacific regionalism, sovereignty,

transparency, accountability, and most of all, led and guided by the Pacific Islands.

With these principles at its core, the Partners in the Blue Pacific aims to:

1. Deliver results for the Pacific more effectively and efficiently.

Together and individually, our five countries will enhance our existing efforts to support Pacific priorities, in line with the Pacific Islands Forum's upcoming 2050 Strategy for the Blue Pacific Continent. To do so, we will work with Pacific partners. We will map existing projects and plan future ones, seeking to drive resources, remove duplication, and close gaps, which will avoid greater burdens and lost opportunities for Pacific governments and Pacific people. In parallel, each of our governments will continue to increase the ambition of our individual efforts in the region.

2. Bolster Pacific regionalism.

The PBP will forge closer connections with Pacific governments and with the Pacific Islands Forum, by facilitating stronger and more regular engagement with our governments. We will further elevate Pacific regionalism, with a strong and united Pacific Islands Forum at its center, as a vital pillar of the regional architecture and of our respective approaches in the region.

3. Expand opportunities for cooperation between the Pacific and the world.

The PBP will encourage and facilitate greater engagement with the Pacific by any other partner that shares the Pacific's values and aims to work constructively and transparently to benefit the people of the region. As it develops, the PBP will remain inclusive, informal, and open to cooperating with additional partners similarly invested in and committed to partnership with the Pacific Islands. Globally, the PBP will identify opportunities to expand Pacific participation in international fora.

At every stage, we will be led and guided by the Pacific Islands. We will seek Pacific guidance on the PBP's selection of its lines of effort and its flagship projects. In meetings in Washington, including at Blair House, our governments and Pacific Heads of Mission discussed diverse areas in which to deepen cooperation, including the climate crisis, connectivity and transportation, maritime security and protection, health, prosperity, and education. We commit to continuing to engage with Pacific governments as well as with Pacific-led regional institutions, particularly the Pacific Islands Forum; we will align our work with outcomes from the upcoming Pacific Islands Forum Leaders meeting in Suva, Fiji. Later this year the United States intends to invite Partner countries' foreign ministers to convene and review our progress.

UK pledges up to £130m for girls' education in Pakistan

World news story

The United Kingdom (UK) on Saturday announced a bilateral programme worth up to £130 million to support girls' education in Pakistan that will impact nearly 17 million children.



Launched in May this year, the Prime Minister's Girls' Education Action Plan sets out practical steps to deliver the UK's global objectives on girls' education. Titled Girls and Out of School: Action for Learning (GOAL), the programme will support the governments of Punjab and Khyber Pakhtunkhwa (KPK) improve outcomes for girls and the most marginalised. GOAL focuses on two main priorities. In Punjab and KPK's least developed districts, it will directly support around 250,000 marginalised children to enrol and stay in school. It will also support an additional 150,000 girls to read by age 10.

GOAL will improve learning outcomes for at least 16.9 million children (7.8 million girls) by strengthening the provincial education systems to improve the quality and equity of education, particularly the quality of teaching, and becoming more resilient post-Covid. The programme will directly support children to access education and learning in several Commonwealth countries.

GOAL will introduce changes to make education more inclusive; ensuring children are taught at their correct learning level, and influencing others to adopt better education practices.

UK High Commissioner to Pakistan Dr Christian Turner CMG said:

No nation can reach its full potential without 50% of its population. Getting girls into school is a key driver of growth. We want to give girls awaaz and marzi, voice and choice and unleash the potential of the next generation.

