



# Taskforce on Innovation, Growth and Regulatory Reform

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Dear Prime Minister,

You asked us to look at ways to refresh the UK's approach to regulation now that we have left the EU, and to seek out opportunities to take advantage of our new-found regulatory freedom, to support innovation and growth. As a Taskforce, supported by a small number of civil servants, you gave us, and we have met, a very tight deadline.

We have consulted widely, particularly with those businesses that are affected by regulation, but also with academics, our colleagues in Parliament, thinktanks and other experts.

This report is the result of those varied discussions. It includes around 100 recommendations, which we believe would, if implemented, make a material difference to the UK's economic growth, competitiveness and productivity, without reducing our commitment to gold standard protections for consumers, workers and the environment.

Our recommendations cover three areas:

1. A bold new UK regulatory framework based on core principles of UK law;
2. Specific regulatory reforms in high-growth sectors in which we see particular opportunities for the UK; and
3. Implementation: proposals for how these reforms could be delivered.

We present them to you without fear or favour as reforms which we judge would deliver a significant boost to the whole of the UK economy.

We recognise that decisions over implementation will of course be a matter for wider political and policy judgements by you, the Government and in some cases the devolved administrations. We appreciate that the Northern Ireland Protocol limits the scope for application of these reforms in that part of our country. We hope that future reform of the Protocol may allow greater scope for regulatory reform in Northern Ireland so that its economy can benefit from the proposals we set out.

Rt Hon Sir Iain Duncan Smith MP (Chair)  
Rt Hon Theresa Villiers MP  
George Freeman MP

## ACKNOWLEDGEMENT

*The members of the Taskforce would like to express our thanks to the many entrepreneurs, businesses, trade bodies, academics, thinktanks and other experts who shared their insights and ideas through dozens of roundtables and meetings with over 125 experts and much correspondence in the evidence gathering for this report.*

*We have endeavoured to do them justice; anything that has been beyond the reach of this Taskforce in the time available has been passed to the Cabinet Office team supporting the Government as it pursues this agenda beyond the completion of this report, with our encouragement to follow it up.*

*We are also grateful to the government departments and regulators that have shared their expertise and thinking. We are particularly grateful to the team of civil servants that has helped us compile this report.*

*In accordance with our invitation from the Prime Minister, the views expressed in this report are ours as Conservative Members of Parliament, and whilst we have framed our proposals in support of the Government's general policy aims to unlock growth, innovation, recover and 'level-up', this report is independent of Government.*

# SUMMARY

1. The UK's departure from the EU after 45 years offers a one-off **opportunity** to set out a bold new UK regulatory framework based on a set of principles embedded in UK common law, which prioritises innovation, growth and inward investment as part of the UK's new global trading freedom, building on the UK's global reputation for leadership in setting the highest standards of environmental and consumer protection. Seizing this opportunity is even more important as our country and our economy look to recover from the catastrophic effects of the coronavirus pandemic.
2. The pace of **global technological innovation** is creating huge new opportunities and challenges for regulation: from AI to space, genetics to autonomous vehicles. We have an opportunity to set out a new regulatory framework which plays to the strengths of the UK's business environment, proud history of research and development, underpinned by eminent universities, and dynamic new business sectors. We have a global outlook, with strong links to Europe and key economies elsewhere in the world, supported by the advantages of time zone and language; and reflected in the UK being the source of many important global standards. We have a legal tradition in common law which is sought after for its predictability and stability.
3. Regulation can be both an unnecessary barrier to growth for many businesses and a catalyst for investment in new sectors. Bad regulation is ineffective, expensive and difficult to implement. Good regulation, set up in the right way, can be a vital part of the infrastructure to support growth. Through setting clear, proportionate, long-term goals, frameworks and standards, **UK regulation can be a significant driver of our international competitiveness.**
4. Many of the examples of best practice in regulation that we have drawn on are in the devolved nations: from plant science in Aberystwyth to cancer trials in Belfast, to electronic patient records in Scotland. We believe our proposals would benefit all parts of our **Union**, and would contribute to the vital levelling up agenda by creating new opportunities through new markets. In many areas considered in this report the decision on whether to take our proposals forward is for the devolved administrations. We recognise that the scope of regulatory reform in Northern Ireland is limited by the Northern Ireland Protocol. We hope that future reform of the Protocol might allow greater scope for the adoption of our ideas in this part of our United Kingdom.
5. Adding more regulation is easily done. Removing it is harder. Leaving the EU offers opportunities both to shed unnecessary EU-derived legislation, and to frame a UK approach to regulation with three aims in mind **boosting productivity, encouraging competition and stimulating innovation.** To achieve this UK regulation should be:
  - a. **Proportionate;**
  - b. **Forward-looking;**
  - c. **Outcome-focussed;**

- d. **Collaborative;**
  - e. **Experimental; and**
  - f. **Responsive.**
6. Our proposed new '**Proportionality Principle**', is absolutely central to the new framework we are proposing: by making regulation proportionate to both the scale of the risk being mitigated, and the capacity of the organisation being regulated, we believe this new UK framework will boost both UK economic competitiveness and UK regulatory leadership.
  7. As an independent Taskforce commissioned by the Prime Minister to grasp the regulatory opportunities available to us outside the EU, we are proposing:
    - a. A bold **new vision for UK regulation and a framework for delivering it.**
    - b. A package of specific regulatory reforms to unleash substantial growth in a range of **high-growth sectors**.
    - c. **Removing unnecessary regulatory burdens** where possible.
    - d. A practical mechanism for **implementation across government.**
  8. UK regulation should put **innovation** at its heart: embracing both innovative ways to regulate more productively and boost UK innovation, while continuing to honour the UK's firm commitments to set the highest standards in protecting workers, consumers and the environment.
  9. This means focusing on **proportionality**, based on a clear assessment of the risks, but also of the rewards available from growth and productivity. In some instances this might mean getting out of the way of innovation. In others it could involve actively promoting innovation through new standards or proportionate rules tailored to SMEs and new market entrants. Where possible, regulation should focus on outcomes rather than on inputs; regulating the end product, not the process. To this end we are making recommendations on stronger duties for regulators to promote innovation and competition, pushing them to play a much more active role in supporting growth.
  10. UK regulation should aim to be as **simple, agile and proportionate** as possible. The complexity of the modern economy means a degree of regulatory complexity is unavoidable, but we should aim for a simpler, more streamlined approach. Freed from the obligation to compromise with 27 other countries, our regulatory system should be reformed to better support the needs of UK businesses and citizens. It should be sharpened by the discipline of 'one in, two out', to temper the natural urge for new rules to respond to perceived new problems. Wherever possible, regulations should be designed to support SMEs and start-ups in navigating regulation. Care should be taken to avoid allowing large, established firms to shape regulation in their own interests where this comes at the expense of smaller competitors and potential market entrants.



11. UK regulation should build on the strengths of common law in being **adaptable**. It should evolve in a predictable way. There is scope for elements of retained EU regulation to be rewritten using the common law method in clear, simple English. Case law should be welcomed, so as to regain the benefits of precedent-based, incremental regulation making. The common law system would allow regulators to apply simpler rules, more of which they make themselves, on the delegated authority of Parliament but within defined parameters. This would be inherently more flexible, but will require checks and balances to deliver legal predictability, fairness and accountability.
12. UK regulation should be **smart**, and **digital** wherever possible. It should aim to expand use of new approaches to regulation, for example by using 'sandboxes' and 'testbeds'. Government departments and regulators should strive for efficient, streamlined processes and innovation in their own activities, as the businesses they regulate do.
13. The way in which regulation is **implemented** can be just as impactful as the regulations themselves. Where the UK is rightly and proudly committed to maintaining the highest regulatory standards, including in relation to food and the environment, that does not mean we have to continue with the same, often bureaucratic and self-defeating, methods of implementation. For example, UK farmers face compliance with potentially hundreds of regulations, depending on their business, enforced by several different agencies and public bodies<sup>1</sup>: hence our proposals for a more integrated framework of implementation in which farmers don't have endless site visits and forms to fill in, but one framework of agri-environmental regulation prioritising the desired *outcome* more than the *process* of compliance.
14. While the prize for the UK may be easily visualised, **seizing the opportunity** is a different matter. Doing so will take sustained drive and focus from the Government, from the Cabinet down, as well as the right structures for scrutiny in Parliament. Much regulation, including from the EU, is enshrined in legislation. Delivering this programme of change over an acceptable period will require a different approach, delegating more responsibility and flexibility to regulators to set rules without requiring new legislation. Unchecked, such discretion would present problems of democratic accountability, so this approach will require an accompanying increase in Parliamentary scrutiny of regulators' actions, to ensure they remain sufficiently accountable. We are therefore recommending **a strengthened system of Select Committee scrutiny, supported by more effective, and more effectively used, economic impact assessments and metrics**. Our proposals go well beyond the current combination of under-staffed select committees and the Regulatory Policy Committee.
15. This new framework of regulation for competitiveness will require commitment of all parties: national and local government, statutory regulators, quangos and agencies, and a clear framework for **annual reporting on clear metrics of delivery**.

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<sup>1</sup> [The Department for Environment, Food and Rural Affairs agencies and public bodies.](#)

16. If the Government successfully implements the vision, framework and proposals we set out in this report, the effects will be seen across **the whole economy**. But in some sectors, the effect of a clearer regulatory framework based on these principles could unlock billions of new investment in the UK. We have highlighted many of the most exciting key high-growth sectors in this report.
17. **Financial services, FINTECH and scale-up venture finance**. Financial services are a key UK strength; but the tangled web of EU-derived regulation needs a thorough overhaul if we are to build on that strength. This will involve moving away from the EU's code-based system to a more principles-based approach based on common law. A lack of provision of adequate capital for scale-up of ventures is a historic UK weakness. The UK finance sector has been limited in the capital it can inject into innovative companies by the way the pensions and insurance sectors are currently regulated. Reforming this judiciously, while maintaining necessary and proportionate protections, would help unleash latent innovation across the economy, through better availability of finance to businesses in their key 'scale-up' growth phase. Reforms to enterprise investment schemes and reporting (e.g. under MiFID II<sup>2</sup>) will help further the UK's position.
18. **Data**. The EU's General Data Protection Regulation (GDPR) aims to give people protection over their data privacy and confidence to engage in the digital economy, but in practice it overwhelms people with consent requests and complexity they cannot understand, while unnecessarily restricting the use of data for worthwhile purposes. We propose reform to give stronger rights and powers to consumers and citizens, place proper responsibility on companies using data, and free up data for innovation and in the public interest. GDPR is already out of date and needs to be revised for AI and growth sectors if we want to enable innovation in the UK.
19. **Clinical trials**. The UK has the capability to be a world leader in clinical trials, as shown by the development of the Oxford / AstraZeneca vaccine. We can make this the rule rather than the exception through reforms to underlying frameworks and architecture. Clinical trials are all about data. The current landscape based on the EU's Clinical Trials Directive and GDPR sees multiple information governance referees with the ability to prevent data flows for life science health research. This is holding back the UK trials sector. We should replace the EU Clinical Trials Directive with a new UK clinical trials framework based on UK leadership in innovative trials design, patient recruitment, translational medicine protocols, streamlined processes and a unified health research data structure.
20. **Digital health**. Health is going digital. The UK should pursue a regulatory vision to support the nascent digital health sector, in which AI and other digital technologies support better health outcomes throughout people's lives; from wellness to diagnosis, all the way to disease treatment. We have an opportunity to create a regulatory framework for digital health based on mandatory interoperability standards to support consumer confidence and NHS take-up of digital apps for disease prevention, portable electronic patient records (EPRs) and digitalisation of NHS systems.

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<sup>2</sup> [Markets in Financial Instruments Directive](#), European Commission.



21. **Energy.** The scale of the pace of decarbonisation and electrification in the transition to a Net Zero economy demands a massive change in the regulatory framework for energy to deliver the smart energy grid. Interoperable data standards, more focus from Ofgem on grid-enhancing investment, clear frameworks to support innovative energy carriers such as hydrogen, and retail regulation updated to adapt to the multiplicity of potential Net Zero-enhancing business models all have their part to play.
22. **Transport.** Technology is transforming the world of transport. The combination of digitalisation, decarbonisation and the shift to Mobility as a Service is driving a wave of transport innovation, from connected and autonomous vehicles to drones to electric aircraft, e-scooters, and hydrogen vehicles. We should aim to be a global leader in these developments through extensive use of place-based testbeds for agile regulation, setting standards and collecting interoperable data across modes for evidence and data-based regulation.
23. **Space and satellites.** The Government should build on the UK's position as a science and engineering superpower to realise the full potential in the space sector. This requires following through on the changes begun through the Space Industry Act 2018 and ensuring that the Government has a clear regulatory vision, which is properly prioritised by the Civil Aviation Authority, Ofcom and the UK Space Agency, all acting in concert to support innovation and growth.
24. **Agri-environment.** Current EU-derived regulations and 'tick-box' compliance framework based on multiple inspections and forms discourages agri-environmental innovation vital for sustainability, biodiversity, food security and investment. The UK would be better served by a more integrated, risk-based, proportionate approach to agri-environmental regulation, incorporating biodiversity offsetting and greater use of agri-tech. Gene editing can offer important benefits, for example in relation to reducing the need for chemical pesticides and promoting sustainable agriculture around the world. It represents an opportunity both for the UK's domestic production and in exporting technology. It should be distinguished from genetic modification and licensed and regulated separately.
25. **Nutraceuticals.** The pace of bioscience is creating a whole new sector of health enhancing 'superfoods' and supplements such as enriched broccoli or probiotics, which don't fit well in our traditional regulatory framework with its binary separation of medicines (MHRA) and food standards (FSA). A new regulatory pathway needs to be established to clarify the grey area between food and pharmaceuticals to allow this sector to realise its potential.
26. **Further important reforms.** Other areas where targeted reform of inherited EU regulation could deliver helpful economic benefits without compromising on consumer and public outcomes, include weights and measures legislation, product labelling, and ports regulation.
27. The evidence we have heard through the course of the Taskforce's work has emphasised the UK's tremendous potential as a powerhouse of **science, technology, engineering and innovation**. Now more than ever, as we see the

economy start to recover from the pandemic, we need to tap into that potential. We need to invest in it, set frameworks for it to be realised; and where necessary, clear regulatory barriers out of its way. All will benefit if we can do this.

28. In some instances - such as on the Common Agricultural Policy - the Government has started the job of charting the UK's new regulatory course outside the EU; but **reforming and modernising EU-inherited regulation is a significant programme of work**. We hope this report will inject some extra energy and urgency into this vital task. Our report should be the start of a process through which government departments review all aspects of EU regulation (especially those rules which the UK voted against in the Council of Ministers) to assess which to remove, reform or retain.
29. We believe that replacing the EU model of regulation with a new UK Regulatory Framework, based on the Proportionality Principle and unlocking global UK leadership in innovative regulation, will be **a major boost to both UK economic recovery and our long-term competitiveness**.

# A BOLD NEW REGULATORY FRAMEWORK FOR THE UK

30. The Prime Minister asked us to form the Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) in February to consider how the UK can best take advantage of its new-found regulatory and trade freedoms outside the EU.
31. In particular, our aim was to explore:
- a. Opportunities which could drive innovation and accelerate the commercialisation and safe adoption of new technologies, cementing the UK's position as a global science and technology superpower;
  - b. Opportunities to reduce barriers to entry to make markets more dynamic and competitive across the economy;
  - c. Opportunities to reduce administrative barriers to scaling-up high-growth businesses; and to tailor any necessary processes to the needs of UK start-ups and SMEs while maintaining the Government's commitment to high environmental standards and worker protections;
  - d. Opportunities to reduce the overall net burden of regulation on start-ups and SMEs;
  - e. Sectors of the economy or regulatory frameworks which should be prioritised for further regulatory deep dives.
32. Innovation is the implementation of new ideas that generate value. It does not have to involve cutting-edge science. It can involve:
- a. the improvement of, or new solutions to deliver, organisational processes;
  - b. the development of new products or product features;
  - c. the creation and introduction of new services or better ways of delivering services;
  - d. the introduction of new or improved business models; or,
  - e. the digitalisation and digital transformation of products and services.
33. We have sought to identify areas where genuinely transformative change is possible, as well as focus on specific areas where regulatory reform could stimulate significant new investment and growth in new sectors or unlock growth opportunities in existing industries. Our proposals should be seen as a starting point for the Government to build on in the months and years ahead.
34. This project is not a simplistic 'bonfire of red tape'. Regulation performs many crucial tasks and the nature of our regulatory systems also affect our trade relationships with other countries. Good regulation - well thought through - can give confidence to global investors, protect consumers, workers and the environment, and secure a range of crucial policy outcomes. Ensuring that our approach to regulation minimises competitive distortions is an important means to deliver long-term growth and

prosperity, as well as putting us in a strong position to conclude free trade agreements with countries around the world. We also need reform to reflect the pace of technological change which is creating new sectors, but where a lack of regulatory certainty is holding back investment.

