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27 September 2018

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## Reforming the governance of technological innovation

Her Majesty's Government aims to raise scientific research and development spend to 2.4% of GDP and make the UK the most attractive place in the world for innovation and investment in new technologies. Many factors determine the attractiveness of Britain to innovators and investors. Among them are the regulatory frameworks that affect how businesses may develop, test and sell applications, products and services built on new technologies. We therefore welcome Government's commitment to making the UK a world-leader in innovation-friendly regulation and its initiatives to realise this ambition, such as the new Ministerial Working Group on Future Regulation and the Regulators' Pioneer Fund.

Regulation faces the challenge of striking the right balance between offering stability and certainty for investment decisions and the need to adapt to changing circumstances. The UK's regulatory frameworks are based on sound principles and, for the most part, have performed well in delivering and balancing a variety of public policy objectives, including providing businesses and investors with clarity on rules, protecting citizens and not creating undue barriers to research and innovation. The UK has often led the way in developing regulation that has benefitted citizens and made us a preferred place for invention and innovation. For example, the Financial Conduct Authority's 'regulatory sandbox', launched in 2014, has allowed many financial services SMEs and start-ups to test innovative products, services and business models in markets and with consumers, thus helping the UK emerge as a leader in fintech. In 2016, following advice from a Human Fertilisation and Embryology Authority (HFEA) panel, the UK became the first country to approve use of a mitochondrial replacement therapy ('three-parent babies'), which can prevent children from inheriting severe mitochondrial disorders that can prove fatal.

Nevertheless, we believe that there is an opportunity for Government to develop further its approach to regulation – particularly in respect of emerging technologies – and, in so doing, to enhance the UK's competitive advantage, promote investment and maximise the economic and societal benefits possible from technological advances. Emerging technologies can present challenges for traditional regulatory structures, which may struggle to keep up with fast-paced developments. The effect of this may be the emergence of undesirable or unintended barriers to the development of innovative products, services and business models that can benefit citizens and the economy. By being a 'first mover' in shaping the evolution of regulation, Government can help ensure that desirable innovation is not stifled. This would benefit citizens and markets, and it would strengthen the UK's ability both to attract investment and to influence the evolution of regulatory frameworks internationally through intellectual leadership and experience. We therefore recommend that the government take the following steps to make the regulatory landscape more favourable to innovation.

## The way ahead

1. <u>Develop a regulatory horizon-scanning function</u>. Better responses to the challenges and opportunities presented by emerging technologies can be achieved by being prepared. Regulators are charged with delivering policy objectives set by Government or Parliament for their sectors or for the conduct they regulate. But they may have little cause to consider the implications of new technologies, they may react late to them, or act inadvertently in ways that discourage innovation. Early attention to the policy and regulatory implications of new technologies (as the UK has done by establishing the Centre for Connected and Autonomous Vehicles) can create 'first-mover advantage' and help maintain the confidence of innovators and investors. Furthermore, technological innovations may cut across sectoral and regulatory boundaries such that, even if individual parts of the system are working well, opportunities and challenges may be missed due to limited strategic coordination. Also, the timely examination of ethical and other societal concerns raised by some technological advances should inform regulatory design and ensure that stakeholders' views are understood early. For example, ethical issues raised by powerful new technologies such as machine autonomy and genome editing (which can be different in different applications and contexts) should be explored.

<u>Recommendation 1</u>: Government should establish a technology horizon-scanning function for regulation in the Better Regulation Executive (BRE) to bring 'foresight thinking' into the strategic planning activities of regulators and their sponsors in Government. This should build on horizon-scanning done by others, including the Government Office for Science. This function should alert and advise Government and regulators on advances in science and technology and their broad regulatory implications, including identifying ethical and other issues that may require expert examination and/or merit public engagement. We suggest that priority areas for consideration include: the use of data and AI in medicine and advanced bio-technologies such as synthetic biology and genome editing.

2. Integrate the development of guidance, codes of practice, standards and formal regulation in order to improve regulation as a whole. The governance of innovation and uses of new technologies should not rely only on, or only consider, formal regulation (i.e. legislation and regulatory rules). Guidance to industry, codes of practice and standards can play an important role with or without formal rules. Such types of intervention can provide innovators and investors with useful knowledge, guidance on good practice and compliance in ways that are more accessible, faster, more flexible and less burdensome than legislation-based rules. We note that the new Centre for Data Ethics and Innovation aims for such an approach to regulation, standards and ethics (and also has horizon-scanning in its remit, as discussed in our previous recommendation).

