Government
Office for Science

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The Rt Hon Jeremy Hunt MP
Chancellor of the Exchequer
By email only

8 March 2023

Dear Chancellor,

Pro-Innovation Regulation of Technologies Review

I recently wrote to you to set out my overarching thoughts on the Pro-Innovation Regulation of Technologies Review you have asked me to undertake, and to share my recommendations on digital technologies.

In advance of my report on life sciences, which I anticipate will be completed by early May, I wish to bring to your attention a matter that has emerged from my discussions with the industry champions, John Bell and Camilla Fleetcroft, following their engagement with the sector to date. I wanted to make sure you saw this before the upcoming budget.

The MHRA is recognised as a global leader in life sciences regulation, playing a fundamental role in shaping global standards, and the regulatory response to COVID-19 demonstrated the speed and agility with which the UK system can act. It should now be our ambition to deliver a progressive UK regulatory offer to unlock innovation in diagnostics, drugs and medical technologies (including devices), and provide a simple regulatory journey for companies to engage with.

Slower access to innovative medicines in the UK can contribute directly to poor health outcomes including survival rates for certain types of cancer, and there are areas where the UK is slower than the EU average in terms of the time taken to make innovative medicines available to patients.

A major focus for UK regulators should therefore be to enable the best innovations to be delivered safely and rapidly to patients through the creation of innovation pathways for MedTech, diagnostics and drugs. Regulators will need to concentrate on domains where truly novel and transformative therapies are emerging, interacting with innovators from a very early stage to define a route to approval, and ensure that regulators play an enabling role throughout the journey to approval.

Ensuring regulators have sufficient funding, capacity and capability to deliver will be key to achieving this aim. While my forthcoming reports will make recommendations on ways in which the government can ensure that regulators are well equipped to tackle the challenges they face more broadly, I consider that there are specific changes that the MHRA and NICE could implement to help free up resources to focus on the most innovative products.

To help achieve this, MHRA and NICE should adopt a broader approach to the mutual recognition of products already approved by trusted international partner organisations, particularly for well-established technologies. This approach should be paired with a rigorous surveillance process. In particular for MedTech and In-Vitro Diagnostics, a new risk-based recognition route to market should be introduced soon to ensure continued supply of safe devices. This approach would operate in parallel to the domestic route, allowing for the MHRA and approved bodies to focus on supporting innovation elsewhere in the market, as well as clinical trials & investigations and post market monitoring. The MHRA and the Approved bodies should establish new ways of working in partnership, given their roles as joint 'gate

keepers' of access to the UK market. However, it is also important to point out that recognition should not be seen as a simple shortcut or a 'quick fix', but should instead be a robust and sustainable process that allows the MHRA to monitor effects in clinical practice and take proactive action as necessary. Funding for the regulators will be required to allow them to work in this way and attract the appropriate skills.

I look forward to submitting further recommendations for action in my final report in due course. On the basis of work conducted to date, it is likely that there will be merit in exploring better data-sharing between regulators and, building on my recent report on digital technology, I expect to make recommendations on the way in which Artificial Intelligence applications can play a role in supporting human health outcomes.

Yours sincerely,

Sir Patrick Vallance
UK Government Chief Scientific Adviser