35. We have sought views from a wide range of businesses, academics and think tanks through dozens of roundtables and meetings with over 125 experts on how the UK can improve how it regulates, now and in the future.
36. Our departure from the EU provides us with a once-in-a-generation opportunity to redesign and improve our approach to regulation across the economy. This is not the first regulatory reform exercise in recent years, but for the first time in forty years it is not constrained by what the EU will or will not allow. And now that we have taken back control of our trade policy we have an opportunity to take a leadership role in integrating our global trade and regulatory standards.
37. The UK is recognised as one of the global leaders in good regulation. The World Bank ranked us ninth out of 190 economies for ease of doing business and the OECD considered the quality of our regulatory practices to be the highest in the world.<sup>3</sup>
38. But two in five businesses currently consider regulation an obstacle to success in the UK.<sup>4</sup> Whilst this figure has gradually dropped over the last decade as the Government introduced pro-growth policies, it is still far too high, especially given the urgency of unlocking a post-COVID-19 economic recovery. The UK's regulatory environment should seek to enable success, not create unnecessary obstacles. It should support innovation, improve safety for consumers and workers, ensure the long-term protection of the environment and drive UK competitiveness, productivity and growth.

## A new regulatory vision for the UK

**Headline Proposal 1: Promote productivity, competition and innovation through a new framework of proportionate, agile and less bureaucratic regulation.**

39. **The UK's regulatory environment is a significant contributor to UK competitiveness. The UK needs to boost its productivity, encourage competition and stimulate innovation to unleash growth, whilst protecting consumers, workers and the environment.**
40. Fundamental reform of the way regulation is developed and made, implemented, and scrutinised is needed to achieve this. One of the most significant burdens of regulation is the sheer volume of rules created often by different organisations with little or no consideration of the overall net burden or impact of regulation on the

<sup>3</sup> [Regulation for the Fourth Industrial Revolution: White Paper](#), HM Government, June 2019. p7.

<sup>4</sup> [Business Perceptions Survey 2020](#), Department for Business, Energy and Industrial Strategy, November 2020. p21.

organisation being regulated. The burden for a community group or small business should not be the same as for a FTSE 100 company (or Government). It should be proportionate. Best practice for developing regulation must start with thinking more deeply about the desired outcome and to take into account the overall impact on both individual businesses and the economy.

## A common law approach

41. Much of the restrictive nature of today's regulatory environment is due to the influence of the EU's approach to regulation over the last forty years. Nowhere is this clearer than the shift from the UK's traditional uncodified systems of common law and Scots law<sup>5</sup> to a more Napoleonic, code-based, civil law approach traditionally seen on the Continent.
42. Uncodified systems such as common law have historically been and continue to be the systems of choice for many successful jurisdictions. The clear trend for new financial free zones - bespoke jurisdictions designed to be magnets for economic activity - is to opt for a common law approach. It is fortuitous that the UK - still regarded internationally as the pioneer and guardian of this tradition - has the opportunity to re-emerge as a global leader in this trend.
43. The EU's code-based system, applies prescriptive statutory rules. It seeks to accommodate the views of an array of national legislators and too often results in complication and statutory inflexibility which ends up limiting innovation and constraining business. These complicated and statutory processes have often ended up with the European Court of Justice, whose purposive method of interpretation seeks to apply detailed political purposes across a swath of provisions. Worse, as any lawmaker will observe, the statutory and inflexible model is difficult and time consuming to change.
44. Having left the EU, unnecessary rules need to be removed and those that remain should be re-written using common law methods and clear, simple English. As for law, so for regulations. Reliance on case law should be encouraged, so as to regain the benefits of precedent-based, incremental regulation making.
45. It is noticeable that the English common law and Scots law systems would allow regulators to apply simpler rules, that they make themselves, on the delegated authority of Parliament and the devolved parliaments. Parliament would set the parameters, including, for example, the requirement to test regulations against their economic impact. This will be inherently more flexible, but will require checks and balances to deliver legal predictability and fairness.
46. It is not just the code-based approach that had an insidious effect on the UK's regulation. The way the 'Precautionary Principle' has been applied by the EU has

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<sup>5</sup> The position in Scotland in this context is similar, even though it has its own legal system. It has a mixed system, containing elements of common law and uncodified elements of civil law. Unlike the civil law regimes of the continent, the Scots system was never codified. As a result, Scots law is akin to the common law system for these purposes and has similar benefits of stability and predictability, obtained through jurisprudence and a relatively strict rule of judicial precedent.

meant some innovations have been stifled due to an excessive caution that is often disproportionate to the associated risk.

47. The UK needs to establish its own modern, agile and effective approach to regulation. The UK should adopt a new **Proportionality Principle** that reflects the risk and the desired outcome. Regulation should protect the rights of consumers, employees, citizens' privacy and the environment: but effective and proportionate regulation should also seek to boost economic competitiveness.

## Common law in practice: avoiding unnecessary red tape

**Proposal 1.1: Reimpose the 'one in, two out' regulatory duty on all government departments.**

48. To put this approach into practice now that the UK has more freedom to set its own regulatory frameworks we must ensure we are only creating new regulation when it is absolutely necessary. Examples include setting a framework for a new economic sector, or to avoid clear harms in a sector that is currently unregulated and where there is an established market failure.
49. The Red Tape Challenge<sup>6</sup> was launched in 2011 to remove unnecessary and burdensome regulation. In 2014, the Government announced that the project had saved businesses £10 billion over four years.<sup>7</sup> Many of the Challenge's proposals were included in the Deregulation Act 2015.
50. In order to focus departments on minimising the creation of additional regulation, with the full knowledge that each new regulation creates costs and burdens for businesses, we should return to the 'one in, two out' regulatory offset principle.<sup>8</sup> This approach could be supported by the Better Regulation Cabinet Committee, who could ultimately be charged with signing off the creation of new regulations.
51. The process we have undertaken should only be the start of a bigger process to identify areas for reforming regulation to remove unnecessary burdens and costs. The Government should undertake a complete audit of EU derived law and look for further opportunities to deregulate and lower burdens on business.

## The extension of common law: agile regulation

**Proposal 1.2: Make the UK a global pioneer and leader in agile, adaptive regulation to increase productivity, competition and innovation.**

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<sup>6</sup> [Press release: Red Tape Challenge](#), Cabinet Office, April 2011.

<sup>7</sup> [Red tape drive saves business a record £10 billion](#), Department for Business, Innovation and Skills, December 2014.

<sup>8</sup> [2010-2015 government policy: business regulation](#). Department for Business, Innovation and Skills, May 2015.



**Proposal 1.3: Create a lead Cabinet Minister and ensure there is a Cabinet Committee responsible for the implementation of regulatory reform.**

52. The Government and regulators should re-think how to regulate, with three aims in mind:
- a. Boosting **productivity**;
  - b. Encouraging **competition**;
  - c. Stimulating **innovation**.
53. If the Government wants regulation for innovation, then it needs **innovation in regulation**. A common law approach allows more forward-looking, judgement-based regulation without needing such complex and exhaustive rules for every situation set out in advance.
54. A consistent message we heard from those on the cutting edge of innovation was that the traditional way of doing regulation is not appropriate today. Too often it is slow when it should be fast, sluggish when it should be agile, and fixed when it should be adaptive.
55. The UK has been at the forefront of thinking on agile regulation; the Government's £10m Regulators' Pioneers Fund was the first attempt to systematically promote and test new innovation-enabling regulatory approaches.

**Regulators' Pioneer Fund (Round 1)**

The Regulators' Pioneer Fund (RPF) was a competition set up by the Better Regulation Executive in BEIS to "*promote cutting-edge regulatory practices that help businesses bring innovative products and services to market.*"

The £10m Fund was awarded to 15 projects across 12 regulators in Oct 2018. It tested ideas like sandboxing in the social care sector, a Business Innovation Privacy Hub to enable innovators to test ideas in a privacy-respecting way, and data exchange in regulated markets.

The evaluation published in March 2021 showed strong positive indications of progress on stimulating and progressing innovation, particularly reducing time or cost of introducing such innovations to the market and increasing business and innovator confidence in regulation.

56. We should build on our comparative advantage by further embedding and disseminating an agile and adaptive approach to regulation. The UK needs regulatory regimes that are proportionate, forward-looking, outcome-focussed, collaborative, experimental, and responsive.

**Proportionate: Regulators should scale their support and requirements appropriately to risk and the size of firms**

57. Regulators need to be conscious of the impact of regulation on start-ups and other innovative market entrants who often have lower capacity and capability to shape

and implement new rules. Proportionate regulation can increase competition by reducing barriers to market entry. The use of waivers and the creation of innovation hubs, trials, testbeds, one-stop shops and better routes to engage regulators can help break down these barriers.

**Forward-looking: Regulators should focus on future growth and risk, actively shaping technological and market developments**

58. Singapore set up a Centre for Strategic Futures in the Prime Minister's Office to create a more agile public service that uses foresight methods to identify possible futures and prepare for them.

**Outcome-focussed: The UK should focus on building technology-neutral regulatory regimes that focus on goals and outcomes rather than inputs.**

59. Outcome-focussed regulation can increase productivity by allowing businesses to use more efficient processes to meet a desired regulatory outcome. Japanese health and safety regulation gives businesses greater freedom by focussing on how well systems can monitor safety, reduce risks, identify issues and intervene when they are detected, instead of setting out stringent design requirements and mandatory processes.

**Collaborative: Regulators must engage with businesses, including SMEs and start-ups, empower innovators and connect with their peers and the public.**

60. Good collaborative regulatory practices include the Danish Business Authority establishing a "one-stop shop" for new business models to help businesses find their way through the regulatory landscape and the Financial Conduct Authority leading the Global Financial Innovation Network to develop a framework to test innovations across borders.

**Experimental: Regulators should make space for businesses to test and trial new business models, products and approaches.**

61. An experimental approach encourages innovation. UK regulators such as the Financial Conduct Authority (FCA) have pioneered mechanisms such as regulatory sandboxes, that permit businesses to test new products and business models. The Regulators' Pioneers Fund invested in 15 experimental new ways to regulate, from using AI to improve access to legal services to using blockchain technology to improve UK telephone number management.

**Responsive: Regulators should take an iterative-learning approach to new and uncertain market developments.**

62. Standards, testbeds, sandboxes and encouraging best practice are all ways regulators can be more responsive, learning and adapting rather than immediately creating definitive across-the-board rules. Using trials and pilots to test new products and business models is an effective way to allow innovative ideas to be put into practice, whilst effectively managing risks.

63. A central driving force, with a clear lead Minister and appropriate Cabinet oversight, will be needed to overhaul the regulatory landscape and ensure that an agile regulatory strategy is adhered to.
64. Some of these functions already exist. The National Economic and Recovery Taskforce (NERT) Cabinet sub-committee on Better Regulation (BRC) was set up in early 2021 to drive growth across the economy by placing competition and innovation at the heart of regulatory decision making. But the UK does not yet have a clear regulatory strategy; it should develop one as soon as possible.

## **Proportionality in implementation: a framework based on risk and outcomes not “tick-box” compliance**

**Proposal 1.4: Mandate a new “Proportionality Principle” at the heart of all UK regulation.**

65. The ‘Proportionality Principle’ is absolutely vital to the new framework we are proposing. One of the longstanding issues with traditional regulation is that it has a disproportionate negative impact on smaller businesses (and creative ‘third sectors’ like social enterprise).
66. Our proposed proportionality principle is designed to operate in two key ways:
  - a. Risk: ensuring the design and implementation of regulations, including their cost, is proportionate with the level of risk.
  - b. Reaching the right outcome: regulation should be based on outcomes rather than assessing mechanistic “tick-box” compliance with rules. Remediation and penalties where a bad outcome (such as a harmful data breach) occurs should be proportionate to the harm caused as well as the size and ability to pay of the business involved.

## **Agile regulation in practice: sandboxes**

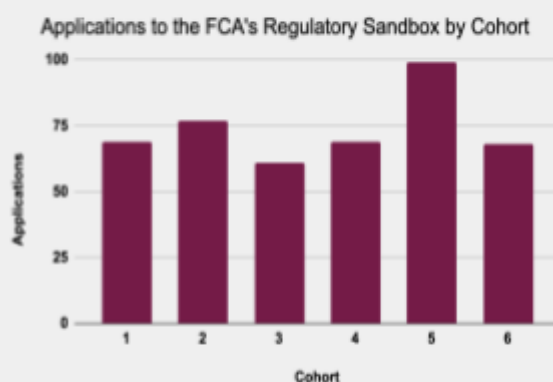
**Proposal 1.5: Use digital sandboxes to test innovations more quickly and ensure regulation is based on evidence of impact.**

67. To ensure agile, proportionate, evidence-based assessments of new products, services and business models we propose a much wider adoption of the ‘sandbox’ approach.
68. A regulatory sandbox is a concept that enables firms to test innovative products, services or business models. Within a sandbox, some regulatory obligations do not apply. Sandboxes also allow regulators to test whether some regulatory obligations

could be removed or changed on a permanent basis. The UK has been a pioneer in this area. The FCA launched the first fintech regulatory sandbox<sup>9</sup> in June 2016.

### Case Study: The FCA's Regulatory Sandbox

The FCA's regulatory sandbox allows businesses to test innovative products and services in the market, with real consumers. It has seen sustained demand across 6 cohorts.



#### Businesses can benefit from:

- testing products and services in a controlled environment.
- reduced time-to-market.
- support identifying appropriate consumer protection safeguards.
- better access to finance.

#### The FCA can give businesses:

- **informal steers** on potential regulatory implications of an innovative product or business model at an early stage of development;
- **waivers or modifications to rules** for the purpose of the test;
- **no enforcement action letters** that give businesses assurance they will not face disciplinary action if unexpected issues arise; and/or,
- **individual guidance** on rules and requirements in the context of the specific test.

69. Since then, the use of FinTech sandboxes has proliferated across the world. And regulators are now beginning to use sandboxes, or sandbox-like processes, to support innovation in other markets: Ofgem, Singapore's Energy Market Authority and the French Energy Regulatory Commission in energy markets; the Solicitors Regulation Authority and the Utah Office of Legal Service Innovation in law; the Information Commissioner's Office, Singapore's Infocomm Media Development Authority and the Norwegian Data Protection Authority in data; Singapore's Ministry of Health in healthcare; the Civil Aviation Authority in aviation; and the Care Quality Commission in social care.
70. Sandboxes are linked to many beneficial outcomes, such as reduced time and cost for bringing innovative ideas to market, increased investment in currently unapproved ideas, improved product testing, and better consumer safeguards.
71. Regulators are also using sandboxes as a vehicle to call for new ideas to meet their other policy goals. For example, the Home Office and the Office for Product Safety and Standards recently launched a regulatory sandbox calling for proposals for new age verification technologies to improve compliance with the licensing objective to protect children from harm in the retail sale of alcohol products.

<sup>9</sup> [Regulatory sandbox](#). Financial Conduct Authority, updated January 2021.

72. The feedback we heard from stakeholders on sandboxes was overwhelmingly positive. A good example is the new Future Mobility testbed project in the West Midlands, which will provide over 180 miles of roads, the largest area in the UK, for developing the next generation of connected autonomous road vehicles. Support for the use of sandboxes also comes from bodies such as the Robotics Growth Partnership. In its view, sandboxes accelerate learning by allowing “the interplay of different technologies, safety productivity and profit, public acceptance and many others. Crucially they enable changes to regulations to be tested.”
73. It is particularly important that sandboxes provide tailored support to start-ups to help them bring new products and business models to market. We recommend greater use of sandboxes in future transport technologies in section 10. This should be complemented by a whole-government approach to encouraging their use.
74. As catalysts for innovation sandboxes can help create new clusters of business opportunity. They can play a big role in levelling up access to opportunity and spreading innovation across the UK. For this reason, it is important that sandboxes are geographically dispersed around the country.
75. Sandboxes should be digital by default and regulators should review and share the data and the lessons they learn from them. Previously sandboxes have been established in silos and the data has not been readily available either in digital format, or for others to learn from. The presumption should be that the data can be shared with other departmental teams and regulators looking to implement sandboxes, or learn similar policy lessons.

## Out of the sandbox: a proportionate approach for growth companies

**Proposal 1.6: Regulators should introduce ‘scaleboxes’ to provide agile regulatory support to high growth innovative scale-up companies.**

76. Scale-ups are companies that achieved growth of 20% or more in either employment or turnover year on year for at least two years, and have a minimum employee count of 10 at the start of the period. These high-growth businesses are driving job creation and growth across the country. In 2018, scale-ups employed 3.5 million people and generated a total turnover of £1 trillion for the UK economy – for an average turnover per employee of £286,000. Scale-ups represent 50% of the total SME turnover output despite making up less than 1% of the SME population.<sup>10</sup> It is critical that our approach to regulation considers the specific needs of scaling firms.
77. As nascent industries grow and mature, it becomes as important to support firms in the growth phase as it is to support start-ups. As the Khalifa Review demonstrated for FinTech, this is more important now than ever.<sup>11</sup>

<sup>10</sup> [ScaleUp Annual Review 2020](#). ScaleUp Institute,

<sup>11</sup> [The Khalifa Review of UK FinTech](#), Independent report on the UK Fintech sector by Ron Kalifa OBE, February 2021.

