HM Government

HM Government Response to Professor Dame Angela McLean's Pro-Innovation Regulation of Technologies Review

Life Sciences

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Contents

Introduction

At Autumn Statement 2022, the Chancellor announced a programme of work to advise how the UK can better regulate emerging technologies, enabling their rapid and safe introduction.

The aim of this review is to establish the UK as the best regulated economy in the world in key growth sectors ensuring that industry and investors have the certainty then need to drive innovation, investment and growth through anticipating new developments in emerging technologies.

This work was initially led by Sir Patrick Vallance, in his role as the Government Chief Scientific Adviser and National Technology Adviser. Since stepping down as Government Chief Scientific Adviser, this work has been taken on by his successor, Professor Dame Angela McLean.

Two leading experts – Sir John Bell and Camilla Fleetcroft – have supported Sir Patrick and Dame Angela throughout the development of the Life Sciences report, working hand-in-hand with industry to identify any barriers to innovation and getting emerging technologies to market. Joyce Tait has also provided invaluable expertise on areas beyond human health. The government is grateful to them for their comprehensive work to inform this report.

Response to recommendations

1. The government is grateful to Dame Angela for this report into the regulation of emerging life sciences technologies. The government is also grateful to Sir Patrick for his work on this issue. The UK has long been a leading location for life sciences companies to innovate and do business. However, this report highlights that there are areas where we can further ensure that the UK's regulatory environment enables innovation and a thriving life sciences sector. From implementing existing plans for innovation pathways and suggesting ways to support and retain talent Dame Angela's report presents ambitious ideas to unlock progress.

2. This report builds on the interim recommendations put forward by Sir Patrick and accepted by the Chancellor at the Spring Budget. These recommendations included moving to a broader approach of recognition for products approved by other trusted regulators paired with a rigorous surveillance process, ensuring the system could focus on supporting innovation, and the provision of funding to support these activities.

3. The government accepts all the recommendations in the report, this response sets out further detail on the government position and implementation plans. The Review report and this response cover a mixture of reserved and devolved policy areas, where areas are devolved the response only applies to reserved policy and regulators. We will continue to work with the Devolved Administrations on areas of shared interest relating to Life Sciences.

Recommendation 1 – Skills

We recommend creating a skills pipeline across those regulators whose remits cover life sciences to build expertise in the long term, including through the use of industry secondments, Centres of Excellence in Regulatory Science and Innovation (CERSIs) and flexibility around pay scales, including through the following actions:

Recommendation 1a: The government should set up a secondment system with appropriate data controls to maintain independence, and placements should be funded by the long-term employer.

Recommendation 1b: Centres of Excellence in Regulatory Science and Innovation (CERSIs) represent a vital resource of expertise, that could support the system in ensuring up to date knowledge, training programmes, research and assessment support in key areas.

Recommendation 1c: The government should further consider how pay and other levers can be used to improve recruitment and retention for skilled roles in organisations in the regulatory system whose remit involves life science applications, such as the MHRA. We have heard from our engagement that this issue is particularly acute in healthcare regulation, but also applies to attracting talent in emerging technology areas such as engineering biology.

Response

4. The government agrees in principle with these recommendations, noting further work would be required to implement any changes relating to these recommendations.

5. It is recognised that there is significant competition within the regulatory ecosystem and the wider life sciences sector for regulatory and wider expertise to ensure the safety and cost effectiveness of products reaching the market and ultimately patients. We will look at options to ensure the regulators and wider system can retain the best talent, building on the great work of the Medicines and Healthcare products Regulatory Agency's (MHRA) graduate development programme which is seeking to train the next generation of regulators, and National Institute for Health and Care Excellence's (NICE) masters programme to build health economics capacity and capability.

6. The government recognises that in recent years there has been a loss of in-house talent out into the private sector, therefore the government will commit to looking at a secondments programme not only from the private sector but from across UK academia to promote regulatory research and innovation. This would of course require strict criteria to ensure the independence of the regulators and the wider system.

7. The CERSI model has proved effective in the United States, in providing additional expertise to the regulators and the wider system, we will look to convene a similar network of expertise here, building on the UK's outstanding academic science base and building a sustainable pipeline of talent for the future.

Recommendation 2 – Fragmentation

Allow different parts of the regulatory system to share data on new technologies and applications.

Response

8. The government recognises the need to ensure the regulatory agencies and wider system are technologically able to carry out their function in the most efficient way possible, including through data sharing. Consideration will be made to the underpinning infrastructure in the near future.

