HM Government

Pro-innovation Regulation of Technologies Review

Life Sciences

May 2023

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This report was presented by Professor Dame Angela McLean, the Government Chief Scientific Adviser, to the Chancellor of the Exchequer and to HM Government, as part of the Pro-innovation Regulation of Technologies Review.

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Context

Life sciences encompasses all study of living organisms. A broad definition includes: medicines, advanced therapies, medical devices, biotechnology, engineering biology and agritechnology. All of these are addressed in this review, which draws a distinction between the life sciences related to human health and those addressing issues not related to human health. In this paper we refer to these two broad topic areas as "Human Health Applications of Life Sciences" and "Life Sciences beyond Human Health". Such a diverse sector has a correspondingly complex regulatory landscape which aims to ensure the safety and security of people, animals and the ecosystem whilst enabling the growth of a vibrant and innovative economic sector.

These dynamic and innovative sectors make use of cutting-edge technologies to solve complex healthcare and environmental challenges. The UK is highly regarded as a centre for life sciences. The Government's Life Sciences Vision, the 10-year strategy published in July 2021 for human health applications, highlights the UK's position as having the highest field-weighted citation in the G7 since 2007, and sets out the ambition to "make the UK the leading global centre for innovative research design and delivery".[1] Beyond human health, the UK Science and Technology Framework[2] published this year identifies engineering biology as one of the five critical technologies where the UK can achieve strategic advantage.

Human Health Applications of Life Sciences

The obligations society places on regulators of medicines and medical devices are substantial. They are responsible for ensuring the safety and efficacy of products that reach the population and this remains, first and foremost, their prime responsibility.

Regulatory frameworks and regulators need to keep pace with novel technologies, such as the emergence of AI and digital tools, or the rapid development of nucleic acid based therapies (gene therapy, gene editing, RNA based therapies). If UK regulators keep pace with such developments and provide the most scientifically capable and supportive regulatory system then innovators are more likely to choose to engage early with the UK regulatory process. Healthcare industries represent a sizeable portion of growth for the UK; the UK industry in Biopharma and MedTech employed 268,000 people and generated a turnover of £88.9bn in 2020, and inward life sciences Foreign Direct Investment (FDI) in the UK was £1.9 billion in 2021, behind only the USA in terms of value.[3]

Life Sciences beyond Human Health

The life sciences beyond human health are potential drivers of prosperity, security and societal gains for the UK. Large parts of the sector use techniques from engineering biology which apply engineering principles to biotechnology to realise a range of applications, from waste processing and agritechnology to healthcare. The UK's research capability in engineering biology is strong, and there is an opportunity to make the UK a world leading destination for innovative companies. Whilst much effort in engineering biology is currently

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1013597/life-sciences-vision-2021.pdf

[2] https://www.gov.uk/government/publications/uk-science-and-technology-framework, published 06/03/23.

[3] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020/bioscience-and-health-technology-sector-statistics-2020, updated 07/02/2022.

directed at healthcare applications, the scale of impact for wider applications is clear. A recent report commissioned by the Government Office for Science looking at modern industrial biotechnology (MIB) - life sciences not addressing human health - found that firms in this sector in the UK accounted for a total turnover of £4.7 billion in 2021.[4] Section 3 of this review focuses on these applications of engineering biology, which can unlock growth through the delivery of commercially viable solutions while delivering significant societal benefit, such as food security. Proportionate regulation of this sector is essential to encouraging innovation and delivering these benefits, while also protecting from potential harms.

Scope of the Review

This report follows the publication of reports on digital technologies and green industries as part of the Pro-Innovation Regulation of Technologies Review. As in those reports, this review focuses on the specific regulatory opportunities we have identified for action within the next 12-18 months. We have undertaken extensive engagement across government, regulators, industry and academic experts to identify actions that could realistically resolve problems in these short time scales. The review explores:

- Overarching barriers to new technologies faced by regulators and those who interact with regulation in numerous sub-sectors within the life sciences,
- Opportunities for changes in the regulation of specific technologies.