78. In addition to sandboxes, regulators should introduce ‘scaleboxes’, which provide additional supervisory support to companies in their growth phase. The service provided could follow the sandbox model, or innovation hubs, one-stop shops and better routes for scale-ups to engage regulators could be used, with a focus on ensuring that regulation is proportionate to the nature and size of the business in question and the specific risks involved.

## **Reforming regulators’ statutory objectives to promote innovation and competition**

**Proposal 1.7: Give regulators statutory objectives to promote competition and innovation in the markets they regulate.**

79. We have set out the principles which regulators should apply to make the UK the home of agile regulation. Government departments and regulators will need to take active steps to implement these principles. This must include giving regulators the right incentives.
80. In delivering their primary objectives, regulators may not always act in ways conducive to enabling innovation or competition. The incentives for regulators will often be simply to avoid risk and focus on short-term priorities; to fall back on the ‘better safe than sorry’ approach.
81. Regulators must be given a clear mandate by politicians to foster competition, facilitate the growth of key emerging technologies, accommodate new business models and remove unnecessary regulatory barriers that obstruct innovation. Instead of their goal being only to avoid risk, they should be encouraged to allow new models to be piloted and to work collaboratively with industry to manage risk and review regulation. Giving regulators<sup>12</sup> statutory objectives to promote competition and innovation would give them such a mandate.
82. A number of regulators have competition objectives, though the emphasis placed on them varies in practice. The Government should give these objectives to a wider set of regulators and ensure that a regulator’s competition objective is on a statutory footing, equal to its other objectives and drawn widely enough to encompass all its activities. There are fewer examples of statutory innovation objectives. A model for our proposed combination of statutory objectives exists in the Payment Systems Regulator.

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<sup>12</sup> At least the following regulators should have competition and innovation objectives (where they do not already): the CMA, the ICO, Ofcom, Ofgem, Ofwat, the CAA, the ORR, the FCA, and the PSR. And the Government should give consideration to whether these objectives should also be given to regulators in other fields, such as law, professional services, the environment, health, and social care



### The three statutory objectives of the Payment Systems Regulator:



- to ensure that payment systems are operated and developed in a way that considers and promotes the interests of all the businesses and people that use them;
- to promote effective competition in the markets for payment systems and services - between the operators of payment systems, firms who provide payment services and firms who provide the underlying payments infrastructure;
- and to promote the development of and innovation in payment systems, in particular the infrastructure used to operate those systems.

## The need for speed: delegating to regulate a fast-moving world

**Proposal 1.8: Delegate greater flexibility to regulators to put the principles of agile regulation into practice, allowing more to be done through decisions, guidance and rules rather than legislation.**

83. The European Union (Withdrawal) Act 2018 retained thousands of EU regulations forming a body of “retained EU law” in UK domestic law to ensure the statute book remained functional. The EU tends to implement international rules through legislation rather than regulators’ rules. For example, Australia, New Zealand, Canada, the U.S. and Singapore all implemented the Basel III financial stability accord through their prudential regulators, whereas the EU chose to implement primarily in legislation.
84. As a result of the ‘onshoring’ exercise to retain regulations at the end of the Transition Period, combined with the EU practice of regulating through prescriptive legislation that is transposed into Member State law, the UK statute book now has a significant amount of inflexible regulation. In many cases this can only be amended by bringing forward primary legislation.
85. The size of the challenges this poses is significant. To take an example, the Bank of England and Prudential Regulation Authority recently assessed over 10,000 pages of financial sector-related EU legislation and over 12,500 pages of EU technical standards and regulators’ rules.<sup>13</sup>
86. Given the scale and complexity of retained EU law, and demands on Parliamentary time, an over reliance on primary legislation to make modest changes to update regulatory frameworks will simply be too slow. Parliament should set the legislative framework, but it will need to delegate additional responsibility to regulators to enable a quicker, more agile approach.

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<sup>13</sup> Analysis provided by the Bank of England to the Taskforce.

87. We were particularly struck by the need to delegate more flexibility to regulators, in our conversation with the Governor and others from the Bank of England. The Bank faces the task of moving our prudential regulation from the emphasis on more and more detailed rules as a means of compliance, which characterised the EU's approach, to a more judgement-based approach focussed on outcomes. This is consistent with the overall principles which we set out earlier. A greater focus on outcomes, rather than processes, will help counter a culture of gaming that can arise from relying only on tick-box compliance with rules. This will only be possible, for the Bank and other regulators, if Parliament delegates greater responsibility to regulators to do more through guidance, decisions and rules that can be adapted quickly. In this process regulators should take account of the often differing interests of participants, including smaller and less well-resourced but more innovative businesses.
88. At the same time officials at the Bank were acutely aware of the need for greater responsibility to be accompanied by greater scrutiny and accountability. We agree that enhanced scrutiny and accountability will be necessary as a counterweight to giving regulators greater responsibility.

## The counterweight: Parliamentary accountability and scrutiny

**Proposal 1.9: Give the Regulatory Reform Committee a remit to scrutinise all regulators and regulatory reform proposals. Bolster its resources, including with seconded experts, to carry out this expanded function.**

89. The scrutiny by elected representatives is important to ensure regulation is serving the public and remains a proportionate and effective response to an identified harm. We need to ensure that our Parliament is fully equipped and resourced to scrutinise the creation and maintenance of updated regulatory frameworks, and the supervisory practices of the regulators. The size of this task cannot be underestimated.
90. It is important that the impact of different regulations and requirements made by different departments and regulators in areas that overlap can be looked at in the round. It is often the case that individual regulations, rules and requirements are well intentioned but end up placing a disproportionate burden on businesses, particularly SMEs, when taken as a whole.
91. The House of Commons Regulatory Reform Select Committee<sup>14</sup> should be given a greatly expanded role. The select committee, currently chaired by Stephen McPartland MP, has completed many important inquiries. However, under its current terms of reference and resource allocation, the committee would be unable to undertake the amount of scrutiny required to hold departments and regulators fully

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<sup>14</sup> [Regulatory Reform Select Committee](#), House of Commons whose remit includes scrutinising Legislative Reform Orders (LROs). LROs are a specific type of delegated legislation that the Government can use to remove or reduce burdens that result directly or indirectly from legislation, or to promote principles of better regulation. They are made under terms set out in the [Legislative and Regulatory Reform Act 2006](#) and are subject to scrutiny in each House.

accountable for the changes needed to enable the UK to become world leader in innovation.

92. An expanded role for the committee would enable scrutiny to ensure departments and sectoral regulators are maximising opportunities to create and maintain world leading regulatory frameworks, rather than choosing the path of least resistance and retaining alignment with EU laws that were not designed with the UK in mind and do not serve our ambition.
93. An expanded remit, and increased resources will also allow the committee a role to keep under review the supervisory practices of the sectoral regulators, which, some stakeholders have commented, can have a chilling effect on innovation, as regulators do not always make it clear whether an innovative practice would be within their rules.
94. Select committees in the Commons and the Lords have a variety of responsibilities, powers and remits, and while some models are more common than others, there is no 'one size fits all', particularly for cross-cutting committees, as opposed to departmental committees. Therefore amending the terms of reference for the Regulatory Reform Committee, known as Standing Orders,<sup>15</sup> would not make the Committee an outlier, it would merely update its remit to ensure that it was able to complete all the scrutiny required in a post-EU environment where the UK has control of its laws.

#### **Regulatory Reform Select Committee**

The current role of the Committee is to examine and report on:

- Draft Legislative Reform Orders (LROs), laid before the House under the Legislative and Regulatory Reform Act 2006;
- Matters arising from consideration of such LROs; and
- Matters relating to regulatory reform.



The Work of the Committee is mirrored in the House of Lords by the Delegated Powers and Regulatory Reform Committee. The full list of Regulatory Reform Committee's powers can be found under SO No. 141 and 142.

95. We suggest that the remit of the Regulatory Reform Committee is expanded to enable the committee to potentially scrutinise any regulatory reform proposal across government, including a requirement that the relevant Minister provide an Explanatory Memorandum<sup>16</sup> (EM) on the proposal for the committee to assess. This proposal would give the committee a similar remit across regulatory reform that the European Scrutiny Committee had on EU matters, and could include a similar power to recommend certain EMs on regulatory reform for debate. This would require a straightforward change to the committee's Standing Orders.

<sup>15</sup> Standing Order [141](#) and [142](#) set out how the Regulatory Reform Committee conducts its business.

<sup>16</sup> [EU financial support for regions and sectors affected by the UK's withdrawal: the Brexit Adjustment Reserve](#), Explanatory memorandum provided to the European Scrutiny Committee, Thirty-fourth Report of Session 2019–21, European Scrutiny Committee, published 26 January 2021.

96. The committee should also be supported by an independent and well-resourced organisation such as the National Audit Office (NAO). A model to use here could be the relationship between the Public Accounts Committee and the NAO, which has been very successful in scrutinising how public money is spent. We are not proposing a new quango, but there is a need for an organisation, whether the NAO or another body, bolstered by experts in the regulatory areas it scrutinises with the capacity to do its own independent assessments of the economic and wider regulatory impacts of proposals. The independent Regulatory Policy Committee<sup>17</sup> (RPC) already has a role in assessing regulatory proposals put forward by the Government, and provides advice in the form of opinions. However, given its present mandate the RPC would not be able to work closely with parliamentary committees in the way the NAO does with the Public Accounts Committee.
97. In addition, the Regulatory Reform Committee's remit could be expanded to include the scrutiny of cross-sectoral regulators. Currently these are part of the relevant departmental select committee's remit. While we do not propose that departmental committees should bring to an end their scrutiny of sectoral regulators, in practice most committees, with the possible exception of the Treasury Committee, do not have the resources to scrutinise in-depth the strategic direction of regulators, nor their supervisory practices.
98. It is imperative that Parliament is able to ensure that sectoral regulators are properly promoting innovation and competition in line with UK aims, instead of continuing to align with EU-designed laws that may not be appropriate for domestic circumstances. Expanding the remit of the Regulatory Reform Select Committee would enable Parliament to work closely with regulators and departmental select committees to ensure that proposals for regulation are rigorously scrutinised before they are enacted.
99. In order adequately to scrutinise regulatory reform under such an expanded remit the committee would require additional staff resources. There are several good models for how an expanded staff resource team could work but we propose that a staffing model similar to the Commons Treasury Select Committee would work well.

#### **Treasury Select Committee**

The staff team at the Treasury Committee is considerably larger than other select committees. In addition to its Clerk-led team, which is broadly the same as other Select Committees, Treasury Committee also has a number of subject experts, seconded to the Committee.



These experts are often seconded from organisations that fall under the Treasury's scrutiny remit, including; the Bank of England, The Financial Conduct Authority, The Prudential Regulation Authority, HM Revenue and Customs and the National Audit Office, for a period of six months to two years.

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<sup>17</sup> [Terms of reference](#), Regulatory Policy Committee.

100. While other select committees also have access to experts, including special advisers, and experts seconded from departments or other organisations, the Treasury Committee has access to far more subject matter expertise than other select committees.

101. Adopting a model based on the Treasury Select Committee would have a significant impact on Parliament's ability to scrutinise regulatory reform, and ensure departments were not relying on outdated EU frameworks. It would not require a change to Standing Orders, although the House of Commons Commission would need to agree to allow the Committee greater budget freedom to increase its ability to second subject matter experts to its staff team for a period of time.

102. The House of Lords also has a committee which scrutinises regulatory reform proposals, the Delegated Powers and Regulatory Reform Committee.<sup>18</sup> However, it would be for the Lords to decide if they wanted to expand the remit of the Delegated Powers and Regulatory Reform Committee to scrutinise wider regulatory reform proposals.

## **Enabling accountability: assessing innovation and regulation**

**Proposal 1.10: Include consideration of the wider effects of proposed policies in Regulatory Impact Assessments, including on innovation, competition, the environment, and trade.**

**Proposal 1.11: Establish a framework for regulators to report publicly on how they have promoted competition and innovation in the markets they regulate.**

**Proposal 1.12: Produce a simple annual innovation scorecard to assess departments and regulators on the markets they are responsible for.**

103. For accountability and scrutiny to work departments and regulators need to create and provide appropriate assessments of proposed policies in advance. A framework is also needed to assess their performance in retrospect.

104. The Government should establish a system for regulators to report publicly on steps they have taken to promote competition and innovation. The heads of regulators should make themselves available to the Regulatory Reform Committee to answer questions on the approach set out in these reports.

105. As part of this framework each regulator should be required to report on any regulatory and policy decisions where it perceived a tension between its objectives to promote competition and innovation and its other statutory objectives. It should say how it resolved this tension in each case and give its rationale so that Parliament can scrutinise whether regulators are giving these objectives sufficient weight.

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<sup>18</sup> [Delegated Powers and Regulatory Reform Committee](#), House of Lords.



106. Policymakers can also improve the quality of their regulatory processes. Under the OECD Regulatory Toolkit and Competition Assessment, governments should regulate in ways that are the least damaging to competition consistent with a publicly stated, legitimate regulatory goal. Policymakers should try to measure the effect of anti-competitive market distortions regulation causes and avoid or mitigate them as far as possible.
107. For regulators to understand what effects their regulation is producing, and to enable proper scrutiny of proposals, all Regulatory Impact Assessments (IAs) should include consideration of the wider effects of proposed policies where possible. This should include the effects of policies on innovation, competition, the environment and trade. The Government should work with the Regulatory Policy Committee<sup>19</sup> to produce clear guidance and IA templates to facilitate this.
108. The Government should produce a simple innovation scorecard that rates government departments on regulators on how innovative they have been and how they have contributed to innovation in regulation and markets they are responsible for.
109. There is a great deal of data on inputs to innovation and innovation activities, but much less on outputs and effects. Over time better data and metrics could be developed on the cost savings, economic benefits and productivity increases resulting from innovation, as well as the rate and geographic spread of the adoption of new technologies in the UK to make these scorecards as informative as possible.

## Making it happen

**Proposal 1.13: Embed our recommendations in the UK Innovation Strategy, use non-legislative and existing regulatory powers where possible and make use of targeted primary legislation.**

110. If we are to seize the opportunities provided by regaining control over how we regulate, there needs to be a clear plan of action that provides a roadmap for changes.
111. In its plan for growth, the Government indicated that it would publish an innovation strategy in the summer of 2021. Our proposals to give regulators statutory competition and innovation objectives, to establish a framework to report against these objectives and to create innovation scorecards to assess departments should form part of that strategy.
112. As this report sets out there are a number of regulatory reforms that can be made to unlock growth and innovation in the UK, and provide a more efficient and competitive regulatory environment. Where possible we have focussed on proposals that will not

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<sup>19</sup> The RPC is a committee of independent experts from a range of backgrounds that assesses, advises on, and scrutinises the quality of evidence and analysis used to inform regulatory proposals.



require new primary legislation, though some proposals would do. A constraint in taking this forward is parliamentary time. Given the impact of the COVID-19 pandemic, we are aware that there is likely to be pressure on the legislative programme for the remainder of the Parliament.

113. Given these constraints, if the Government wishes to fully realise the potential gains offered by regulatory freedom it must consider innovative approaches to delivering change. The Taskforce favours a three-pronged approach, which involves:

- a. Maximising non-legislative options for change, including using existing headroom to undertake pilot activity, and greater use of guidance to indicate policy intent and the direction of travel in certain areas;
- b. Using existing powers, including making changes via secondary legislation where possible. In particular, the Government should consider making greater use of Legislative Reform Orders (LROs). These can repeal and replace, amend or restate legislation which is imposing burdens on any person, including a business, an individual, a voluntary organisation, or a charity. As the definition of a burden includes financial cost, administrative inconvenience, and an obstacle to efficiency, productivity or profitability, the Government may be able to amend regulation in some areas without the need for primary legislation;
- c. Targeted primary legislation that devolves powers to the regulators and, where appropriate, to Secretaries of State, to set the strategic direction in their areas.

114. There are likely to be concerns about delegating further powers and discretion to regulators, particularly from the House of Lords. However, we believe the Government can make the case that these proposals, including enhanced parliamentary scrutiny of regulatory reform and regulators, would actually increase certainty, by making the legal framework around who has the power to make decisions in each sector much clearer than it was when we were part of the European Union.