Recommendation 3 – Capacity: Engagement

Regulators should be supported to engage with innovative technologies and deliver regulatory pathways to enable them to reach market through appropriate resourcing and sustainable funding.

Response

9. The government agrees with the principle of this recommendation. There is significant activity underway already to ensure where required early engagement can take place, through the MHRA's innovation service and NICE's early engagement functions, for example, the scientific advice process. Through the upcoming relaunch of the Innovative Licensing and Access Pathway (ILAP), it is the intention of MHRA and NICE to offer joint scientific advice to further enable this. The relaunch should also make best use of NHS clinical and commercial surgeries, ensuring early engagement with the NHS on the data required for pricing discussions. For Medical Devices, there is further work underway to ensure the MHRA is engaging with system partners, including the Approved Bodies.

10. We recognise the need to ensure sustainability of the regulatory and wider system, this will be supported by the activities government will take in response to recommendation 1. As part of this, it is important for the system to have a sustainable funding model. The regulators and wider organisations are largely fee generating, and in line with government principles set out in managing public money, they work to a cost recovery model through fees where possible, with grant-in-aid for the remainder.

11. Moving forward, it is the intention of most organisations to review their fee models on a yearly basis. The government expects through outcomes of this report that there may be a change in activities and therefore we must ensure each organisation is appropriately resourced and funded to carry out this activity. We commit to ensuring regular reviews of the funding models.

Recommendation 4 – Capacity: Timelines

Regulators should set timelines to approval that are in line with international best practice for their sector to ensure that the UK remains globally competitive in their sector. They should take a proportionate approach at different stages of the regulatory pathway, while recognising this will vary between organisations and technologies. Speed and transparency are both important, so regulators should publish their expected response timelines in real time so that industry knows what to expect.

Response

12. It is a key obligation for regulators and the wider system to ensure patient safety. However, where there are products where approval presents a low risk to patients, there should be a proportionate approach, which could be enabled using our post Brexit freedoms. Many of the organisations within the regulatory and wider system, either have their timescales published or are committed to in legislation. We recognise that prioritisation of pandemic work and post pandemic peaks in staff turnover have resulted in backlogs, particularly in the medicines and medical devices space across the system. These are currently being worked through.

13. Through programmes such as ILAP and the soon to be launched Innovative Devices Access Pathway (IDAP), government is seeking to have a targeted pathway for specific products that will have a transformational impact for patients. The government is clear that for any reduction in timescales to be meaningful, these need to be tracked through the entire system pathway to adoption and patient access to ensure real value is delivered and avoid creating or moving bottlenecks within the system.

14. The government will consider how data can be collected, monitored and published with regard to different organisations meeting their published timelines. NICE already publish data on their performance against timelines and the MHRA publishes monthly performance metrics for clinical trial and established medicines as part of a commitment to being transparent about its performance in reaching regulatory decisions.

Recommendation 5 – Routes to Market

We recommend ensuring the domestic routes for approval (of medicines and devices, including for AI) are predictable, transparent and proportionate. MHRA should be supported to deliver this and should convene a group of responsible organisations in the regulatory system to agree what products should go through innovative licensing pathways. For those novel products which will deliver transformative outcomes in areas of unmet clinical need, the system should collaborate to create an effective innovation pathway. This has already taken place for medicines in the form of ILAP (Innovative Licensing and Access Pathway), but there are key issues to be resolved. The work to create the same innovation route for medical devices (IDAP) should be progressed.

Response

15. The government recognises the opportunity afforded by our post Brexit freedoms to create an agile system which leverages the decisions of other trusted jurisdictions through international recognition, whilst creating accelerated pathways to ensure world beating innovative technologies can reach patients safely and at pace.

Recommendation 5a: We recommend that outstanding issues within the existing Innovative Licensing and Access Pathway (ILAP) are resolved, and that the learnings from this are translated to Innovative Devices Access Pathway (IDAP).

Response

16. The government accepts this recommendation. We are currently undertaking a review of the ILAP to ensure improvements ahead of a future relaunch. It will be key to ensure all parts of the system are working in lockstep to deliver this.

Recommendation 5b: We recommend redefining a proactive partnership between the MHRA and the UK Approved Bodies, to act as dual gate keepers.

Response

17. The MHRA are already undertaking significant activity to transform the Medical Devices regulatory regime. As part of this, the government agrees the MHRA should ensure a strong relationship with the Approved Bodies is maintained.