We offer recommendations on:

- Common regulatory challenges that impact innovation and growth across multiple areas of life sciences,
- Regulation of medicines, advanced therapeutics and medical devices in the UK, including with regard to the Medicines & Healthcare products Regulatory Agency (MHRA) and the wider regulatory system through the National Institute for Health and Care Excellence (NICE).
- Opportunities for better regulation in the life sciences beyond human health, including novel foods, waste valorisation and cell free systems,

Agile regulation is only one tool to encourage innovation. Standards, international protocols, R&D tax credits and policy decisions also play a role in stimulating growth and signalling that the UK is an attractive place to do research. We note that there are challenges in accessing scale up and translational facilities, such as wet lab space and large-scale fermenters, as well as local planning constraints – which have been flagged as a major issue for the sector – and access to global talent. Addressing these challenges of inadequate infrastructure will require cross cutting policy decisions to enable delivery of a comprehensive plan, as set out in the Science & Technology Framework. Taken boldly, such decisions could set the stage for the UK to become a unique environment for life science research and development.

This advice should be considered in the context of the Council for Science and Technology's Report on Engineering Biology[5], the UK Science and Technology Framework[6] which

[4] Cambridge Industrial Innovation Policy (2023). *Life Sciences beyond human health: modern industrial biotechnology in the UK.* IfM Engage. Institute for Manufacturing, University of Cambridge.
[5] https://www.gov.uk/government/publications/advice-on-engineering-biology
[6] https://www.gov.uk/government/publications/uk-science-and-technology-framework

addresses challenge in scale-up infrastructure; interim advice from Sir Patrick Vallance to the Chancellor on recognition and reliance for medicines and medical devices[7]; and the independent review into Clinical Trials led by James O'Shaughnessy.[8]

[7] https://www.gov.uk/government/publications/pro-innovation-regulation-of-technologies-review-life-sciences-interim-report/letter-from-sir-patrick-vallance-to-the-chancellor, published 15/03/23.
[8] https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review

Section 1: Key Challenges and Cross-Cutting Recommendations

A regulatory system which makes decisions in a timely manner, and which includes smooth and predictable pathways through which new technologies can safely come to market as quickly as possible, is vital for unlocking innovation, delivering growth, and providing the best outcomes for society. A series of cross-cutting challenges impact the work of regulators right across the life sciences sector. These combine to slow the pace of decision-making by regulators and hence slow the progress of innovation.

Skills

Across the life sciences regulatory system, regulators - such as the Food Standards Agency (FSA) and MHRA - report challenges in attracting relevant skills and talent in a competitive environment with the private sector; this also applies to NICE in its role in cost-effectiveness approvals. This can undermine their ability to engage credibly with innovators and creates a risk of slow and inflexible application of regulations to new technologies. Civil service pay scales and processes have also been cited as issues.

Recommendation 1: 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 within life science regulators whereby industry staff are placed within regulators, and regulatory staff within industry, to build capability and capacity within regulatory bodies and improve understanding of the regulatory system within industry. This is in line with the government reform agenda to encourage public sector staff to gain experience in the private sector and *vice versa*.[9] This would require 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 source of expertise, that could support the system in ensuring up to date knowledge, training programmes, research and assessment support in key areas. All regulators in the life science sector should foster stronger partnerships with the growing number of centres for both engineering biology and healthcare. UK Research and Innovation (UKRI) should work to establish a collaborative network of regulators and centres to facilitate collaboration in emerging technology areas. This will help maintain best practice within regulators.

[9] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/993902/FINAL_Declaration_on_Government_Reform.pdf

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.

Fragmentation

Technological innovations and their applications in life sciences often cross multiple regulatory remits, including to regulators outside the life sciences. This complexity leads to overlaps, duplication and inconsistencies in implementation, all of which make it difficult and slow for innovators to navigate the regulatory landscape. The challenge is particularly acute for start-ups and SMEs. The result is that innovative companies are hindered from investing in the UK and bringing new products and services to market that can benefit society. This challenge persists along the regulatory pathway through to implementation of new technologies when they reach market.

Recommendation 2: We recommend allowing different parts of the regulatory system to share data on new technologies and applications, including through the following actions.

The government should invest in integrating cloud-based data platforms into the regulatory application system. This should not be siloed to individual organisations but should be a dynamic system to enable regulators from multiple organisations involved in the same regulatory pathways to access data as needed for decision-making. This platform should have underpinning guidance on standardising data requirements and formats to ease data input from one applicant to multiple regulators, and to enable future automation as it becomes possible and appropriate. In the Human Health Applications of Life Sciences section of this paper, further recommendations are made on enabling data sharing in the healthcare regulation landscape.