115. There may also be concerns about the impact that devolving further powers to regulators could have on business. As detailed elsewhere in this report, we advise that any delegation of powers be accompanied by a strong government and parliamentary oversight function to ensure that:

- a. New regulation is only introduced where there is either a clear and pressing need, or when regulation is needed to set a framework to unlock an emerging or nascent sector;
- b. Regulatory proposals are accompanied by a statement setting out the cost and innovation benefits;
- c. Departments and regulators can be held to account for the amount of regulation they are proposing;

- d. Parliament and government are in a position to promptly require explanations from regulators if any proposals or decisions appear to be beyond their remit; and,
  - e. The Proportionality Principle is evidenced in the approach taken by regulators, including through annual reports and metrics.
116. The EU (Withdrawal) Act 2018 severely restricted the ability of the lower courts to depart from EU case law relating to unmodified retained EU law, even if there is a good reason to do so. Government could make the necessary changes to retained EU law to give the UK courts more freedom to make judgements that are in the best interests of UK business. When the Government modifies the substance of a piece of retained EU law, it allows the lower courts more freedom to make judgements, and case law, on it that depart from EU precedent. This is because the provision of the Withdrawal Act that restricts the ability of the lower courts to depart from EU case law only applies if that law has not been modified in substance.

## Exporting our approach: the UK as a standard setter

**Proposal 1.14: Set a UK standards strategy to promote the use of British standards internationally as a way to boost UK influence and promote trade and exports.**

### *Standards to boost innovation*

117. UK leadership in the setting of standards is a key tool in our global competitiveness: history shows that leadership in the setting of standards can play an important role in establishing international leadership. An example is the UK's leadership in maritime law and maritime insurance which has left us as the global headquarters of maritime law long after we ceased to be a major shipbuilding nation.
118. The existence of a clear regulatory framework for a new sector is often a key precondition for investment: as we show in the report, a lack of clarity and regulatory risk is holding back investment in areas like space, digital health, 'mobility as a service' and autonomous vehicles.
119. Standards define best practice in many different areas. In this report, we use the term in the sense of agreed ways of doing something, written down as a set of criteria so they can be used as rules, guidelines or definitions. Some are set out in law but many are industry led.
120. The UK has been a world leader in standard setting for over 100 years, with the British Standards Institute (BSI), formed in 1901, the world's first national standards body. The BSI Kitemark, first registered in 1903, has grown into one of the world's most recognised consumer quality marks, and the longest running kitemark has been in place since 1945. Many of these standards, first developed in the UK, are now recognised at the international level.

121. Independent research carried out by the Centre for Economics and Business Research (Cebr) for BSI in 2015 analysed the contribution of standards to the UK economy, drawing on data going back to 1921. The report suggested that standards contributed towards 28.4% of annual UK GDP growth (£8.2bn at the time of the study), and supported up to 37.4% of productivity growth, and an additional £6.1bn of additional annual UK exports.<sup>20</sup>
122. British Standards are seen as an off-the-shelf solution to many productivity challenges faced by companies of all sizes, from SMEs to large national and multinational corporations in all sectors. They are a tool that can be used to influence the operation of companies and organisations and are seen by leading enterprises as a strategic tool for business performance improvement.
123. In the case of productivity, improvement is achieved through the implementation of better practices to support staff, production capacity, supply chain resilience and product quality to meet customer demand. Standards support the removal of trade barriers within and between markets and are vital to UK national interests. Standards form an important aspect of the UK internal market and support the minimisation of technical barriers to trade across the world.
124. In the case of innovation, standards are seen as an essential tool, alongside intellectual property. This work often starts with developing a strategy to involve stakeholders, which permits the development of a suitable standards landscape. Opportunities that the UK has to lead world standards of the future include:
- a. **Batteries**, where the BSI is leading the standards programme to respond to the UK Government's Faraday Battery Challenge with three standards relating to safe and environmentally conscious design, the use of batteries in battery electric vehicles, and environmentally friendly handling of battery packs and modules.
  - b. **Connected and autonomous vehicles**, with three standards relating to control systems for automated vehicles, assuring safety for autonomous vehicle trials and testing, and operational design domain for an automated driving system.
  - c. **Responsible innovation**, a broad and general standard to promote responsible innovation, particularly in areas that may not yet be regulated.
  - d. **Digital manufacturing**, working with the High Value Manufacturing Catapult (HVMC) on four fast-track publicly available specification standards covering aspects such as readiness to adopt digital technologies, trustworthiness and data of networked sensors, through-life engineering services, and guarding against cyber threats.
  - e. **Hydrogen energy**, a "roadmap" in line with the UK's Net Zero 2050 policy objectives.

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<sup>20</sup> [The Economic Contribution Of Standards to the UK Economy](#), CEBR for British Standards Institute, June 2015.

- f. **Artificial intelligence**, the Government announced in March 2021 that it is developing a National AI Strategy<sup>21</sup>, including a new plan to make the UK a global centre for the development, commercialisation and adoption of responsible AI. The strategy will be published later this year and is a chance for the UK to set clear principles for the development of responsible and innovative AI standards.

125. Precise and effective standards are vital for both business and consumers, as they set a clear framework that enables healthy competition, and safeguards consumer choice. It is therefore essential that the UK, now free from the constraints of EU law, ensures that it is engaging both in regulatory diplomacy at an international level. It should also be open to adopting innovative approaches to standard setting, as showcased by entrepreneurial countries including Singapore and South Korea. Interoperability is also an important part of standard setting.

### *Promoting UK standards through international trade*

126. Our approach to regulation has an impact on our trade relationships. A regulatory system which minimises competitive distortions makes it more likely that we will be able to continue to secure new trade agreements and the major economic opportunities which they provide. Leaving the EU's regulatory frameworks creates a unique opportunity for the UK Government to promote high standards via our global trade policy. For example, now that we control our tariffs on food imports, the UK could use variable tariffs to promote crucial animal welfare and environmental goals and to help farmers in the developing world. This approach will also provide opportunities for the UK to promote the transfer of UK technology to developing countries, to help them meet higher standards of production set by the UK.

127. UK regulators should work with international counterparts to promote British standards, and increase cooperation in innovative areas such as AI, cybersecurity, agri-tech and fintech and to improve market access for cross-border service providers.

128. The UK should use its position in key international bodies to try to agree a common set of global principles to shape the norms and standards that will guide the development of emerging technology.

129. The Government's regulatory strategy should provide a roadmap, setting out the UK's areas of focus and how it wants to champion these areas internationally.

130. With the right strategy the UK can use its reputation to take on a leadership role in tackling global challenges, combining its expertise in areas such as science or finance with its reserve of political and diplomatic skill. The UK showed this capability, for example, in successfully putting the need for action on antimicrobial resistance (AMR) on the global agenda.

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<sup>21</sup> [New strategy to unleash the transformative power of Artificial Intelligence](#), Department for Culture, Media and Sport, March 2021.

### **Case Study: UK leadership on anti-microbial resistance**

Antimicrobial resistance (AMR) arises when the organisms that cause infection evolve ways to survive treatments developed to kill them. In the absence of appropriate action 10 million people per year could die worldwide by 2050, with a cumulative impact on the global economy of \$100 trillion.

The UK has been at the forefront of international efforts to tackle AMR through the World Health Organisation (WHO), Food and Agricultural Organisation, World Organisation for Animal health, and in the G7, G20. It was instrumental in developing the content of the WHO-led Global Action Plan on AMR in 2015, at the forefront of lobbying for the pivotal 2016 UN high-level meeting, leading to a declaration endorsing the Global Action Plan, the alignment of action on AMR with the 2030 sustainable development goals and clear commitments by all signatories to ensure adequate action is taken to mitigate the threat.

Much of this effort was led by Professor Dame Sally Davies, former Chief Medical Officer for England, and now UK Special Envoy on AMR, who sat as co-convenor on the UN Inter-Agency Coordination Group, which gave its recommendations to the UN Secretary General in April 2019.

# SECTOR PROPOSALS

## Financial services and investment reform

**Headline Proposal 2: Reform regulations limiting UK pension and insurance funds to enable greater investment in UK domestic growth.**

131. Delivering on the Government's levelling up and Net Zero agendas, and building back better from the pandemic, will require substantial private sector investment. Institutional investors, including pension funds and insurance firms, are already playing a role but current regulation is holding back transformative investment. In particular, companies across the country are faced with a long-standing lack of sufficient growth capital, especially in areas outside of London and the south east.<sup>22</sup>
132. Outside the EU and with control over our financial regulation for the first time in fifty years, we have a unique opportunity to reform the rules. With sensible changes to pensions and insurance regulation that preserve the highest standards of consumer protection and uphold financial stability, the Government could unlock over £100bn of investment in small and scaling-up businesses across the UK, green projects, infrastructure and a range of other areas.<sup>23</sup> Whilst HM Treasury is leading work on these issues,<sup>24</sup> there is a sense of confusion as to which departments, for example DWP or the Treasury, are responsible for driving this forward. We must ensure these transformative reforms are not missed through slow delivery or a lack of ambition.

**Proposal 2.1: Enable Defined Contribution (DC) pensions schemes to diversify their investments into venture capital and businesses that drive Net Zero and levelling up commitments.**

133. Sensible reform of DC pension scheme regulation could allow the Government to address the double challenge of unlocking investment in growth companies across the UK and secure better returns for UK pensioners in one intervention.
134. The UK's total pension market value reached £2.2 trillion at the end of 2019, of which DC schemes made up £146 billion thanks to the introduction of auto-enrolment.<sup>25</sup> In 2028 the UK's DC pension pot is expected to reach £1 trillion,<sup>26</sup> if the UK is able to unlock just 5% of this figure by then, that is a staggering £50 billion in additional

<sup>22</sup> This challenge is often labeled the 'Patient Capital Gap'. The Government has been considering this issue for some time, starting in earnest with the [Patient Capital Review](#) in 2016.

<sup>23</sup> The Association of British Insurers (ABI) estimates that the measures outlined in paragraphs 146-50 could unlock £95bn. If 5% of the current DC pension vault was invested in these sorts of illiquid assets, as the BVCA has recommended (see paragraph 139), this would unlock £7.3bn immediately, with further potential investment as DC pensions schemes grow.

<sup>24</sup> [Chancellor statement to the House on Financial Services](#), November 2020.

<sup>25</sup> [UK pension surveys: redevelopment and 2019 results](#), Office for National Statistics.

<sup>26</sup> Oliver Wyman analysis. See also: Oliver Wyman, The retirement franchise opportunity report, 2018



investment. The charge cap (0.75%) on the fees and administrative expenses that can be borne by savers is a sensible investor protection measure in principle, but in practice has driven many schemes towards passive investment to keep the charges well within the cap. UK savers therefore have limited exposure to high-performing 'illiquid' assets, including private equity and venture capital that tend to outperform public markets.

#### Key statistics:

Retirement savings could be increased by 7-12% for a 22-year old if their DC pension scheme made 5% of investments in the UK's fastest growing and most innovative companies. (British Business Bank and Oliver Wyman, 2019)

UK private equity and venture capital have delivered five- and ten-year annual returns of 20.1% and 14.2% respectively (net of all fees and carried interest), compared to the FTSE All-Share, which returned 7.5% and 8.1% over the same period. (Annual BVCA Performance Measurement Survey, 2020)

135. The largest obstacle for DC schemes accessing private equity and venture capital (PE/VC) funds is the calculation method for the 0.75% charge cap. This currently treats profit-sharing models such as carried interest as a performance fee and includes them in the cap (unlike other countries such as Israel). Whilst we understand the rationale for the cap, it is also a key barrier. It does not accommodate long-term incentive models such as carried interest that benefit both investors' returns and the growth trajectory of the companies the industry invests in.

136. The Government has already identified a single, smart solution that would address both of these challenges through Long Term Asset Funds (LTAFs). We are also aware that in March, DWP published draft new rules, due to come into force in October, to calculate performance fees on a rolling average basis over five years,<sup>27</sup> but further change is needed.

137. We recommend that the Government looks at these alternatives:

- a. **Investment Allowance:** Exclude carried interest from the free charge cap through an 'Investment Allowance' whenever a DC scheme invested in an investment fund which met — and the investments of which met — certain specific and predetermined criteria, such as levelling up.
- b. **Charge Cap Fee:** Reviewing and re-adjusting the UK's charge cap fee by looking at introducing calculation performance fees over a multi-year rolling period. The UK should also consider giving DC trustees appropriate protection against any liability for any inadvertent breaches caused by performance fees or carried interest (accrued or paid). This could take the form of an ability to explain or cure any such breaches within a reasonable timeframe (12-18 months, as exists in the Israeli system). Any exclusion of liability should be subject to appropriate conditions, relating, for example, to

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<sup>27</sup> DWP, '[Incorporating performance fees within the charge cap](#)', March 2021.

excess returns, or the proportions in which any profit share is allocated (for private equity funds this is typically 20:80 in favour of investors).

138. Safeguarding consumers' pensions should rightly remain the Government's priority in this space. There is always a risk that funds could perform poorly and concerns that trustees will end up out of pocket in order to pay management fees. However, carried interest payments<sup>28</sup> are contingent on the fund generating value and making a realised overall profit on investments. This is only ever paid out of capital proceeds realised by the fund. Therefore, no investor money is used to pay carried interest and it is never paid out if a fund fails to make a profit. In addition to this, as the fee cap is 75bps, we would not expect a DC portfolio to have a large or significant allocation to PE/VC that would cause it to breach the cap.

139. Should effective changes be made to the charge cap calculation and investment allowance, our expectation is that larger firms and those managing funds of funds, in particular, will seek to offer illiquid assets to DC schemes. These firms are typically more likely already to have the platform expertise and operational ability to help DC schemes clear the regulatory and operational hurdles that exist. Protections for trustees would also help eliminate any liability for DC schemes that breach the charge cap because their investments have performed too well, and could provide further comfort that investing in the more successful PE/VC funds would not have negative consequences for DC trustees.

140. This proposal would require legislative changes to the Occupational Pension Schemes (Investment and Disclosure) (Amendment) Regulations 2019.

### Proposal 2.2: Amend matching adjustment and risk margins in Solvency II to release significant capital for investment in the UK.

141. Solvency II is probably one of the world's most restrictive prudential regimes. Parts of the regulation do not suit the UK's insurance sector, are a block to investment and have reduced competitiveness. The number of retail annuity providers on the open market in the UK has declined since the Solvency II implementation period from 13 prior to 2014 to just 5 today.<sup>29</sup> A targeted recalibration of these regulations could free up £95bn to invest in the UK economy, while upholding high levels of protection for customers and financial stability.<sup>30</sup>

142. Although the Treasury is looking at this through a review, it needs addressing now. We recommend that the following three changes be made without delay to deliver this transformative change now:

- a. **Reduce Risk Margins by 75%:** The risk margin is an additional buffer insurers are required to hold on top of their liabilities to pay claims. The Prudential Regulation Authority (PRA) and the industry agree that the current

<sup>28</sup> Carried interest is a share of any profits that the general partners of private equity and hedge funds receive as compensation.

<sup>29</sup> Association of British Insurers (ABI) analysis, provided in a submission to the Taskforce.

<sup>30</sup> ABI and KPMG analysis, provided in a submission to the Taskforce.

Risk Margin is excessive in size and too sensitive to interest rates. KPMG analysis commissioned by the ABI shows that a 75% reduction would release roughly £35bn of capital that could be used to support the post-COVID-19 economic recovery and investments in productive long-term assets in the UK without a material impact on policy holder protection.<sup>31</sup>

**b. Refine Matching Adjustments to broaden access to long-term assets:**

The Matching Adjustment is an important mechanism that smooths out day-to-day fluctuations in market prices for assets held over the long-term and estimates future liabilities. The current framework skews investment towards non-green assets – for example, it is currently much easier to invest in a corporate bond from a mining company, than to make a 30-year investment in a wind farm. KPMG analysis indicates that this measure could help £60bn of funds already held in Matching Adjustment portfolios to be re-invested in productive long-term assets to help with the economic recovery and the green transition.<sup>32</sup>

**c. Simplify and streamline reporting and approvals to increase transparency:** Solvency II increased the volume of regulatory reporting required of industry by between 4 and 8 times.<sup>33</sup> There is a need to reduce duplication, cost and delay in regulatory engagement, liberate more management time to focus on key issues, ensure proper market efficiency, and boost the international competitiveness of UK insurers.

143. These proposals would also continue to uphold high levels of consumer protection and insurers would still be required to hold sufficient capital to survive a one in 200 year stress event. There are many refinements that should be considered for Solvency II, but the three above provide the quickest wins.

144. These reforms would optimise allocation of capital removing upwards pressure on the price charged to policyholders, increasing product choice for consumers and, at a time when others in Europe seek to compete with the UK, such a change will help make us a more attractive and competitive market. This could provide an extra £1.4bn in tax annually by 2030 as a result of the economic growth from these changes<sup>34</sup>.

145. Should the Government agree with the proposed changes set out here, then primary legislation will be required to amend the three levels of laws that were used to implement the Directive (Financial Services and Markets Act 2000 (FSMA), SIs under FSMA 2000 and rules implemented by the Prudential Regulation Authority).

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<sup>31</sup> Ibid.