18. We have witnessed the difficulties the EU has faced implementing their own Medical Devices regulatory reform, and government has an opportunity to learn from this, including to consider whether our own programme of regulatory reform, presents any further opportunities to be bolder on market access requirements whilst protecting patient safety.

Recommendation 5c: We recommend moving to a system of early market access for MedTech where there is an unmet need or significant benefit to patients, combining better patient outcomes with the gain of vital data for full market access.

Response

19. First and foremost, the responsibility of the system is to ensure the products that progress through the system are safe and effective, with appropriate post market surveillance activities. Following the Independent Review by Baroness Cumberlege a number of activities have been taken forward to implement our commitment to improving both patient safety and how the health and care system listens to patients.

20. There are mechanisms in place which enable early market access where the is a specific clinical need, these powers will be used to support the rollout of the IDAP programme. The Office for Life Sciences (OLS), Department for Heath and Social Care (DHSC), NICE, MHRA and NHS England have worked jointly to develop the IDAP programme, which will be targeted to specific technologies in a first the pilot phase to ensure the sustainability of the programme before wider rollout in future. Our ambition is to move towards a rules-based approach for the uptake of innovative medical devices, and IDAP will inform our consideration of this. As part of this, consideration will be made to adoption of products in the NHS and whether it would be appropriate to move to a rules-based approach for the uptake of medical devices.

Recommendation 6 – Acceleration

We recommend speeding up the route to market for innovative products through the wider regulatory system by improving efficiency and enabling quicker decision-making on NICE approvals.

Recommendation 6a: NICE should consider how it can enable the innovation pathway by speeding up decisions that allow NHS adoption and reviewing its use of committee processes and consider the need for novel ways of working as a result of the move to recognition and reliance.

Response

21. The government agrees that it is important that NICE's decision-making processes are as streamlined as possible while maintaining the rigour, independence and transparency that have been the hallmark of NICE's success. The changes that NICE introduced in 2022 following a comprehensive and transparent review of its methods and processes for health technology evaluation build on those foundations and ensure that NICE's evaluations are fairer, faster and more consistent.

22. Over the past year, NICE has also piloted new approaches to make its processes more proportionate to the technology being evaluated to drive rapid patient access to effective new medicines by optimising use of its appraisal capacity. As part of the pilots, NICE has simplified, removed or reconfigured parts of the appraisal process where it was appropriate to do so for simpler evaluations. For example, NICE piloted a streamlined, more efficient decision-making approach using a subset of committee members that reduced the time those medicines were in appraisals from 44 weeks to 30 weeks. Overall, these pilots have reduced the length of the appraisal process by up to 45% and NICE is now planning to embed the outcomes of the pilots into its health technology evaluation manual.

23. NICE is continuing to identify opportunities to streamline its processes and will be testing three further approaches over the coming year through its proportionate approach to technology appraisals programme. We will consider with NICE the need for further changes to ensure that it is able to issue timely guidance on new technologies with the transition to increased reliance and recognition on decisions made by trusted international regulators.

Recommendation 7 – Data

We recommend enabling a consent-based approach of sharing industry data between different bodies within the regulatory system to enable access to accelerated progress of applications through different regulators.

Response

24. The government agrees with the principle of this recommendation in order to ensure a better joined up system. Whilst in current legislation, (Regulation 332 of the Humans Medicines Regulation) there are barriers to full data sharing, more could be done to streamline the process. The MHRA, NHSE and NICE are already piloting this approach for applications for medicines, where with consent of the individual companies, operational data is shared to streamline the application process. It would not be the intention of government to share commercially sensitive data or intellectual property between organisations.

25. The requirements for data sharing will evolve over time. The government will commit to a review of regulation 332 and related regulations, ensuring that UK health bodies are able to share data and information that enables system wide coordination, and promote patient access. The government also recognises that whilst we can enable data sharing to occur, there needs to be a willingness from those using the system to partake in data sharing to get the full advantage of this.

Recommendation 8 – Cell Biotechnologies

The MHRA and Human Tissue Authority (HTA) should work together to review regulatory oversight for the use of human cells or tissues collected for the specific purpose of manufacturing advanced therapy medicinal products (ATMP), with the aim of clarifying and simplifying the regulatory pathway.

Response

26. The government agrees it is important to ensure clarity within the regulatory system and endorses the recommendation for the MHRA and the HTA to consider this area further.