<u>Recommendation 2</u>: The work that Government is undertaking to promote innovationfriendly regulation should consider as a matter of course the role of guidance, codes and standards alongside formal regulation. In developing new regulation, particularly in fastmoving areas, Government and regulators should consider in advance the potential need for future adaptation. For example, principles-based approaches (i.e. approaches based on fidelity to well-defined and well-regarded principles) that are not overly rigid may be appropriate in some circumstances. Government and regulators should also plan to review relevant governance frameworks as technologies and their applications develop. The UK has well-regarded standards-setting bodies, such as the British Standards Institution (BSI) and the National Physical Laboratory (NPL), and they should be brought into the strategic discussion as appropriate.

3. <u>Make the regulatory system more accessible and work better for innovators and investors</u>. Innovators and investors should be able to access the information and guidance they need about regulation in a timely fashion and to raise queries and provide feedback. Uncertainty about regulatory requirements can deter investment, lead innovators and investors to move to other jurisdictions those activities that they see as risky in the UK, or to abandon projects at an advanced stage when unforeseen regulatory barriers are encountered. Such difficulties can be compounded by the need, potentially, to deal with multiple regulators.

<u>Recommendation 3</u>: To improve the access to information and guidance offered to innovators and investors by regulators and by Government, Government should ensure that innovators and investors are provided with a 'one-stop-shop' for regulatory enquiries. This service should be coordinated so that innovators are provided a good service across regulatory boundaries. This support should enable innovators to consider the implications of a technology or innovation they are developing and then to navigate the regulatory and legal landscape effectively.

4. <u>Adopt a research and learning approach to regulation and boost our capabilities in regulatory</u> <u>science and experimentation</u>. Innovative approaches, whether pioneered in the UK or elsewhere, to the governance of the applications of technologies should be encouraged by UK regulatory authorities and Government agencies, rigorously evaluated and best practice shared widely. For example, regulatory innovations such as test beds (being used in the UK for the development of autonomous vehicles) and sandboxes (being used for certain types of new financial services) can allow a degree of experimentation – for both regulators and innovators – in controlled, learning environments without compromising other public policy objectives such as consumer protection and fair competition. In addition, regulation should be designed so that it is proportionate for the current time but in the knowledge that it may need to be adapted in future when, for example, a technology advances and its applications are taken from controlled environments, such as laboratories, to the wider public domain, or as evidence of its effectiveness improves such that it becomes possible to judge which approaches will better deliver desired outcomes.

<u>Recommendation 4</u>: Government should establish a coordinated programme to improve the evaluation of traditional and emerging innovative approaches to the governance of applications of new technologies, such as regulatory sandboxes used in fintech, in order to ensure that the design of future regulation is beneficially informed by such learning. Alongside this, an innovation network for regulators should be set up to promote faster adoption of best practice across the regulatory landscape. While the Regulators' Pioneer Fund has been launched recently, Government should consider broadening its scope in future, for example to address the issues identified in this letter, and to ensure funding commensurate with the number of high-quality bids received.

We recommend that the implementation of these measures be led by the Better Regulation Executive, reporting to the new Ministerial Working Group on Future Regulation. By taking forward these recommendations, with commitment for the long term backed by the necessary resources, HM Government can make the UK an even more attractive and welcoming place for technological innovation. This would in turn encourage inward investment, foster R&D and help ensure that we are better prepared for future challenges and opportunities, to the benefit of our citizens and the British economy.

Government should also engage internationally on regulatory reform. In addition to investment, regulation affects the capacity to trade. By collaborating with like-minded international partners, including plurilateral and multilateral initiatives and organisations, while reforming at speed, the UK can better influence others, thus promoting alignment between UK approaches and those of others and keeping overseas markets open to British trade. The development of regulation and standards should, therefore, be part of the Government's forthcoming International Research and Innovation Strategy.

We are copying the letter to the Chancellor, the Secretary of State for BEIS, the Cabinet Secretary, Permanent Secretary at the Treasury and Permanent Secretary at BEIS.

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Professor Dame Nancy Rothwell Co-Chair