<sup>32</sup> Ibid.

<sup>33</sup> Ibid.

<sup>34</sup> Ibid.

## *Attracting private investment to support local infrastructure*

### **Proposal 2.3: Attract private investment to help regenerate local infrastructure and support the UK's levelling up agenda.**

146. The proposals suggested for DC pensions funds and Solvency II focus on unlocking existing capital, however this is just one piece of the puzzle. The other half is looking at what mechanisms need to be put in place to help create new investment opportunities in UK infrastructure and regeneration.
147. The Government has put the modernisation of the UK's ageing infrastructure at the heart of its agenda. In order for this to be successful, infrastructure projects will need to attract billions in investments to drive them forward. We urge the Government to look at establishing a simple mechanism for public, pension and private investment to promote co-investment in local regeneration vehicles to help promote the UK's levelling up agenda.
148. There are many ways to promote infrastructure investment, but we recommend considering the following in the first instance:
- a. Introduce regulations that encourage and enable local authorities to invest their pension funds in their own local economic regeneration.
  - b. Consider creating a new generation of Local Regeneration Corporations with the powers of compulsory purchase of public sector land, Land Value Capture Gain, tax increment funding and raising of asset backed private investment to fund local infrastructure.

### **Headline Proposal 3: Amend the Seed Enterprise Investment Scheme (SEIS) and the Enterprise Investment Scheme (EIS) to maximise Private Equity and Venture Capital investment in growth industries.**

149. The Enterprise Investment Scheme (EIS) and the Seed Enterprise Investment Scheme (SEIS) have incentivised significant investment in early stage companies. 31,365 firms have received £22 billion of investment through the EIS to date, and the SEIS has generated over £1 billion.<sup>35</sup> However, the current rules disproportionately favour companies in London and the south east. The Government has the opportunity to strengthen these schemes to further increase early stage firms' access to capital, in conjunction with the investment proposals above.

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<sup>35</sup> HMRC, '[Enterprise Investment Scheme, Seed Enterprise Investment Scheme and Social Investment Tax Relief](#)', May 2020.

**Proposal 3.1: Amend the age eligibility requirements for companies to access investment through EIS and SEIS to ensure businesses outside London and the south east benefit equally.**

150. There are maximum age limits for both SEIS and EIS,<sup>36</sup> which are exaggerating regional disparities in access to capital for early stage and growth firms in the rest of the UK compared to London and the south east. This is because companies outside Greater London tend to take longer to grow to a size at which VC will invest. Data from the British Venture Capital Trust Association (BVCTA) shows that business in Greater London appear to:

- a. Receive subsequent investments sooner with the average age of business being 6.01 years vs. 9.01 years for Rest of UK;
- b. Receive more funding rounds: 2.0 vs. 1.8 rounds for Rest of UK;
- c. Receive larger total amounts of investment £3.70m vs. £2.85m for Rest of UK.<sup>37</sup>

151. Data since 2015 shows this gap is widening, with Greater London increasing its share of total investment from 50.7% at initial Investment to 54.5% including follow-ons.<sup>38</sup> In 2019 the Department for Business, Energy and Industrial Strategy identified a range of factors contributing to this trend, including:

- a. Supply side factors (e.g. London having more VC funds, international investors and angels investors) and importantly;
- b. Demand side factors (e.g. lower proportion of family company ownership in London, greater experience of taking investment, available talent pools etc).<sup>39</sup>

152. It is therefore crucial that we look to adjust SEIS and EIS to allow a more equal distribution of investment to all regions in the UK if these schemes are to continue to deliver much needed investment for growth companies across the UK.

153. Currently, 80%<sup>40</sup> of all investment made was into businesses where the age of a business was less than 7 years old (or less than 10 years old for Knowledge Intensive Companies), so under the current legislation 20% of businesses need to rely on an additional eligibility to access VCT funding. It's also worth noting that there is a wide disparity between regions with some regions of the UK; such as east of England, south west and Scotland where just 27% to 58% of businesses that received investment qualified under the age limits.

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<sup>36</sup> To issue SEIS qualifying shares a company must have commenced its trade less than two years previously and it (or its 51% qualifying subsidiary) must not have carried on another trade. EIS qualifying shares must be issued within seven years of the first commercial sale or, if the company is a knowledge-intensive company, ten years from the date of first commercial sale or, if the company chooses, the date from which the annual turnover of the company exceeds £200k.

<sup>37</sup> VCTA Regional Data Analysis study (2020).

<sup>38</sup> Ibid.

<sup>39</sup> Ibid.

<sup>40</sup> Ibid.

### **Proposal 3.2: Increase the maximum level of SEIS investment.**

154. On average the majority of start-up companies are seeking investment in excess of £150,000 in their first investment round.<sup>41</sup> Under current regulation, investors need to seek the first £150,000 from SEIS and the remaining sum from EIS or elsewhere. The effect of this, to be compliant with the SEIS rules, is that the investment must be tranced over two days. This added complexity requires more detailed and correspondingly expensive investment agreements to be drawn up, as a result of which many investments have failed to materialise.

155. This change will need to be designed and delivered carefully. It is crucial that its effect is not to push yet more investment towards London and the south east. The Government should explore, for example, whether increasing the maximum investment for regions that currently receive less capital could help.

### **Proposal 3.3: Commit to the continuation of EIS beyond 2025.**

156. Investment in innovation is critically important. Banks simply will not lend to most early stage businesses, so these businesses need to turn to investors to get going and fund their expansion.

157. The EIS scheme is a significant job creator, and for many firms, their only option for investment. When the 10-year scheme limit was enacted, much consternation was expressed. We are now over half way through that window and investors need assurances that the scheme will continue, so that investment and job creation does not dry up.

### **Headline Proposal 4: Restore a common law principles based approach to financial services regulation.**

158. UK law is based on common law and Scots law. As a result, our legal reasoning is cautious, iterative and pragmatic, placing its reliance on independent judges. No single group is treated as omniscient and Parliament is responsible for bolstering the law on specific policy matters. By contrast, EU law seeks to impose grand, codified schemes. Those framing the law seek to find answers in advance of every problem. The system operates to exert control over individual and business activity, ensuring it serves interests that are centrally determined.<sup>42</sup>

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<sup>41</sup> VCTA Regional Data Analysis study (2020).

<sup>42</sup> For a fuller discussion see Barnabas Reynolds, '[Restoring UK Law: Freeing the UK's Global Financial Market](#)', February 2020.



159. As a result of this philosophy, the UK regulatory system as it applies to financial services has become too rigid and far too detailed. The EU codified system of rulemaking has been applied to financial infrastructure, such as exchanges and central counterparties (CCPs, or clearing houses), on a one size fits all basis, with highly prescriptive rules which are stifling business. The UK should move away from this approach, and HMT's Financial Services Framework Review is a welcome start.<sup>43</sup> We provide two examples of the specific changes that could be made under this approach.

**Proposal 4.1: Amend inherited MiFID II Position Limits to introduce greater flexibility while preserving protections on critical contracts.**

160. The aim of setting position limits in the commodity derivatives market to prevent market abuse and excessive speculation is valid. However, the rules set out in the second Markets in Financial Instruments Directive (MiFID II) for particular contracts are overly precise and inflexible. Without reform, the UK will remain at a competitive disadvantage compared to other global financial centres in attracting new commodities markets. Intercontinental Exchange, for example, moved 246 nascent but fast growing commodity markets to the US in February 2018 following the launch of MiFID II position limits. Since then, developing new markets in the UK and EU has been a challenge compared to other financial centres.

161. Position limits set the largest position that a firm may have in a particular contract that is traded on an exchange. Prior to the introduction of MiFID II, the management of position limits was left to the exchanges to address within principles and market abuse rules, which included restrictions on single players cornering a market.

162. The concern behind these rules is that no one market participant should build up too large a position such that they would be in a position to "squeeze" the market, and that traded positions should not exceed the size of physical commodity available for delivery at the point at which delivery obligations materialise. However, the rigidity in position limits has had two effects. First, for large and liquid markets the risk identified above is better mitigated by the more granular and tailored position monitoring and management activities already undertaken by exchanges. The MiFID II position limits simply add a further layer of cost and complexity to the market without in any way increasing protections. Where similar products are available on alternative exchanges, in the US for example, this additional layer of complexity makes it more attractive to trade elsewhere.

163. Secondly, the limits stifle the development of new products for new and emerging markets, or the use of more illiquid contracts, which necessarily will tend to have a small number of market participants or trade sporadically. It is nearly impossible to launch or operate these in Europe, since the 25% hard limit on average positions means that an exchange would need multiple interested players and market makers to come together and trade consistently from the very start. If a new contract is traded only once, the two parties to the contract would each have 100% of the

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<sup>43</sup> HM Treasury, [Future Regulatory Framework \(FRF\) Review](#), October 2020.

position. The risk of going over 25% is only mitigated by an active marketplace with multiple participants, which does not always exist.

164. A more discretionary approach would be preferable, more along the lines of that of the common law US system, and based on the UK's traditional model and the UK's experience of managing these markets. The definition of "commodity derivatives" and the breadth of the contracts within the scope of this restriction should be reviewed to focus on the most critical contracts and clarify that limits do not apply to securitised contracts and to contracts with no physical underlying commodity. Government and the FCA should consider excluding contracts relating to liquidity provision and risk mitigation and explore an exemption from the requirement to aggregate group positions where the relevant group entities are not under common management. We know the Financial Conduct Authority (FCA) is supportive of this, as it has been since before the MiFID II rules came into effect.

**Proposal 4.2: Introduce a more discretionary and judgment-based approach to calculating Central Counterparty Clearing House (CCP) margins.**

165. There is an EU-inherited rule that CCPs must run a model for the calculation of margin, and obtain regulatory validation of any significant change to the model before adopting the revised model. Only if "duly justified" may the CCP's regulator, the Bank of England (and, within the EU as well as extraterritorially, the European Securities and Markets Authority (ESMA)), agree that the change can be adopted before validation. The rules are too mechanical in application and limit the opportunity for appropriate levels of innovation to be achieved in the UK.
166. This point is further compounded by the fact that the EU's rules for the holding of margin are highly prescriptive (with "margin period of risk" (MPOR), anti-procyclicality requirements and constraints on certain types of collateral (e.g. letters of credit) being examples of that). In the commodities markets, one-off events, such as the recent power crisis in Texas, show that a more discretionary and judgement-based approach is needed in some situations, when market pricing becomes unrealistic. Interactions by CCPs, who have their own regulatory functions, and the regulatory supervisors, need to be capable of being more highly nuanced.
167. In the recent Texas outage, automated margin requirements could have put some market participants into default, when human evaluation showed the event to be one-off, not systemic. Following the model blindly would have likely increased the systemic market impact. A model cannot deal with all of the uncertainties of unusual weather patterns or natural disasters, any more than Lloyd's of London has managed to standardise its approach to insuring such events.

**Headline Proposal 5: Deliver a regulatory framework that supports UK global leadership in FinTech and digitalisation of financial services infrastructure.**

168. Fintech is a term used to describe financial technology, an industry encompassing any kind of technology in financial services, from businesses to consumers. It describes any company that provides financial services through software or other technology and includes anything from mobile payment apps to cryptocurrency. Broadly, fintech describes any company using the internet, mobile devices, software technology or cloud services to perform or connect with financial services. Many fintech products are designed to connect consumers' finances with technology for ease of use, although the term is also applied to business-to-business technologies as well.

169. Fintech is often considered the crown jewel in the UK's world leading international financial sector, representing 10% of global market share<sup>44</sup> and £11bn in revenue<sup>45</sup>. It can drive efficiency across financial services, support financial inclusion, prevent fraud, improve operational resilience, and promote competition. Investment into UK fintech was £4.1bn in 2020, more than the next five European countries combined. If the UK is able to get this right, fintech can be a core driver of UK economic growth and prosperity for decades to come. It represents the future for innovation in financial services, and it is an area that is ever expanding. If the UK is to retain its position as a global leader in financial services, then we must lead this technological revolution.

170. The UK already leads the way globally in its policy and regulatory approach to fintech. As businesses, technologies and solutions scale, we need to ensure the policy and regulatory approach continues not only to protect consumers but also creates an enabling environment that encourages growth and competition.

**Proposal 5.1: Mandate the expansion of Open Banking to Open Finance quickly, and take a more market-led, Australian-style approach.**

171. Open Finance<sup>46</sup> is a natural evolution from Open Banking.<sup>47</sup> Financial data such as mortgages, savings, pensions, insurance and consumer credit, could be opened up to trusted third party APIs which would benefit the consumer by:

- a. Increased competition through greater access to a wider range of financial products/services;

<sup>44</sup> [KPMG Analysis: UK Fintech Focus 2020](#), written by Micheal Pearson founder of Clarus Investments

<sup>45</sup> [UK FinTech: Moving mountains and moving mainstream](#), Ernst & Young, commissioned by the City of London and Innovate Finance, September 2020.

<sup>46</sup> Open Finance refers to the extension of open banking-like data sharing to a wider range of financial products, such as savings, investments, pensions and insurance.

<sup>47</sup> Open Banking is a banking practice that provides third-party financial service providers open access to consumer banking, transaction, and other financial data from banks and non-bank financial institutions through the use of application programming interfaces (APIs).

- b. Greater control over financial data; and
- c. Smarter analytics, empowering better financial decisions.

172. Open Finance will allow the development of financial dashboards, bringing together customer data such as investments, savings and cash flow all in one place. By sharing financial data with trusted third parties, customers could be offered tailored products and services that represent a better deal and could open the door to automated switching, renewals and more accurate creditworthiness assessments. Open Banking has the potential to add £1 billion to the UK's GDP on an annual basis and Open Finance's potential is even greater.<sup>48</sup>

173. Currently, international competitors are drawing up plans that go well beyond the scope of the UK's existing Open Banking regime, with the ambition of superseding UK dominance. To avoid this, the UK should look to return to a principles-based, market-led approach to Open Finance. This would create a digital Big Bang in fintech and benefit consumers by increasing competition across all of the financial services sector.

174. The UK should look to return to a principles-based approach to regulation, rather than overly prescriptive technical standards. This could help unlock the benefits of Open Finance in as little as two years. It has been the approach taken by the Australian Government which has introduced arguably the most expansive open data regulatory initiative in the world. The Australian Consumer Data Right (CDR) will give consumers the right to access not only their financial data but also utility and telecom data by 2021, even though they started on their journey two years later than us.

175. The Kalifa Review<sup>49</sup> has recommended that the Government facilitate and mandate the sharing of data across various sectors, with Open Finance marked as a priority. However the FCA recently indicated that it would wait for BEIS to lay the enabling legislation for Open Finance (as well as wider Smart Data initiatives) to operate. The timeline for this is not concrete and looks set to take place in Q1 2022. This is far too slow. It would mean that Australia, which started out on its Open Banking journey three years after us, would have a more developed open data ecosystem than ourselves.

176. If the UK wants to retain its fintech crown, it is vital that BEIS brings forward its Smart Data legislation as soon as possible this year. At the very least, in the interim, the nine largest retail banks in the UK ('The CMA 9') should be compelled to open up data for their non-invested savings, credit and mortgage products through APIs. Data is already standardised and digital for these products, and many Payment Services Directives 2 mandated banks already offer this suite of products and services, so they can easily level up their offering.

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<sup>48</sup> [Analysis from The centre for Economic & Business Research \(Cebr\)](#)

<sup>49</sup> [Kalifa Review of UK Fintech](#), February 2021.

**Proposal 5.2: Increase competition in the banking sector by adopting a graduated regulatory approach for challenger banks.**

177. The challenger bank and building societies sector has been neglected in relation to other financial services regulation and legislation. The capital and liquidity requirements in the Capital Requirements Regulation II (CRR II), pose huge barriers to growth for smaller and new banks, preventing them from challenging incumbents. As a result, the UK has one of the most concentrated retail banking sectors in the world which has lowered market competition. Outside the EU, we can move away from the CRR II and implement a regime that encourages greater competition in the retail banking space.
178. The current regulations apply equally to all banks regardless of size. They are intended to create a “level playing field” between banks but the fixed costs of implementing the regulations have a greater impact on smaller banks as they incur higher regulatory costs in relation to their turnover.
179. The unintentional consequences of regulation were regulatory rules such as leverage ratios and minimum requirement for own funds (MREL) combined to disadvantage smaller players. The Internal Ratings Basis (IRB) weighting of capital helped to tip the balance in favour of larger established banks. It effectively means that larger banks had cheaper access to capital as their mortgage risk was calculated as being 15-16% lower than their smaller competitors. Research by the Prudential Regulation Authority (PRA) shows that these metrics are more effective for large firms than small ones, whereas supervision of their governance seems to be even more burdensome for small firms than for large ones.<sup>50</sup>
180. The EU’s approach to regulation has never been solely motivated by prudential considerations, but it is driven by the requirement to harmonise practice across the different countries within the EU, and by the difficulties of agreeing a definition of “small” which works for everyone given the widely varying sizes of national economies within the EU. By contrast, the US and Switzerland have been able to implement more proportionate regimes for new entrants, which has enabled them to have more competitive retail banking sectors.<sup>51</sup>
181. Although the CRRs were intended to ensure that banks hold enough capital to be able to stay solvent in the case of a financial crisis, they have done little to break the UK’s highly concentrated retail banking sector. The nine largest banks own over 90% of the retail banking market, which actually means that it is still vulnerable to shocks.<sup>52</sup>

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<sup>50</sup> [Strong and Simple](#) Speech given by Sam Woods, Deputy Governor for Prudential Regulation and Chief Executive Officer, Prudential Regulation Authority Mansion House, London Thursday 12 November 2020.