Capacity

While positive in terms of their impact on supporting innovation, programmes such as sandboxes and innovation hubs are resource-intensive and regulators report challenges in sustaining these ‘upstream’ activities from existing funding and staff resource. For example, part of the MHRA’s responsiveness to the pandemic came at the cost of mobilising staff from other business as usual operations, creating significant backlogs. While this is an extreme example, regulators need responsiveness and flexibility around resourcing to address emerging technologies and support innovation, while also delivering business as usual regulatory activities within appropriate timelines.

In his letter to the Chancellor dated 8 March 2023[10], Sir Patrick Vallance, the previous Government Chief Scientific Adviser, provided interim advice on his findings on the life sciences sector as part of the Pro-Innovation Regulation of Technologies review, and highlighted that “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

[10] https://www.gov.uk/government/publications/pro-innovation-regulation-of-technologies-review-life-sciences-interim-report/letter-from-sir-patrick-vallance-to-the-chancellor

pathways for MedTech, diagnostics and drugs" and that "ensuring regulators have sufficient funding, capacity and capability to deliver will be key to achieving this aim". The regulatory system for medicines and MedTech is still in a period of recovery following the challenges of the Covid-19 pandemic, and we note the MHRA is working to address backlogs which industry reports are significantly impacting the speed of access to market. As regulatory agencies return to business-as-usual following the pandemic there is a need for them to learn the lessons from that experience, refocus on day-to-day activities, ensure companies are kept updated on the progress of applications, and position themselves as thought leaders in the regulation of innovative new medical products.

Recommendation 3: Regulators should be supported to engage with innovative technologies and deliver regulatory pathways that enable them to reach market through appropriate resourcing and sustainable funding.

Supporting regulators through appropriate resourcing and sustainable funding should ensure they are better able to redeploy people across teams and to increase the headcount available where needed in the organisations to deliver the necessary flexibility to address upcoming technologies. This should be specifically linked to improved timeliness. We have heard from industry that there are organisational challenges in the regulatory system which include gaps in the expertise required across regulators to support new technologies; these teams should be supported to develop and attract the expertise necessary in their respective areas of responsibility.

Recommendation 4: 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.

Following engagement with industry, we have heard that capacity within regulators is a major barrier to providing approvals at multiple stages of the regulatory pathway and across sectors. For example, the FSA is taking on average 17 months[11] to approve novel food applications. Similar challenges are also faced in the wider regulatory pathway for medicines and MedTech, with the average time for a new product to go from central approval to availability to patients at 329 days in England.[12] [13] Across a series of broader applications these delays are preventing the UK from making the most of opportunities to meet targets on carbon emissions, food security, innovative treatments and economic growth, as recently highlighted in the Government Chief Scientific Advisor's report to the Chancellor on Green Industries. Regulators should set clear timelines and expedite processes, for example through innovation pathways for specific technology applications, so that novel products can be safely brought to market. However, we note that industry workflows can also cause delays, and

[11] https://www.food.gov.uk/business-guidance/regulated-products/novel-foods-guidance#how-long-will-my-application-take

[12] IQVIA EFPIA Patients W.A.I.T. Indicator 2022 Survey https://efpia.eu/media/677311/efpia-patient-wait-indicator.pdf. The average wait time from central approval to availability in Germany is 128 days.

[13] This figure does not include products under the MHRA's Early Access to Medicines Scheme, which account for a small subset of medicines, and which are not reimbursed.

there is a need for companies to engage constructively with the regulatory pathway to enable organisations to adhere to published timelines.

Section 2: Human Health Applications of Life Sciences

This section considers a range of regulatory opportunities to enhance innovation in the health system. It also explores issues which currently restrict the UK's potential to be the best place in the world to develop, test, trial, manufacture and commercialise innovative new medical products (medicines, medical devices, IVDs). This builds on the interim recommendations provided by Sir Patrick Vallance on the need for: innovation pathways for MedTech, diagnostics and drugs; risk based international recognition routes; and ensuring the capacity and capability to deliver these enhancements.