Recommendation 9 – Engineering Biology: EBRNs

The government should commission and resource the creation of an Engineering Biology Regulatory Network (EBRN), utilising the expertise within existing regulators. The EBRN should enable collaboration and sharing of capacity between regulators and should provide clarity and support to the companies who navigate the existing regulatory landscape. This network of regulators should explore opportunities to adapt regulatory structures to

accommodate the evolving needs of innovative technologies in the sector. This is likely to include the following regulators but should not be taken as an exhaustive or final list as technology evolves: Environment Agency, Food Standards Agency, Health and Safety Executive, Human Tissue Authority, Medicines and Healthcare Regulatory Agency.

Recommendation 9a: We recommend the EBRN creates a coherent taxonomy to classify which products fall under which regulator's remit and a roadmap to outline the relevant regulatory pathways, with clear starting points and timelines.

Response

27. The government accepts this recommendation. Setting up an EBRN would make a significant contribution to growing the UK's engineering biology sector. Stakeholders inform us that a lack of join-up between regulators creates uncertainty for innovators, consumers and investors. The government agrees that using the EBRN to create clear product taxonomies, regulatory pathways and streamlined timelines for new engineering biology products would also be proactive steps for creating regulatory clarity. DSIT will take forward the EBRN as part of its approach to growing the engineering biology sector.

Recommendation 10 – Engineering Biology: Sandbox

The EBRN should launch regulatory sandboxes to ensure that a clear regulatory pathway for the regulation of specific emerging technologies can be established.

Response

28. The government supports the creation of regulatory sandboxes generally and their application to alternative proteins specifically. Alternative proteins are a significant economic opportunity for the UK with a cohort of innovative firms focused on it. However, this sector is currently being held back by regulation inherited from the EU. A sandbox approach will allow the UK to make rapid progress on legislation in this space which preserve both safety and innovation.

Recommendation 11 – Novel Foods

We recommend the government support the Food Standards Agency (FSA) to find ways to enable the acceleration of plans to reform the approval process for Novel Foods.

Response

29. The government accepts the recommendation. It recognises that technological advances are accelerating the development of novel foods, including in the alternative

protein sector, and that this represents a commercial and economic opportunity for the UK in the immediate years ahead.

30. The Food Standards Agency (FSA) (covering England, Wales and Norther Ireland) works collaboratively with Food Standards Scotland (FSS) on existing streams of work dedicated to the regulatory oversight of novel foods across the UK. This work includes reviewing regulated product applications, supporting businesses through approval processes and exploring potential reforms. The FSA is actively pursuing reform in two areas: proposing to use opportunities in the Retained EU Law Bill to streamline the regulatory process and developing a new regulatory framework for Precision Bred food and feed, a current government priority. Alongside this, the FSA continues to improve the operation of the current system, for example, introducing a new regulated products application system due for launch in summer 2023.

31. The government accepts that additional resourcing would be needed for the FSA to explore further reform opportunities. Future funding beyond 2024-25 will be determined at the next spending review, and the Government will agree budgets with the FSA considering current priorities and future opportunities, including reform of Novel Food regulation.

Recommendation 12 – Waste Valorisation

We recommend Defra updates its 2011 waste hierarchy to include waste valorisation of residual waste to improve awareness, support scale up of valorisation infrastructure and secure feedstocks for engineering biology companies. This builds on the recommendation made previously in the Pro-Innovation Regulation of Technologies review on Green Industries to establish a regulatory sandbox for the innovative use of waste products.

Response

32. Taking the waste hierarchy as our guide, the best environmental outcome for waste that cannot be either prevented or prepared for re-use is for its value to be maximised by that material being recycled. Where waste cannot be re-used or recycled, the government supports maximising the social value of residual waste. The government is committed to work in harmony with the waste hierarchy and has recently set a legally binding target via the Environment Act 2021 to effectively halve residual waste (excluding major mineral wastes) by 2042 relative to 2019 levels. This will require both preventing and recycling more biological waste to minimise its environmental impact.

33. The UK has a thriving competitive market for waste management services, which the government encourages, and welcomes new players to join the field. There are a range of residual waste treatment and management options - both established and emerging - available to waste handling operators, which will be selected according to market conditions and local needs, taking account of the waste hierarchy and the need to ensure the best available environmental outcome for the waste. The government agrees there is potential for greater innovation to get more value out of

the end-of-life treatment of biological residual waste that cannot be prevented or recycled. This requires clear evidence that it leads to more sustainable outcomes than other forms of residual waste treatment. In no instances should innovation risk diverting recyclable materials to residual waste treatment.

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