<sup>51</sup> COADEC Analysis 2021, provided in a submission to the Taskforce.

<sup>52</sup> BIS Analysis: [Evolution of the UK banking Industry](#) produced by Alex Bowen, Glenn Hoggarth and Darren Pain, Directors at the Bank for International Settlements.

182. The Bank of England and Prudential Regulation Authority should implement a graduated regime in which, as a bank grows, it can migrate through levels of regulation. The smallest bank should be subject to the simplest regulations which gradually increase with the largest banks aligning with the current inherited EU standards. The gradual stages of regulation would also avoid having a large jump in regulations which may encourage banks to limit their size in order to take advantage of simplified regulations. There are similar rules that other countries around the world, such as Australia and Canada, have introduced to make it easier to set up new institutions, such as mutuals and challenger banks.<sup>53</sup>

**Proposal 5.3: Reducing Anti-Money Laundering (AML) burdens for new Open Banking/Fintech services, which have been caught in the scope of the EU AML Directive.**

183. Open Banking services that provide huge benefits to consumers like Account Information Services (AIS) and Payment Initiation Services (PIS) have been caught in scope of AML legislation, even though the money laundering risks are so low they are virtually non-existent.

184. These services never come into possession of a customer's funds, yet are defined as a 'Financial Institution' in legislation when they are clearly not. Banks already perform AML/KYC checks on consumers so making AIS and PIS perform these checks is extremely duplicative. It forces fintech businesses to endure unnecessary regulatory costs, and makes the customer journey confusing. This is probably one of the reasons why consumers have not fully taken up open banking services.

185. Account Information Service Providers (AISPs) allow customers to view their bank account data across multiple banks in one place (to help budgeting and financial management), e.g. moneydashboard. AISPs aren't doing anything that could even remotely imply money laundering risk. Yet the implication is that fintech businesses providing this service have to conduct due diligence on their customers and conduct transaction monitoring. It's hugely duplicative because the customer of the AISP has obviously already done full due diligence with their bank provider, and will wonder why they're having to do it again just to add that bank account to an app. Other EU member states have already de-scoped AISPs from AML law, e.g. Denmark.<sup>54</sup>

186. A Payment Initiation Service Providers' (PISP) role is limited to placing an instruction for a payment with a bank on behalf of their customer. They have no control over executing transactions or moving money - which is the bank's role. PISPs never come into possession of funds. Yet as above, PISPs are currently subject to money laundering regulations.

187. This puts PISPs at a competitive disadvantage when competing as a payment method with cards. Whereas a customer using a card can move through an online check-out quickly (given the customer has done due diligence with the card issuer).

<sup>53</sup> COADEC Analysis 2021, provided in a submission to the Taskforce.

<sup>54</sup> [New guidance on AISP and PISP AML requirements in Denmark](#), November 2020.



The implication of PISPs being subject to AML regulations is that they would have to ask the customer for due diligence information at the checkout. Again, it is duplicative for a PISP to need to ask a customer to undergo due diligence before initiating a payment from their bank, when the customer will already have done due diligence with that very bank.

188. All 'Financial Institutions' are subject to the anti-money laundering requirements. But currently this definition includes AIS and PIS, which brought these services into the scope of AML, possibly without intent or at least without a thorough investigation of its unintended consequences. The UK's money laundering regulations should be amended to exclude AIS and PIS, and make clear that AIS and PIS are not classified as 'Financial Institutions' for the purposes of AML regulation.

**Proposal 5.4: Accelerate UK plans to develop a Central Bank Digital Currency (CBDC) and launch a pilot within 12 - 18 months.**

189. Interest in Central Bank Digital Currencies (CBDC) has skyrocketed in recent years following significant changes in the digital infrastructure of the payments industry, the launch of cryptocurrencies and the declining use of cash. A CBDC would be a new form of digital money issued by the Bank of England and for use by households and businesses which would exist alongside cash and bank deposits, rather than replacing them. All major central bank currencies, such as the Pound, Dollar and Euro, will eventually be digitised and the important thing is that it should be done on the UK's terms.
190. The platform used to operate a digital currency will provide a huge number of competitive advantages compared to the current, hybrid, and interconnected systems that form the backbone of global finance. The benefits of digital currency are clear: massive reduction of cost, instantaneous transactions reducing the need for cash holdings, high security and opportunities for real time regulation and supervision, significantly reducing risk in financial and other markets.
191. The introduction of CBDC could support the adoption of new technologies, such as blockchain. A wholesale CBDC could also include atomic settlement, leading to zero exposure risk, increased resilience, and less system downtime. A retail CBDC could provide individuals with access to central bank money in digital form and would create a more resilient, efficient and competitive payments system.
192. The design and introduction of a CBDC will not just raise monetary and financial stability questions; it will raise fundamental issues about how consumers and businesses would use a digital currency, as well as privacy and security concerns. It will require a coordinated effort from government to deliver and we therefore welcome the announcement of a Digital Currency Taskforce<sup>55</sup> and support their objectives. If the UK wishes to remain a fintech world leader and compete with

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<sup>55</sup> [Bank of England statement on Central Bank Digital Currency](#), Bank of England, April 2021.

international rivals, we recommend launching a CBDC pilot scheme within the next 12-18 months.

193. There are various models for retail CBDCs that the UK could look to adopt, but in our view, the UK should consider a hybrid model like the one proposed in the CityUnited Projects proposal<sup>56</sup> whereby the CBDC is a claim on the central bank, with intermediaries onboard to handle the retail payments. The involvement of payment services providers would allow for innovation and speed, which would allow the UK to be the first to introduce such a hybrid retail model. Interoperability between the CBDC and other forms of money is essential, if we hope to encourage widespread consumer adoption.

194. We strongly urge that this group moves at pace and puts delivery and regulation at the core of its priorities, given global competitors are moving at speed. China will launch a digital yuan (or renminbi) in 2022, and is already running limited pilots to study how this will work. Singapore is focussing on providing faster, cheaper cross-border payments and currency exchange. Germany has already conducted trials to introduce blockchain settlement between central banks and the EU announced recently its intention of taking forward a digital euro initiative. If the UK is able to move quickly and capitalize first mover advantage, then it will be able to take a global lead in ensuring that such digital currencies are rolled out in the most effective and safest way.

**Headline Proposal 6: Amend disclosure and transparency requirements for financial services products to make them more proportionate and less burdensome.**

195. Many aspects of the EU's transparency and disclosure regime for financial services is onerous. MiFID II is a prime example, which requires 65 data points for every transaction by both buyer and seller, and has increased the overall transaction data-gathering requirement on businesses by 270%.<sup>57</sup> MiFID II and a range of other EU directives, which the UK has retained, were designed for EU regulators capturing data on (as was) 28 different Member State markets. As HMT and the FCA have already recognised through ongoing work to reform the system, these requirements are disproportionate for the UK outside the EU and do not always deliver useful transparency for consumers.

196. Outside the EU, we have an opportunity to reform disclosure requirements. They should be proportionate for business, and incentivise bespoke information provision to consumers, rather than excessive reports set out to prescriptive templates. This will be an extensive project to undertake and thus beyond the scope of this report. However, we suggest some illustrative changes, set out below.

<sup>56</sup> [CityUnited Project TIGRR Digital Finance Proposals](#), CityUnited Project, February 2021

<sup>57</sup> Shanker Singham and Radomir Tylecote, '[Plan A+: Creating a prosperous post-Brexit UK](#)', September 2019.

**Proposal 6.1: Remove the requirement to provide costs and charges reports to professional investors and eligible counterparties from MiFID II.**

197. This requirement in the MiFID II to provide costs and charges reports to professional investors and eligible counterparties should be removed. These reports are costly and time-consuming to produce (increasing the transaction data-gathering requirement by 270 per cent).<sup>58</sup> Such disclosures are not beneficial to wholesale clients as the information is already received from brokers. Clients ask for it on an ad hoc and very infrequent basis, so even a different set of standardised disclosures would not be helpful. The benefits of a full exemption for wholesale clients include (i) wholesale clients no longer having to receive homogenised information they have often asked to stop receiving; (ii) investment firms being able to meet wholesale clients' requests not to receive such information; and (iii) unnecessary complexity removed from the regime.

198. The FCA has suspended the requirement for firms to provide best-execution reports until the end of 2021. Industry has called for the requirement to be removed indefinitely. We think this should be considered seriously, provided it can be shown that these reports do not add value for recipients.

**Proposal 6.2: Remove the "investment recommendation" disclosure requirements from MAR for wholesale clients.**

199. The Market Abuse Regulations (MAR) sets out "investment recommendation" disclosure requirements. Where trading and sale information needs to be provided to wholesale clients, subjecting that process to those requirements is burdensome and costly. It is also not supported by the buy-side it is intended to help. The obligation creates an ongoing cost for producers that outweighs perceived benefits.

**Proposal 6.3: Confine the key information document disclosure requirement in PRIIPs to genuinely complex packaged products.**

200. The Packaged Retail and Insurance-based Investment Products (PRIIPs) Regulation requires those who manufacture, advise on or sell insurance based investment products to present information to clients based on a template called a key-information document. The obligation aims to ensure investors can understand and compare the key features, risks, rewards and costs of various products in an accessible way.

201. The PRIIPS requirements should be confined in its application to genuinely complex, packaged products that require special explanation to the retail market. Vanilla bonds should be exempt from the scope of the products it governs in order to galvanise retail participation in capital markets. Outside of the retail market, the UK should

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<sup>58</sup> Ibid.

allow for key information to be provided in less-prescriptive ways than those set out in the Regulation's templates.

202. There is the potential to apply a more proportionate approach to a range of other disclosure and reporting requirements, including:

- a. **Cross-Border Payments Regulation:** The pre-initiation transparency requirements in articles 3a and 3b require the same information is provided for business and retail customers. However, business customers use sophisticated payment platforms that do not charge customers at the time the transaction is initiated, so these requirements are unlikely to result in a change of behaviour and do not, in practice, increase transparency. A specific corporate opt-out could be achieved by applying the language contained in the third paragraph of article 3a (6) to the whole of articles 3a and 3b.<sup>59</sup>
- b. **Deposit Guarantee Scheme Directive:** This currently requires customers opening new deposit accounts to confirm receipt of a standardised disclosure on deposit protection. The opportunity here is to diverge from the standardised template and devise a far more customer-friendly disclosure that has a better chance of landing key messages on the key deposit protection available through the Financial Services Compensation Scheme in the event of bank default.
- c. **Mortgage Credit Directive:** This currently requires lenders of foreign-currency mortgages to contact customers every time the exchange rate changes significantly. This has reduced the number of players in the market, to the detriment of high-net-worth customers and borrowers. Better consumer protections can be provided by ensuring customers understand the impact of currency fluctuations at the outset.
- d. **Payment Accounts Directive:** This currently requires information to be provided to customers in a durable medium. In practice, that has been interpreted in favour of paper-based statements. It should be changed to allow movement toward full customer choice, with the potential for significant environmental improvement through reduced paper use.

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<sup>59</sup> i.e. "The payment service provider and the payment service user may agree that articles 3a and 3b do not apply in whole or in part where the payment service user is not a consumer".

## Replace GDPR with a new UK framework for data protection

**Headline Proposal 7: Replace the UK General Data Protection Regulation 2018 with a new, more proportionate, UK Framework of Citizen Data Rights to give people greater control of their data while allowing data to flow more freely and drive growth across healthcare, public services and the digital economy.**

203. In 2018, the digital sector contributed £149 billion to the UK economy—equivalent to £400 million a day. Growth in the sector is nearly six-times larger than growth across our economy as whole.<sup>60</sup> But the pace of digitalisation has given rise to serious concerns about the risks of improper use of data in a range of areas. Citizens and consumers need to be able to be confident in our national data protection framework.

204. We now have the opportunity to reform UK General Data Protection Regulation 2018 (GDPR) to create an even more innovative and cutting-edge business landscape and to attract the top start-ups and leaders in tech. UK tech grew dramatically in 2020, with the UK securing a record £15bn of Venture Capital investment in tech companies, the third highest rate in the world behind only the US and China, it has the potential to grow even further.<sup>61</sup>

205. Consumer data is highly profitable and a currency in itself. It's hard to pinpoint the exact value of consumers' data—one study estimates the email address of a single internet user to be worth \$89 and the total data of the average US resident \$2,000 - \$3,000.<sup>62</sup> There is a multi-billion dollar industry of data brokers—companies that collect consumer data and sell it to other companies.<sup>63</sup> Studies show that on average Google holds the equivalent of roughly three million Word document pages per user in personal data and Facebook holds around 400,000 pages of data per user.<sup>64</sup> This data is extremely valuable.<sup>65</sup>

206. The UK has the opportunity to cement its position as a world leader in data, through a combination of proportionate, targeted reforms that boost innovation, and by maintaining its enthusiasm for digital. The Government should use an approach to data based more in common law, so case law can adapt to new and evolving technologies such as artificial intelligence and blockchain.

207. GDPR is prescriptive, and inflexible and particularly onerous for smaller companies and charities to operate. It is challenging for organisations to implement the necessary processes to manage the sheer amounts of data that are collected, stored and need to be tracked from creation to deletion. Compliance obligations should be

<sup>60</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/959053/DCMS\\_Sectors\\_Economic\\_Estimates\\_GVA\\_2018\\_V2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/959053/DCMS_Sectors_Economic_Estimates_GVA_2018_V2.pdf)

<sup>61</sup> [The Future UK Tech Built](#), Tech Nation, 2021.

<sup>62</sup> [How Much Is Data Worth?](#) from Permission.io, April 2020.

<sup>63</sup> [Do You Know Which Companies Are Collecting Your Personal Information?](#) from WebFX, March 2020.

<sup>64</sup> [Tech Giants Get Rich On Your Data](#) from Entrepreneur Europe, September 2018.

<sup>65</sup> [Know Your Data's Worth](#), PC Mag, November 2020.

more proportionate, with fewer obligations and lower compliance burdens on charities, SMEs and voluntary organisations.

208. Reforming GDPR could accelerate growth in the digital economy, and improve productivity and people's lives by freeing them up from onerous compliance requirements. In a survey by DataGrail 49% of business decision makers reported spending over 10 working days a year just to sustain GDPR compliance, with 12% spending over 30 working days a year.<sup>66</sup> A more proportionate approach would free up many businesses to provide more value to the consumers and other businesses they serve.

209. GDPR is centred around the principle of citizen-owned data and organisations generally needing a person's 'consent' to process their data. There are alternative ways to process data that do not require consent, but these are not well defined or understood, causing confusion amongst data processors and controllers. The overall effect is that growth and innovation are stifled. GDPR is not delivering for the consumer either. Tech giants oblige consumers to 'consent' to use their platforms before selling and profiting from the data collected, with the illusion that the consumer has control.

210. Any reform of GDPR must of course continue to ensure that privacy is protected. Data sharing can deliver important benefits in healthcare and other public services as well as in innovative industries in the private sector. But this must be balanced with appropriate safeguards.

211. Extensive work is already underway in government on data. As the Secretary of State for Digital, Culture, Media and Sport set out in the DCMS National Data Strategy, the UK is a leading digital nation. The data market in the UK (i.e. money made from products or services derived from digitised data) is the largest in Europe.

### **Proposal 7.1: Reform GDPR to give people meaningful control of their data.**

212. One of the most important business models of recent years has involved the big tech companies collecting people's data in return for access to a service; and then using that data to make money, including by reselling it. We believe that people should have more control over the use of their data, including its resale.

213. GDPR aims to give people control over their personal data but rarely does so. In many cases it results in, quite literally, a tick-box exercise. The kind of privacy self-management where consumers have to read, consent to and manage options in individual privacy policies to use products and services is simply not scalable. The overemphasis on consent has led to people being bombarded with complex consent requests. An illustration of this is the cookie consent banner that appears every time you visit a website. Both behavioural science and common sense tell you that putting a 'tick to accept' box in front of someone at the point they want to access a website

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<sup>66</sup> DataGrail - [the cost of continuous compliance](#).



or service does not generate genuine informed consent, it just means people are likely to tick 'accept' without thinking.

214. This status quo benefits the tech giants, which are able to present consent requests at the opportune moment of access to their platforms. Moreover, because they are profiting from people's data, they can afford the compliance burden that comes with GDPR, unlike many SMEs.