There are several key bodies involved in the regulation of medicines and medical devices in the UK, as well as a number of important bodies in the wider ecosystem whose decisions and activities impact the UK's desirability as a place to bring products to market and to grow and scale a company. These pathways should be aligned and combined where possible so that progress through the system is made on the basis of quick decisions that are informed by the best scientific advice. The simplified diagram below sets out the pathway for medicines and medical devices to patient access that we address in this review. Elements of this pathway run in parallel, but applications are often subject to sequential decision making which creates months of delay. We consider that, in the era of cloud infrastructure, it should be easier for multiple parts of the system to work simultaneously on products. While the recommendations in this section focus on regulatory approvals for reserved matters and matters relating to England only where policy is otherwise devolved, the functioning of the wider regulatory system (including cost effectiveness approvals through NICE) is also considered.

Simplified diagram setting out pathway for medicines and medical devices to patient access

Organisations mentioned: National Institute for Health and Care Research (NIHR), Human Tissue Authority (HTA), Health Research Authority (HRA), Medicines & Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE), National Health Service England (NHSE).

Several stakeholders have emphasised to us the need for more rapid and useful support for manufacturing, clinical trials, Health Technology Assessment, and device or drug approvals. We have heard from industry that the lingering effect of the Covid-19 pandemic on MHRA has been that industry no longer get the kind of rapid and engaged responses that would make businesses choose to bring products to market here. This can partly be explained by the backlog of work that developed while MHRA was dealing rapidly with the emerging Covid-19 pandemic. Alongside these specific regulatory opportunities, it will be important for the government to support the MHRA in building back the right regulatory expertise in its staffing after a major transformation programme and a higher than average staff turnover. It will be important to ensure that the MHRA has the best expertise for the future in house if they are

to be able to deliver on these ambitions. There are many aspects of regulation which fall outside our definition of the regulatory system for healthcare but which nevertheless create barriers for the sector, some of which are set out in section 1. Whilst not a regulatory issue, the final stage of the pathway - procurement of products by the NHS - was also brought up repeatedly as an issue. Although out of scope of this review, the procurement and uptake function of NHS England is crucial for providing access to new products by the healthcare system. The regulatory system and any proposed changes should be viewed in this wider context.

The O'Shaughnessy Independent Review into Clinical Trials has recommended actions to improve the speed and efficiency of decision-making on clinical trials. We welcome these recommendations and emphasise the need: for the HRA and MHRA to work together to reduce the regulatory burdens on clinical trials, to increase system efficiency, to reconsider the need for Trust-specific sign off for governance for every trial. We note that the review focuses on commercial clinical trials and consider that similar challenges and opportunities exist in earlier stage and academic settings.

There is a real opportunity for the UK to provide global leadership in Life Sciences regulation in medical devices and medicines. The European Union is in the process of transitioning to its Medical Device Regulation framework and its In-vitro Diagnostic Regulation framework. An example of where the UK is acting as an international leader is on point of care manufacturing of medicines. This refers to the manufacture of new and innovative molecules and treatments with very short 'shelf lives', i.e. hours or minutes between the time of manufacture and expiry e.g. RNA therapies. The next steps of implementation of this regulatory framework are clear, and accelerating these plans would enable more rapid patient access.

Routes to Market: Innovative pathway for therapeutics and devices

The UK has an opportunity to design an agile system which leverages approvals of other trusted jurisdictions, creating the space for the system to focus on novel and innovative products. A key message from industry is that clarity is required on the regulatory pathway and on the support available and how that support can be accessed, with clear information on the roles and responsibilities of the regulator and other key partners across the sector. A clear domestic offer will be necessary to complement the international recognition regime that the MHRA was tasked with delivering at Budget 2023.

Innovation pathways already exist, such as the Innovative Licensing and Access Pathway (ILAP). However, we have heard from industry that a number of issues exist with this pathway. Too many products are being assigned to it which is overwhelming regulator capacity and leading to slow processing of applications, while the administrative burden on industry is reported as being onerous.

Recommendation 5: 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.**

Following the Independent Medicines and Medical Device Safety Review[14], chaired by Baroness Cumberlege, a step change is required to ensure that clear, appropriate regulations are in place, with patients and the public at their core. The UK has the opportunity to become a global leader in the giving of regulatory approval. Smoothing the pathway will encourage innovators to use the UK as a 'springboard' to other jurisdictions, with the goal that, over time, the UK Conformity Assessed marking (UKCA), which indicates conformity with the applicable requirements for products sold within Great Britain, will be recognised in many global jurisdictions. A demonstration of agile regulation in practice is the Software and AI as a Medical Device Change Programme Roadmap, which has applications from preventative medicine through to acute healthcare. It strikes a balance between legislation and guidance that seeks to make the process easier to navigate whilst ensuring the MHRA has sound regulations in place to monitor this sector. This work should be supported to progress through addressing challenges around capacity and skills as set out in section 1 of this review. For these changes to be successful, it will be important for NHSE to establish and implement the early planning and research that will be necessary to ensure rapid uptake and deployment of products that successfully complete the innovation pathway.