Notes to editors:

- 1. There are 132 million girls out of school in the world about 9.2% (12.2 million) are in Pakistan.
- 2. Girls' education remains a significant challenge with lower enrolment rates and higher drop-out rates for girls, particularly at the transition from primary to secondary school. The poorest rural girls are most affected: 54% of the poorest 25% of girls are out of school and these girls are only achieving one third of the learning of the wealthiest 25% of girls and boys.
- 3. In Punjab, the average literacy rate for women is 54% (44% in rural areas) compared to 72% for men. A recent study shows that 2.2 million adolescent girls aged 15—19 years in Punjab are neither at school, nor employed or married. In Khyber Pakhtunkhwa (KPK) more girls are out of school (66%) than boys (34%). Only 40% of girls are enrolled in primary schools in the Newly Merged Districts and out of those enrolled, just 3% transition on to middle school. At higher secondary level, there are only approximately 250 girls still studying across the whole province.
- 4. The UK is a world leader in championing girls' education. Between 2015 and 2020 the UK supported 8.1 million girls to gain a decent education.
- 5. The set-back of Covid-19 has been huge this is the third consecutive year of school disruption with 616 million children still affected by partial or full school closures.
- 6. Global learning poverty is at crisis levels and continues to worsen in the wake of Covid-19; the worst shock to education and learning in a century. The context in which education is being delivered worldwide is becoming increasingly challenging. Extreme weather events, slower-onset climate change, conflicts, protracted crises, and other disasters are on the rise, causing significant disruption to education and children's wellbeing.
- 7. These programmes will support us in ensuring the most marginalised children can re-enter education and learn whilst they are there. They are a core enabler of the UK government's manifesto commitment to 'stand up for the right of every girl to access 12 years of quality education'.

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New £27million funding partnership announced with VSO at Commonwealth Heads of Government Meeting

The UK Government has today (Saturday 25 June) announced a new £27m partnership with the UK's leading overseas volunteering charity, VSO, to empower people living in low-income countries across the Commonwealth and other countries to take control of their futures.

The Active Citizenship Through Inclusive Volunteering & Empowerment (ACTIVE) programme aims to reach 2.5 million people across 18 countries by mobilising marginalised groups — including women, young people and those with disabilities — to act on the issues that are most important to them and their local communities.

This funding will build on the volunteering for development model to help strengthen locally led organisations and create a culture of volunteerism, whilst building the capacity of the UK's partner countries, including Rwanda, Kenya, Malawi, Mozambique, Eswatini, Sierra Leone, Zambia, Tanzania, Nigeria, Sierra Leone, Uganda and Bangladesh to respond to the demands of their citizens.

It will include twinning partnerships between hospitals in the UK and those in our partner countries to exchange skills and learning, including on areas like childhood cancer and family planning. Lewisham and Greenwich NHS trust and Rwanda's Nyagatare District Hospital are already working together, and further partnerships are planned with hospitals across the UK.

Education partnerships will also be a cornerstone of the ACTIVE programme, including the Numeracy for All project, which will support teachers to make and use low — and no-cost — teaching aids that encourage active and playful maths learning.

Lord (Tariq) Ahmad of Wimbledon, Minister of State for South and Central Asia, North Africa, UN and the Commonwealth, said:

The new ACTIVE programme will be a unique opportunity to use British expertise through volunteering to support our partner countries to take the lead in their own development.

By unleashing the potential of individuals and communities through voluntary work, while supporting the best locally led organisations to meet the priorities of the people and communities they benefit, we can bring about lasting, inclusive change.

I am delighted that the UK Government can take their partnership with VSO to the next level through this exciting new programme.

The FCDO Minister for the Commonwealth announced the Partnership for Change at a roundtable with Rwandan civil society whilst at CHOGM in Kigali.

ACTIVE will build on the success of VSO's FCDO funded (£70.5m) Volunteering for Development programme, which ended in March 2022. Over the course of the five-year programme FCDO supported over 350 local partner organisations and more than 6,500 volunteers in 24 countries, to improve access to health, education and livelihood services for 5 million people.

Dr Philip Goodwin, CEO of VSO said:

Volunteering for development has helped to make the UK a global leader and authority in quality and inclusive volunteering practices that put volunteers and the most marginalised people at the centre of the influencing change in their own lives

The ACTIVE grant will enable VSO to continue to support national and community-based volunteers to be agents for change.