215. To address this the Government should reform GDPR to create new regulatory infrastructure for citizens to take greater control over how their data is used, and allow for more meaningful informed consent in a way that is less intrusive. In the new framework greater emphasis should be placed on the legitimacy of data processing and whether it is really in the interests of the data owner and society, rather than a legalistic version of consent where businesses comply with the letter but not the spirit of the law. A good measure of whether reform is successful will be the end of pointless cookie banners, together with securing a greater understanding among the public of how their data is used, if and how they benefit from their data and what their realistic privacy and consent powers really are.

216. One way which was proposed to us was that through the creation of regulatory architecture that enables "Data Trusts" or "Data Fiduciaries" to be formed—private and third sector organisations to whom consumers would delegate their data authorisations and negotiations. We believe that this may be an area the Government would wish to explore further.<sup>67</sup>

**Proposal 7.2: Reform GDPR for artificial intelligence, including by removing Article 22 of GDPR and focussing instead on the legitimacy of automated decision-making.**

217. Artificial intelligence (AI) has a key role to play in innovation, both in the UK, and globally over the coming years.

218. AI has the potential to transform a number of traditional industries and create whole new growth sectors, such as in medical diagnostics, Mobility as a Service (MaaS), smart grid energy systems and traffic management.

219. In healthcare and medicine AI is already transforming traditional practises which is why we propose AI be regulated as a medical device, as part of our proposals for digitalising healthcare. One study showed that machine learning algorithms can

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<sup>67</sup> Data Fiduciaries could enable large-scale delegation of authority by consumers over their data assets based on their instructions. Ultimate ownership of user data should be enshrined in such a way that technology providers would be required to provide the technical means for effective delegation to data fiduciaries - for example allowing data fiduciaries to mediate queries to web services. As part of this it will be critical that new regulations are established on how data trusts operate to ensure that vulnerable citizens do not feel obliged to give access to their data. It could be possible to enable people to profit from their data, in a way analogous to royalties, with data owners receiving a share of the revenue when their data is sold by a second- or third-party. This would require a strong evidence base and the Government would need to be sure the policy was designed in a way that would not have a chilling effect on start-ups and scale-ups.

detect skin cancer from images more reliably from dermatologists.<sup>68</sup> But, machine learning algorithms require vast amounts of high-quality training data. Access, collecting and the sharing of data are the top GDPR-related barriers to successful AI projects.

220. In order for the next phase of AI to be realised, we must ensure that the restrictions on the data required for AI and machine learning do not hamper this much-needed progress.

221. Given its huge potential, it is vital that regulation of AI is efficient, sensible and robust. While we expect the Government's forthcoming AI Strategy to lead on setting the framework for regulation, we also need to look at this area in the context of GDPR.

222. GDPR specifies rules for how data can be accessed, rectified, transferred and deleted by third parties and prohibits organisations from using data for any purposes other than those for which they collected it. Article 5 of GDPR requires data be "collected for specified, explicit and legitimate purposes," and "adequate, relevant and limited to what is necessary". These restrictions limit AI because they prevent AI organisations from collecting new data before they understand its potential value and they also mean that existing data cannot be reused for novel purposes.

223. Article 22 of GDPR stipulates that individuals should "[not] be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her, or similarly significantly affects him or her". This requirement makes it burdensome, costly and impractical for organisations to use AI to automate routine processes because they must also have a manual process for individuals who opt out of automatic processing.

224. Article 22 of GDPR applies solely to automated decision-making. It does not apply when the output of algorithms is subject to meaningful human review. There are many examples of automated decision-making that involve human review, but where the output itself may well be wrong, not explainable or biased. Conversely, uses of automated decision-making that can perform better than human decision-making are often not allowed.

225. Article 22 of GDPR should be removed. Instead a focus should be placed on whether automated profiling meets a legitimate or public interest test, with guidance on how to apply these tests and the principles of fairness, accountability and an appropriate level of transparency to automated decision-making provided by the Information Commissioner's Office. This would mean that proper consideration to the interests of the data owner had to be given in all instances of automated decision-making. Any new legislation to replace article 22 would also need to consider that automated decision-making should not be based solely on explicit consent, which is too often given without understanding or as part of a contractual requirement that cannot easily be refused. This would enable the use of data where a legitimate or public interest

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<sup>68</sup> [Man against machine: diagnostic performance of a deep learning convolutional neural network for dermoscopic melanoma recognition in comparison to 58 dermatologists](#), Annals of Oncology, Volume 29, Issue 8, p1836-1842, August 1st 2018.

does exist but where the process of collecting explicit consent from all the data subjects involved makes the use of AI untenable.

226.If removing Article 22 altogether is deemed too radical, GDPR should at a minimum be reformed to permit automated decision-making and remove human review of algorithmic decisions. It should also be changed to permit basic explanations of how automated decisions are made rather than obliging organisations to detail complex information about how their systems work and the logic involved.

227.It is particularly important that changes are made<sup>69</sup> to permit automated decision-making for machine learning and to remove the human review of algorithmic decisions required by GDPR.

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<sup>69</sup> Articles 5, 6, 13-15 & 22 of GDPR.

## Smart energy grid of the future

**Headline Proposal 8: Create the ‘smart’ energy grid of the future, through interoperable data standards, reforms to the energy retail market, regulation, and licencing, and a new regulatory framework for smart appliances.**

228. The energy economy is being transformed by the pace of technology development and the Government’s ambitions for Net Zero transition. The scale of the changes underway requires fundamental reform of the regulatory framework for the energy market, created by the 1989 Electricity Act, the current system was devised in a very different energy landscape. The role, remit, and responsibilities of the energy regulator Ofgem, the National Grid, its ESO arm, and the energy companies themselves, have all changed significantly.
229. By creating this new regulatory framework, the UK can lead the way in the creation of a 21st century smart energy grid, providing national coordination and a clear framework for the transformational development of the UK’s energy infrastructure. Energy will underpin the UK’s next era of innovation and growth. Modern regulation that supports the Net Zero transition is vital to supporting the UK economy and the new energy businesses of tomorrow.
230. Smaller, more numerous energy producers; smart energy technologies; a greater role for consumers in the marketplace; and a changing electricity value-chain all mean a new approach to energy regulation is needed. By taking steps now to support and build the grid of the future, the Government can foster innovation in a broad range of sectors, both within, and beyond energy.
231. In addition, we must ensure that the regulators and the energy market are able to set the conditions to support the customers of the future, and the next generation of energy needs, by creating the regulatory frameworks for the energy systems of tomorrow, today.

**Proposal 8.1: Support the deployment of low-carbon technologies on to the National Grid, by accelerating creation of a platform to facilitate data-sharing across the energy sector, through shared data standards and interoperability.**

232. Consistent and clear data standards, supporting interoperability between both devices and market participants are key enablers of the future energy grid. They are fundamental to fostering robust competition and innovation in emerging sectors and products. Targeted reforms to support this interoperability will boost innovation and investment in the energy sector. To this end, the Government should accelerate delivery of a data-sharing platform for the energy sector, following the expected recommendation of such a platform by the UK’s first Energy Digitalisation Strategy.
233. This strategy will be jointly published by the Government and Ofgem later this spring. It will set out concrete action to ensure millions of assets across the grid – from solar

panels, to heat pumps, to electric vehicles – can be optimised to help the UK achieve its Net Zero ambitions. One of the main aims of the strategy will be the creation of a new platform for data interoperability so that datasets, critical to the deployment of low carbon assets and operation of the grid, can be easily combined. This interoperability is vital in promoting competition in the sector, enabling SMEs and new entrants to the market and to offer new products. The Government should ensure that such a platform is accompanied by the creation of a framework for digital energy metrics.

**Proposal 8.2: Create clear consistent technical and regulatory standards for ‘energy smart’ appliances to support their roll out - creating a more stable energy network in response to growing demands for energy.**

234. There will be a radical increase in the uptake of ‘smart appliances’, able to respond automatically to price and/or other signals by modulating their electricity consumption. Some will be suitable for consumer use, such as electric heating, fridges and washing machines. If deployed effectively across the UK grid, these will reduce energy bills and drive decarbonisation by matching consumption to the availability of renewable generation on the grid.
235. The Government should make more robust use of the powers it already has committed to taking, when parliamentary time allows, to regulate “energy smart” appliances in a sensible way to ensure interoperability, data privacy, cyber security and grid stability.
236. In tandem, the Government has funded the British Standards Institute to develop industry-led technical standards for smart appliances. Published in May, these standards will help develop energy smart appliances that are secure and interoperable. They will also support further innovation by establishing a shared technical framework within which they can operate effectively, generating benefits for consumers, the electricity system and the environment.

**Proposal 8.3: Modernise energy retail regulation to support novel and innovative participation in the energy market and improve consumer protections by using activity-based regulation rather than supply licenses.**

237. The Government and Ofgem should modernise their approach to energy retail regulation. A flexible, activity-based approach to regulation should be adopted in light of the development of digital comparison tools and other, innovative methods of retail. The existing energy supply licence structure is no longer fit for purpose, having been designed to apply to the traditional business models of large energy retailers. Since then, more novel market operators, including digital comparison tools, and non-traditional energy retailer businesses, such as auto-switchers have entered the market. Others will continue to do so as the future of the energy grid begins to take shape. This creates gaps in the regulatory landscape.

238. Under an activity-based approach the relevant rules would apply based on the activity a business is engaged in, rather than the type of firm it is, and whether it holds a license. For example, a firm engaged in sales and marketing activity in the retail energy market would be subject to sales and marketing rules. This would ensure a level playing field based on the activities a business is engaged in without unnecessarily bringing digital comparison tools and other innovative companies into the current energy supply licensing regime.

239. Reforming the approach to energy retail regulation in this way will allow further innovative firms to participate in the energy market. This would encourage novel approaches to pricing and distribution that leverage cutting-edge clean energy generation methods, alongside providing more uniform protection for consumers. In particular, this will enable new 'smart' approaches to retail as generation moves away from large, predictable and controllable fossil fuel generation to more numerous, smaller sources of energy that are harder to predict and control.

**Proposal 8.4: Reform the regulation framework for the retail energy market to enable innovative approaches to tariff pricing and new products.**

240. The Government should implement changes to the energy retail market regulatory framework to better support innovative tariffs and pricing mechanisms that work for consumers and contribute to Net Zero. This should include a review of whether the current supply licence framework strikes this balance between innovation and consumer protection effectively. The need for radical rather than incremental change should be assessed in the approach to pricing overall. These changes should also clearly be designed to support and enable test-bedding new 'Energy as a Service' models of retail.

**Proposal 8.5: Prioritise investment in infrastructure in pricing negotiations with energy market operators.**

241. The Government should prioritise aggressive investment in future energy and grid infrastructure as a policy outcome in its Strategy and Policy Statement made under section 131 of the Energy Act 2013.<sup>70</sup> Ofgem should have due regard to this in its pricing negotiations with market operators. This will enable, and underpin, the major investment and concerted action that is needed to deliver a decarbonised energy system for the UK and to support disruptive technology advancement in the energy sector. Setting regulators this priority will also provide an opportunity to align gas and electricity price reviews, creating a more strategic, cross-sector approach to pricing and investment overall.

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<sup>70</sup> [Strategy and policy statement consultation](#), Department for Energy & Climate Change, October 2014.



## Net Zero technologies

**Headline Proposal 9: Reform the current UK regulatory framework governing energy generation and distribution to match the Government's ambitions for green growth and Net Zero.**

242. The UK's commitment to Net Zero transition demands adoption of transformational new technologies on a scale not seen since the creation of the internal combustion engine. This will require a massive injection of pace, energy, vision and agility into UK regulation.
243. New and emerging technologies, fostered by innovative regulation in the energy sector, will be a key enabler for the UK achieving its ambitious Net Zero targets, and making it a leading country in decarbonisation. There are also economic growth opportunities in these areas, particularly in the expansion and development of offshore wind, hydrogen and low carbon transport.
244. There is already significant work ongoing across government to identify ways to reform regulation that will enable innovative Net Zero technologies to be better exploited. However, an historically cautious approach to the UK's energy infrastructure has created a system of rigid and complex codes, which industry point out are rarely conducive to innovation. As set out in our bold new framework for regulation earlier in this report, to rectify this the Government must take a more innovative approach to regulating technologies.
245. This should include adopting an approach to regulation that focuses on future opportunities rather than maintaining market stability. Regulation should target outcomes rather than processes by adopting more agile standards; fostering better collaboration between regulators and policy makers to set joint, longer-term goals. This should include promoting new digital and AI-based approaches within the energy sector.

### *Offshore wind*

246. The Government's target to achieve 40GW of offshore wind by 2030,<sup>71</sup> and the Prime Minister's aim to become the 'Saudi Arabia of Offshore Wind'<sup>72</sup> will require large scale construction of additional offshore energy infrastructure. The infrastructure challenge facing the National Grid is unprecedented, and will require planning and regulatory policy changes to support the timely delivery of this new infrastructure. Without reform, the electricity network reinforcements will not be delivered in time to achieve the 2030 ambition.

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<sup>71</sup> [New plans to make UK world leader in green energy](#), Prime Minister's Office and the Department for Business, Energy & Industrial Strategy, October 2020.

<sup>72</sup> [Prime Minister's statement at the Leaders Summit on Climate](#), 22 April 2021.

**Proposal 9.1: Fully implement the short-term findings of the Offshore Transmission Network Review, reforming offshore transmission connections to support disruptive ‘pathfinder’ projects in the industry.**

247. A key element of the reforms needed in this sector is the Government’s ongoing Offshore Transmission Network Review (OTNR).<sup>73</sup> The OTNR was launched in 2020 to review the Government’s approach to transmission connections for offshore wind generation.

248. This review is considering short-term changes to the transmission network with the aim of facilitating developer-led ‘pathfinder’ projects. This includes changes to Ofgem’s cost assessment process governing the transfer and sale of assets for Offshore Transmission Owners; changes to industry codes including Security and Quality of Supply Standard (SQSS) and System Operator-Transmission Owner Code (STC). The review also considers reforms to cost allocations and local charging for using Transmission Systems. The Government should prioritise implementing these at pace.

**Proposal 9.2: Reform the regulatory framework for offshore wind to simplify responsibilities across government, and create a more coordinated offshore network that uses standardised designs and can link with interconnectors at scale.**

249. Alongside adopting the recommendations of the OTNR, if the Government is committed to increasing offshore capacity, they should quickly and aggressively pursue reform of the overall regulatory framework for developing and connecting offshore wind. The aim should be to create a more rationalised, coordinated approach to regulating the offshore network that better supports innovative offshore generation projects, and improvements to offshore connections.

250. Currently, offshore wind infrastructure and the interconnectors required to support large scale growth are considered under different regulatory regimes. If offshore wind is to link into interconnectors at scale, a consolidated regime will be required. A reformed regulatory framework will also need to incorporate energy companies, equipment manufacturers and standards organisations to consider options for the standardisation of offshore network designs.

**Proposal 9.3: Reform OFTO regulations to unblock industry coordination of offshore wind projects.**

251. Changes to the regulation of offshore wind will also help unlock growth in the sector. Industry told us that the current developer-build regime, which requires developers to

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<sup>73</sup> [Terms of reference](#), Offshore Transmission Network Review, Department for Business, Energy & Industrial Strategy, July 2020.

build the connecting infrastructure for their projects and then sell them to an Offshore Transmission Owner (OFTO) can act as a blocker to the coordination of offshore wind projects. OFTO regulations should therefore be reformed to consider the practical roles, responsibilities, and configuration of the offshore market and how it functions in reality.

**Proposal 9.4: Review the Grid Code and other relevant technical codes and standards, to ensure they adequately support innovative Net Zero and decarbonisation technologies.**

252. The current 'Grid Code'<sup>74</sup> is outdated, with the rules for wind generation in the existing code not fully accounting for the characteristics of offshore wind farms connected to high voltage offshore transmission networks through particular means, such as meshed connections. The Government should undertake a review of the Grid Code and other relevant technical codes and standards to ensure that they cover and support the innovative Net Zero technologies the UK will need to meet its decarbonisation goals.

**Proposal 9.5: Design and deliver an energy network 'blueprint' to support further delivery of offshore wind power.**

253. Further, the National Grid, BEIS and Ofgem should agree and publish an optimised electricity network 'blueprint', currently championed by the National Grid, to secure the delivery of 40GW of offshore wind by 2030. This 'blueprint' should provide a strategic view of the delivery of offshore wind generation technology nation-wide, to support communities and local authorities in avoiding obstacles in the planning process. It should also strategically inform regulatory decisions, and provide further certainty on future energy supply chains.