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).

This should include ensuring appropriate governance and decision making for the products to be granted an ILAP designation, so as not to overwhelm the system, and ensuring enhanced speed and efficiency of ILAP by enabling parallel evaluation of data by multiple agencies as well as data sharing between those agencies, with a consent mechanism for industry.

The MHRA is in the process of implementing its future medical devices regulatory regime. Leadership and resource will be required to ensure this can be delivered whilst appropriately keeping pace with innovative technologies, such as AI. Individuals with the right background and expertise in those fields will be required.

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

In the context of health systems, the Approved Bodies are organisations that have been designated by the MHRA to assess whether manufacturers and their medical devices meet the requirements set out in the Medical Devices Regulations 2002.[15] The Approved Bodies carry out conformity assessments, which require experience and skill. We therefore recommend a new and strengthened partnership that shares responsibility for domestic

[14] https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report
[15] Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

market access. MHRA, with new powers to issue market access (UKCA mark), should work alongside the Approved Bodies to ensure efficiency in the system.

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.

There should be an emphasis on close monitoring, ensuring any issues impacting patient safety are quickly identified, which could be supported by IDAP. This would include setting up a single point of approval for medical devices across NHS trusts, with advice for implementation in clinical settings. IDAP could have an important role in this by ensuring join-up across the regulatory systems. It will be important for NHSE to accelerate plans to set up a single outcomes data registry for medical devices. This would collect real-world, real-time data on details of devices, implementation, and outcomes of medical devices from multiple sources, including practitioners and patients, that could be used to gather the efficacy data on medical devices that is needed for regulatory approval.

Acceleration of the pathway

The usual routes to market access, as well as innovative pathways, should be as efficient and streamlined as possible to ensure safe patient access to products in a timely manner.

Recommendation 6: 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.

NICE has a strong and pioneering track record as a health technology assessment agency and many countries have followed its example. However, the changes to regulatory approvals, and the move towards recognition, mean that cost effectiveness approvals will also need to adapt to ensure that the whole regulatory system is joined-up and effective. Industry reports that, even before these changes, NICE approvals were too slow, constraining access by patients to new innovations and reducing the duration of exclusivity. Industry further highlights the lack of a customer service ethos. Work is already underway to address this within NICE, however our engagements with industry and organisations in the regulatory system have identified options for further acceleration. These include proportionate regulation and a focus on ensuring that academic expert committees (rather than regulatory professionals) do not slow decision making particularly for innovative products on the ILAP pathway. NICE should be supported with appropriate resourcing and funding, in conjunction with clear targets for speed of decision making.

While it is important to develop a methodology which accelerates highly innovative and impactful products, such as those that go through ILAP or IDAP, other ‘business as usual’ products also need appropriate types of regulation and scrutiny rather than a single path. Creating a more proportionate and efficient process should be a pre-requisite for any increases to resourcing envelopes.

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.

NICE, in collaboration with NHS England and the devolved administrations as appropriate, should develop a proportionate approach such that efficiencies from regulatory reliance and recognition processes translate to safe, timely, and cost-effective patient access. NICE should also review its use of committee processes[16] with a view to enabling strategic decision-making and horizon scanning of the innovative technologies that are being developed globally. These actions could dramatically increase the speed of decision-making and therefore the speed at which products reach patients and begin to provide benefits to patient health. We have heard from industry that the current position is too slow and prevents the UK's regulatory system from being truly competitive in global markets beyond the EU.

Data

In the GCSA Regulation for Innovation report on digital technology we made recommendations on how access to data could be improved. We note that access to health data, in secure environments that protect patient confidentiality, could provide major benefits to innovators. For health records of people who have consented to allow innovators access to their data, it is important that their wishes are respected and the data made available in an anonymised format. We consider that - as set out in Data Saves Lives[17], the government's strategy for health and care data published in June 2022 - improved access to data will make the NHS more efficient and will also save lives and support innovation. We note that work is already underway on transforming data use for a digital future. Further work will be required to fully unleash the potential of NHS data, and the timeline for realising this aspiration is likely to extend beyond the scope of this review. For instance, NHSE could consider how it makes data accessible to enable: improved recruitment to clinical trials, application of AI and Machine Learning, Real World Evidence studies to track efficacy and safety, and the development of improved approaches to prevention and early diagnosis. With regard to primary care data, the government could work to simplify data controllership, recognising the complexity outlined in the Goldacre review[18] and commitments made to simplify information governance made in Data Saves Lives. In doing so the government could consider approaches taken in other countries where relevant, and the potential role of Integrated Care Boards. It should also recognise the rights of individuals to have their consent to provide their health data for research honoured. The government could consider the long-term investments required to support the transition to Secure Data Environments in NHSE. If data from all parts of the NHS, including primary care, are to be provided in a high-quality platform, continued long term investment will be needed to ensure a high-quality service is available for researchers, while maintaining high standards of safety and security.

Recommendation 7: 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.

[16] We note that NICE reports that of the appraisals published by NICE in 2021 to 2022, 2% were delayed due to NICE committee capacity. This excludes the topics that were paused during early stages of the COVID-19 pandemic which were not deemed therapeutically critical or related to COVID-19 therapeutic interventions. https://www.nice.org.uk/public-board-meeting-agenda-and-papers--july-2022- access to new medicines performance data.

[17] https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data

[18] https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis

We are hearing from industry that there are barriers to the appropriate sharing of data between regulators for the public good. Regulators and organisations in the pathway appear to be exercising overly cautious interpretations of rules about disclosure of data. There are two issues that should be addressed. Legislative change in the short to medium term could help to overcome these barriers. Under Regulation 332 of the 2012 Human Medicines Regulation, restrictions are placed on disclosure of information where MHRA staff must not disclose any information relating to a manufacturing process or trade secret, other than in the performance of their functions. In practice, this prevents effective data sharing between regulatory organisations. Statutory changes would facilitate iterative dialogue between organisations and industry occurring in a transparent way and should be paired with guidance to facilitate enhanced collaboration between organisations. Secondly, industry should be able to consent to share data in order to access accelerated applications through different organisations in the regulatory system. Implementation should be considered carefully, maintaining public trust, as we note there are areas in medicines regulation where there is reluctance from industry to agree to information sharing between different bodies in regulatory and access pathways. Patient safety and privacy must be prioritised and protected. The above recommendations would apply to medicines and medical devices through the MHRA and NICE, but would also intersect with other sectors such as the interface between the FSA and medicines. This should be considered in light of recommendation 2 on the need for data sharing platforms between organisations involved in the same regulatory pathways.

Cell biotechnologies

Both UK-based and international advanced therapy medicinal product (ATMP) developers point to a lack of consistency between tissues and cell legislation (the Human Tissue Act and associated regulations) and legislation governing medicines, and their application to the different stages of advanced therapies development. This has slowed down product development, increased the risk of non-compliance, and makes the UK less attractive as a location for developing ATMPs. Addressing this would help signal to industry, accelerate ATMP development, increase their availability to clinical trials and marketed products and make the UK a more attractive location for manufacturers to invest. Together these present a compelling opportunity for the UK to gain a competitive advantage in the manufacture of ATMPs.

Recommendation 8: 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.

Section 3: Life Sciences beyond Human Health

In life science applications beyond human health, the regulatory landscape is seen by stakeholders as complex, with different agencies involved in regulating different technologies and/or use cases. Currently, the onus is on individual companies to fit their products into an often-outdated regulatory landscape. As technology advances, a shift is required so that regulators are challenged to adapt their regulatory system to fit better with the needs of innovative technologies. The British Standards Institute's roadmap on Industrial Biotechnology[19] explores how such flexibility can enable technologies to reach markets and thus support broader societal benefits. In an example of good practice, recent legislative changes through the Genetic Technology (Precision Breeding) Act 2023 provide a framework from which to build more proportionate regulations for plants and animals bred using precision breeding techniques. Such organisms contain only genetic changes that could arise through traditional breeding. Precision breeding technologies, such as gene editing, could help to develop crops that are more nutritious and less reliant on pesticides, and develop animals that are resistant to disease and more resilient to climate change. The ability to carry out this research in the UK will attract innovative companies and is an example of how the UK regulatory system could adapt to accommodate growth technology areas.

Engineering biology

As the Engineering Biology sector continues to mature, so does the suite of potential solutions to solve some of the most pressing issues faced by society. However, this growth continues to create novel technologies and/or applications that do not fit easily into current legislative boundaries. There is a need for regulators to collaborate to understand where there are gaps and how to fill them in ways that support innovation and quickly deliver safe, valuable solutions to society. We engaged with industry to understand the key issues they face in bringing innovation to market. These included a lack of clear entry points for companies subject to multiple regulatory frameworks; a lack of coherent and assured advice; no opportunity for early engagement with regulators; and the absence of a roadmap illustrating regulatory pathways, linkages with other regulators and timelines.

Recommendation 9: 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 products Regulatory Agency.

[19] https://www.bsigroup.com/globalassets/localfiles/en-gb/standards-services/consulting/BSI-industrial-biotechnology-strategic-roadmap-for-standards-and-regulations-FINAL.pdf

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.

The EBRN should provide a clear, simplified and cohesive process where manufacturers and innovators can navigate a specified pathway, specific to the properties of their product's innovation and the sector where it will be applied. This would decrease the bureaucratic burden on small companies and reduce the time for a product to be approved for market. This process would require collaboration between existing regulators. It will be necessary to specify these pathways with care, particularly because engineering biology applications can create new regulatory questions not covered by existing frameworks. A collaborative approach between regulators will allow the creation of new solutions for these new questions whilst avoiding the need for a specific stand-alone regulator. It could model itself on existing functions in other sectors such as the Multi Agency Advisory Service[20] for AI and digital applications in healthcare, or the UK Regulators' Network, which brings together regulators from various sectors for the benefit of consumers and the economy and sets strategic priorities and ways of working to strengthen cooperation and regulatory capabilities.

Recommendation 10: The EBRN should launch regulatory sandboxes to ensure that a clear regulatory pathway for the regulation of specific emerging technologies can be established.

As set out in the Digital Technologies paper published in March 2023 as part of this review[21], "a regulatory sandbox is a live testing environment, with a well-defined relaxation of rules, to allow innovators and entrepreneurs to experiment with new products or services under enhanced regulatory supervision without the risk of fines or liability."

An EBRN sandbox should be timebound, focus on areas where the underpinning science or technology is at a stage to make a major breakthrough feasible, and be ambitious in seeking to solve a societal challenge. Topics for sandboxes should be reviewed on an ongoing basis, and this report does not aim to set out an exhaustive or final list of technologies to be explored.

An initial focus could be on alternative proteins for livestock feed. Livestock feed is a topic in which the UK is at a serious risk of missing the opportunity to become a world leader because of regulations inherited from the EU that slow innovation. A sandbox in this area could mitigate the risk of slowing down innovation, demonstrating how agile regulation can speed up innovation. The sandbox would brigade resource and urgency around alternative proteins and provide much needed confidence to firms working in this space that regulatory barriers are being addressed as a priority and at pace. We explore alternative proteins for human consumption in more detail in recommendation 11.

Another sandbox application could be on cell-free systems, or 'programmable liquids'. These are rapidly becoming viable as a source of future transformative innovations in bio-manufacture and diagnostics developments, removing the need to engineer cells genetically

[20] https://transform.england.nhs.uk/ai-lab/ai-lab-programmes/regulating-the-ai-ecosystem/the-ai-and-digital-regulations-service/

[21] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1142883/Pro-innovation_Regulation_of_Technologies_Review_-_Digital_Technologies_report.pdf

by using unencapsulated biosynthetic systems. This innovative technology has seen rapid advances in the manufacture of healthcare products, although cell free systems have applications across many sectors including beyond human health, highlighted by UK manufacture of non-polluting dyes and environmental diagnostics. A lack of clarity regarding the regulatory processes required to bring resulting products to market as the technology continues to progress could impact innovation. The UK has an opportunity to gain an international advantage in this nascent technology by taking early action to clarify how regulators will classify cell free systems and how they will be regulated.

Novel foods

Technological advances combined with pressure for more sustainable sources of protein have led to an acceleration of innovation and product development in novel foods. Novel food regulations apply to foods for human consumption and include foods which were not widely consumed by people in the UK or European Union before May 1997. This can include completely new foods, foods eaten elsewhere in the world, or foods produced from new processes.[22]

A particular growth sector is alternative proteins. This is an example of foods produced from new processes, which includes plant-based and food-technology alternatives to animal protein with the aim of reducing environmental impacts. Research by the Food Standards Agency (FSA) identifies 4 types of alternative proteins: plant-based meat substitutes, novel protein sources, proteins biosynthesised by microorganisms and cultured meat proteins. [23] Alternative proteins present a major opportunity for economic growth. The National Food Strategy highlighted how developing and manufacturing alternative proteins in the UK, rather than importing them from abroad, had the potential to create around 10,000 new factory jobs and secure a further 6,500 jobs to produce protein crops and other inputs.[24] Market revenue for plant protein ingredients has been projected to reach £16.8 billion by 2026[25]. While the long term commercial and environmental viability of cultivated meat is still uncertain due to the economies of scale involved, its price has been falling. In 2013, the price of one lab grown burger was £215,000, which fell to £8 within 5 years.[26] If cultivated meat matures into a commercially viable product it could become a multi-billion-dollar industry in the future.[27] These technologies represent great economic opportunity for the UK, but those opportunities should go hand in hand with the emerging applications being able to meet their claims about sustainability and nutritional benefits.

To access opportunities from alternative proteins and other novel foods, the FSA should ensure the regulatory model is easy to navigate for businesses with innovative products, removing barriers to innovation whilst maintaining standards and consumer safety. The FSA are reviewing the Novel Foods regulatory framework, and recently completed an external review to identify lead options for future reform. Outcomes from this review will be published by the FSA in their Novel Foods Review in late Spring. Proposals under consideration include

[22] https://www.food.gov.uk/business-guidance/regulated-products/novel-foods-guidance
[23] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/alternative-proteins-for-human-consumption
[24] https://www.gov.uk/government/publications/national-food-strategy-for-england
[25] https://www.great.gov.uk/international/content/investment/sectors/food-and-drink/
[26] https://www.adamsmith.org/research/dont-have-a-cow-man-the-prospects-for-lab-grown-meat
[27] https://www.gov.uk/government/publications/national-food-strategy-for-england

time limited conditional authorisations for products with evidence of safe use in other countries, fast track routes for innovative applications, use of hybrid authorisation for products which do not fit into existing legislative boundaries and expanded pre-application support.

We have heard the key barrier for implementation of this reform is capacity and resourcing within the FSA, which is vital for initial policy development and for implementing future reforms. Most will require legislative change and public consultation, in line with the FSA's statutory duties and commitment to transparency. Food policy is devolved, requiring the FSA to engage with the devolved administrations under the terms of the relevant Framework Agreements.

Recommendation 11: We recommend the government support the FSA to find ways to enable the acceleration of plans to reform the approval process for Novel Foods.

Waste valorisation

Updating the waste hierarchy is an opportunity to encourage growth and support the implementation of a circular economy. In any industrial sector, two main strategies are needed to achieve a circular economy: reducing waste levels; and finding the most sustainable solution to manage the remaining waste. The circular economy is addressed in the 2011 Waste Hierarchy[28], but that hierarchy does not include waste valorisation - the process of converting waste materials into higher value products. Currently, organisations are focused on the responsible recycling or energy recovery of waste rather than potential valorisation opportunities. Using valorised residual waste - defined in this context as non-hazardous waste that cannot be reused or recycled[29] - as feedstocks in new processes can offset costs for companies by reducing disposal costs and introducing new streams of income from industrial engineering biology companies that specialise in valorisation. Updating the waste hierarchy could encourage scale-up of biorefining technologies that use waste to produce feedstocks and address the security of supply of domestic biomass feedstock. While there are support mechanisms through external bodies such as the Industrial Biotechnology Innovation Centre, the Beacon Bioeconomy Research Centre, and BioVale, the current hierarchy should be updated to address emerging technologies in the engineering biology sector. Updating the current hierarchy to ensure it defines how to capture value from residual waste will enable the growth of efficient, scalable systems to capture resources, secure feedstocks for engineering biology companies, and support UK net zero targets.

Recommendation 12: 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.

[28] https://www.gov.uk/government/publications/guidance-on-applying-the-waste-hierarchy
[29] https://www.legislation.gov.uk/ukdsi/2022/9780348242973

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