## Hydrogen

**Proposal 9.6: Create a new regulatory framework for hydrogen via a new Office for Hydrogen within BEIS, encouraging investment and innovation in the sector.**

254. The Government's Net Zero commitments will also require the rapid scaling of hydrogen solutions through the 2020s. This means the UK supporting and building a robust domestic market in hydrogen, including the development of demand-side technologies, and the creation of large scale projects supported by network and storage assets. Setting clear standards and regulatory rules for hydrogen will encourage investment in the sector, and the delivery of innovative goods and services within it.

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<sup>74</sup> The [Grid Code](#) details the technical requirements for connecting to and using the National Electricity Transmission System (NETS). Compliance with the Grid Code is one of the requirements of the Connection and Use of System Code (CUSC).

255. Building on the work of the Hydrogen Strategy expected to be published this year, the Government should focus on developing a new regulatory framework for hydrogen, supported by and underpinning the training and retraining of additional hydrogen scientists, engineers and technicians through a new national skills competency framework.
256. Such a framework should then be leveraged to help create a market for hydrogen, for example by targeting the roll-out hydrogen-ready domestic boilers as an exemplar market for applying a new, flexible, post-EU approach to UK regulation. The Confederation of British Industry (CBI),<sup>75</sup> and all five of the UK's gas grid operators and gas boiler manufacturers have already called on the Government to do this.
257. Further, the Government should publish business models for hydrogen. These should provide assurance to investors to promote funding for hydrogen. For hydrogen production, industry experts have suggested this could be through contracts for difference (CfD), and potentially more straightforward grant schemes for smaller-scale businesses. For Carbon Capture Usage and Storage systems (CCUS) and pipeline infrastructure, this could be through a regulated asset base (RAB) model. Finalising business models as soon as possible would, for example, help provide the UK develop the world's first Net Zero industrial cluster.
258. These recommendations should be consolidated and driven forward by creating an Office for Hydrogen within the Department for Business, Energy and Industrial Strategy. The technology is currently being managed across a number of departments and government bodies. The Government should provide a central coordinating unit to drive forward hydrogen, which would also serve as a clear statement of intent to industry of its priority.

**Proposal 9.7: Increase the legal limit on hydrogen blending by amending the Gas Safety (Management) Regulations 2016.**

259. There are a number of changes to existing legal restrictions the UK can make to unlock massive growth in hydrogen sectors. The first of these is enabling hydrogen blending. Currently there is a legal limit on hydrogen in the national gas grid (0.1%). This should be increased to stimulate hydrogen demand, and also begin reducing carbon emission from heat. Industry, in collaboration with the Government are already conducting trials to provide safety assurance, such as through the HyDeploy programme. Increasing the amount of blending would require the Gas Safety (Management) Regulations 2016 to be amended.

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<sup>75</sup> [No new conventional gas boilers in homes after 2025](#), Confederation of British Industry, July 2020.

## *Net Zero transportation*

**Proposal 9.8: Create a testbed UK airport to act as a first-in-the-world location for trialling future Net Zero transport technologies.**

260. The decarbonisation of our transport sectors, including personal road vehicles, railways, commercial aviation and maritime shipping, is a key pillar of meeting our Net Zero targets. This should be supported by the Government prioritising regulatory changes to Net Zero technology development and innovations that are applicable to transport.

261. In particular, innovation in the aviation sector is currently held back by restrictive regulations. The Government should create a testbed airport to act as first-in-the-world for trialling the operation of hydrogen, SAF (Sustainable Aviation Fuel), electric, lighter-than-air and other low-carbon powered aircraft and airships, as well as designing and trialling innovative regulatory approaches to supporting them.

262. In tandem, the Government should work with UKRI and the Civil Aviation Authority to build on the success of the Future Flight Challenge, detailed below.

### **UKRI Future Flight Challenge**

This challenge is investing up to £125 million into developing greener ways to fly, such as all-electric aircraft and deliveries by drone, by advancing electric and autonomous flight technologies. The investment by UKRI, from the Industrial Strategy Challenge Fund is matched by £175 million from industry.

Crucially, as part of the challenge, regulators, such as the Civil Aviation Authority (CAA) are engaged from day 1, providing ideal opportunities for regulatory development and dialogue.

263. To accelerate the pace of UK rail decarbonisation, we also urge the Government to consider international regulatory best practice and look at where existing regulations can be simplified to accelerate the electrification of the UK's railways and the roll out of hydrogen train technology.

264. Specifically, we understand that DfT has a regulation mandating the minimum depth of concrete foundations for Network Rail electrification gantries which go way beyond that of other countries or rational engineering standards. This should be addressed urgently to help accelerate UK rail electrification.

## Future transport technologies

**Headline Proposal 10: Create a new regulatory framework to support UK leadership in the future of transport, promoting UK transport R&D, digital sandboxes, and agile, anticipatory regulation that sets global standards.**

265. The transport sector, both in the UK and globally, is on the cusp of a technological transformation driven by the scale of the Net Zero transition. This is changing attitudes to travel car ownership, digitalisation, the advent of Mobility as a Service (MaaS), decarbonisation and automation. This represents both a massive regulatory and economic challenge and a huge opportunity for growth. For example, the annual economic contribution of connected and autonomous vehicles in the UK is predicted to grow to £51 billion by 2030, creating an additional 320,000 jobs.<sup>76</sup> For drones, it is predicted that growth in the UK could bring 628,000 jobs and contribute £42bn to UK GDP by 2030.<sup>77</sup>

266. If the UK is to fully unlock the growth and innovation opportunities in transport sectors like autonomous vehicles, micromobility, Mobility as a Service, drones and other urban transit innovations, it must have the right standards, regulations and frameworks in place. Regulators must also be equipped to meet the challenges new technologies bring. This example illustrates the principle discussed at the start of this report that establishing the right regulatory framework at an early stage in the development of a new sector is key to UK growth and innovation. Providing regulatory stability gives businesses the confidence to invest.

**Proposal 10.1: Create a world leading regulatory framework for autonomous vehicles and other disruptive mobility solutions.**

267. The Government has already made strong headway in developing reforms through the Future of Transport programme.<sup>78</sup> This work is expected to focus on a number of key areas:

- Deliver a world-leading regulatory framework for the safe deployment of automated vehicles on public roads;
- Speed up delivery of chargepoint infrastructure to support the transition to electric vehicles outlined in the Prime Minister's Ten Point Plan<sup>79</sup> for a green industrial revolution;
- Modernise maritime law to support safe testing and deployment of Marine Autonomous Surface Ships; and

<sup>76</sup> [Connected and Autonomous Vehicles - The UK Economic Opportunity](#), KPMG for the Society of Motor Manufacturers and Traders (SMMT), March 2015.

<sup>77</sup> [Skies Without Limits: Drones, Taking The UK's Economy To New Heights](#), PriceWaterhouseCooper, May 2018.

<sup>78</sup> Department for Transport, [Future of Transport programme](#), 24 November 2020.

<sup>79</sup> [The ten point plan for a green industrial revolution](#), Department for Business, Energy and Industrial Strategy, 18 November 2020.



- Create a micro mobility regulatory framework, enabling the potential legalisation of e-scooters for use on the road and potentially other forms of micro mobility deemed safe and appropriate in the future.

**Proposal 10.2: Develop and support sandboxes for autonomous vehicles, and other advanced trials of zero-emission passenger and logistics services.**

268. Regulatory sandboxes<sup>80</sup> are an important way of developing the evidence-based safety cases key to building regulatory confidence with both users and investors, to unlock growth for innovative transport/future of mobility technologies, such as e-scooters, autonomous cars and drones. Arguably, a greater challenge to growth is public perception regarding safety to passengers, other road users and pedestrians. Safety cases are developed through completing trials and experiments to gather data and modify technology to present the best safety case possible.

269. The Government should increase the use of regulatory sandboxes to help drive innovation of new transport technologies. As set out in this report, pilot schemes of this kind can lead to many beneficial outcomes, such as reduced time and cost for bringing innovative ideas to market, increased investment in currently unapproved ideas, improved product testing, and better consumer safeguards. A good example of an existing government commitment that could be expanded and made into a sandbox is the West Midlands Future Mobility Testbed.<sup>81</sup>

**(West) Midlands Future Mobility Testbed**

Through £31m of investment by government and industry, the Midlands Future Mobility Testbed, once complete, will comprise of a network of over 200 miles of roads to form a world-class environment for developing the next generation of connected autonomous vehicles (CAV).

270. The Government should continue to support Phase 1 of the West Midlands trial, which will focus on supporting early uses of high-technology automated transport solutions currently constrained by existing regulation. It will also consider any barriers to understanding how to navigate the regulation ahead of rolling out wider trials across the UK.

271. If the Government wants to achieve the maximum value from testbed status, particularly if changes to the law are pursued via a Future of Transport Bill, it should conduct advanced trials with industry in the West Midlands in both zero-emission automated passenger and logistics services.

<sup>80</sup> Regulatory Sandboxes are designed to provide a real-world environment for testing and trialing new technologies without certain legislation applying that would otherwise prevent or constrain this work being carried out.

<sup>81</sup> [Midlands Future Mobility testbed](#). Transport for West Midlands.

**Proposal 10.3: Create a micromobility regulatory framework for the regulation of e-scooters and other emerging forms of micromobility on the road.**

272. The UK should create a new regulatory framework allowing e-scooters and other, emerging forms of micro-mobility to be adopted, tested, and assessed through sandboxes: then licensed, in accordance with the evidence, for safe use on our roads.
273. Under UK law, e-scooters are classed as a type of motor vehicle under the Road Traffic Act 1988, which means a number of requirements around their legal use apply but in practice are not adhered to by users. Some of these may not be proportionate to the risk posed by a micro mobility vehicle compared with conventional, heavier and faster motor vehicles that are bound by the same requirements.
274. To establish if e-scooters should be recategorised, DfT began national trials in over 30 regions in the UK, and this year they are expected to evaluate the evidence gathered, focusing on safety and mode shift. Regulations are due to be amended in 2022 if the results of these trials are favourable.
275. In addition, we recommend the Government creates a broader regulatory framework to cover much more than the 'generic' e-scooter design being considered at the moment. Doing so would help drive innovation across the diverse micro mobility and MaaS sector.
276. At a minimum, legislation to enable the use of e-scooters should be adaptable to future innovation. Here, an option could be to look to regulate e-scooters as part of a new 'Personal Light Electric Vehicle' (PLEV) or 'Personal Mobility Device' (PMD) category with the aim of putting in place an adaptable regulatory framework able to more rapidly consider and, if desirable, legalise future forms of PLEV. For this to function effectively, consideration will also be required around the application, testing and approvals process for innovative forms of PLEV or PMD in the future.
277. Although bicycles and e-bikes sit outside the scope of PLEVs, there will be an opportunity to apply relevant areas of the e-scooter regulatory framework to e-bikes, for example, when considering possible new local authority powers over rental e-bike/e-scooter schemes.

**Proposal 10.4: Empower the Civil Aviation Authority to better regulate the use of remotely piloted air systems (RPAS) (i.e. drones and UAVs), specifically to enable the use of RPAS beyond visual line of sight (BVLOS) by 2024.**

278. The CAA has received significant additional responsibility since the UK left the EU. CAA's levy funding comes in large part from their work on continued airworthiness for traditional airline and airport businesses. We consider this could hold back work on supporting business models which do not contribute to these levies. The current lack of CAA support for experimental and innovation technologies runs the real risk of not

meeting industry demands for guidance, enforcement, regulation and certification. Industry are concerned this could decrease the attractiveness of the UK to international companies looking to run trials for aircraft and other technologies. This would represent a loss to UK plc.

279. The CAA is ensuring that safety is the priority for certifying the use of RPAS,<sup>82</sup> including experimental designs. However the current restriction on beyond visual line of sight (BVLOS) operation is a key barrier to innovation of RPAS. In practice, this means drone operations in the UK are restricted to within visual line of sight of the pilot/operator, exempt in some limited circumstances. Additional regulation requires any UAS to apply for designated airspace in which it can operate. This process is time-consuming for applicants and industry has told us that it does not necessarily promote safe and integrated airspace. Therefore, the Government should empower the CAA to regulate RPAS for BVLOS operations by 2024. This would allow them to be operated in non-segregated airspace, which would benefit the economy and innovation landscape by providing new use opportunities for businesses and public services. BVLOS operation must be introduced safely, with appropriate checks in place, and apply to business and public service providers as opposed to amateurs.

280. The CAA should specifically investigate how the operation of aircraft, including drones can be regulated to operate safely in close proximity to each other. Key applications where this could help unlock growth include the use of drones to deliver goods and the provision of public services, such as health care.

#### **Drones for enabling better public services**

An example of UAV use for supporting the provision of vital public services is in Argyll & Bute Health & Social Care Partnership (HSCP). COVID-19 test samples and other medical materials are being carried on drone delivery flights between medical facilities. The UAVs carry PPE, COVID-19 testing kits and essential medicines to the region, reducing transport times from 36 hours to 15 minutes and increasing the frequency of pick up.

#### **Proposal 10.5: Reconsider regulation to allow the spraying of plant protection chemicals from drones.**

281. The use of precision farming techniques is a space for innovation. One example is the use of Unmanned Aerial Vehicles (UAV) to spray agrichemicals (fertilisers and pesticides). UAVs can improve the precision with which fertilisers, pesticides and fungicides are applied, improving crop health and reducing the volume of chemicals used. Greater precision in spraying has obvious environmental benefits as well as reducing costs for farmers.

282. A consortium of farmers recently won approval from the CAA to 'drop' from UAVs, with specific restrictions, enabling spraying from drones. Regulations made under the

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<sup>82</sup> Remotely Piloted Air Systems, also referred to as Unmanned Air Systems (UAS) or drones.

Chemicals Regulation Directorate (CRD) require a number of conditions to be satisfied before aerial spraying permissions can be granted. These requirements are preventing the agricultural sector from using drones to spray agrichemicals. We encourage the Health and Safety Executive to reconsider these requirements at pace and allow aerial spraying from UAVs, allowing innovation in the future farming and drone sector.

## Regulatory architecture for global UK leadership in clinical trials

**Headline Proposal 11: Establish a new UK Clinical Trials Regulatory landscape to build on the success of the COVID-19 RECOVERY trial and UK leadership in genomics, novel trial design, faster patient recruitment and use of disease cohort data to make the UK a world leader in clinical trials.**

283. In recent decades the UK has seen a gradual decline in its global share of international clinical trials. In 2011 the first UK Life Science Strategy made a number of commitments to reduce the time, process, and patient recruitment targets for clinical trials. There has been some real improvement in the last decade, but recent public health emergencies (most recently COVID-19 but before that the Ebola and Zika outbreaks) have revealed what is possible in the acceleration of trials.
284. Figures from the National Institute for Health Research (NIHR) show that in England, clinical research was worth £2.7bn in 2019, including £1.5 billion from commercial sources, and supports more than 47,000 jobs. Additional revenues and cost savings, such as provision of medicines to patients in trials, provided approximately £28.6m of savings to the NHS, and an additional £335m from commercial income.<sup>83</sup>
285. The clinical trials agenda has a major role to play in the Government's 'Levelling Up' programme. As was demonstrated in the COVID-19 RECOVERY Trial, the most effective hospitals at patient recruitment were the non-teaching District General Hospitals (DGHs) with large numbers of patients, but which have not traditionally been seen as part of the clinical trials and 'research medicine' sector. Given that pharmaceutical clinical trials generate substantial local income, career opportunities and access to innovative treatments – at no cost to the NHS – widening the geographic spread of patient recruitment and trials around the UK can play a big part in accelerating UK patient recruitment for the national trials sector and support local levelling up.
286. Despite the systemic improvements since 2010, the UK clinical trials landscape is still not in a position to capitalise systemically on the UK success with the Oxford AZ vaccine trials and use that to re-establish a global leadership position.
287. The key to a competitive clinical trials landscape is collecting data on how different patients respond to a new medical treatment. Decisions by companies and regulators and purchasers are made on the basis of data, which is why the process for setting up the trials and recruiting patients must be first rate. We set out the building blocks that make up a first rate service below.

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<sup>83</sup> <https://www.abpi.org.uk/media/7607/rmi-0128-0919-clinical-trials-report.pdf>

288. Clinical trials don't exist in a vacuum, but within the context of the health system they are conducted in. The competitiveness of UK clinical trials is a function of the whole clinical trials system. The key strengths of an effective system are:
- a. an ability to identify patients and profile by genotype and phenotype;
  - b. the speed of recruitment;
  - c. the bed and nurse capacity of clinical infrastructure;
  - d. the molecular diagnostics capability in the system;
  - e. the capacity to monitor patients in the trial;
  - f. the quality of data captured;
  - g. the quality of the data collation, assimilation, and interrogation infrastructure;
  - h. the linkage of trials to the regulatory and health system, and procurement.

### *Regulatory opportunities in clinical trials*

**Proposal 11.1: Repeal the EU Clinical Trials Directive, and develop a replacement UK Accelerated Access Translational Clinical Trials framework to restore global UK leadership in clinical trials.**

289. Having left the EU Single Market the UK needs to use its new found regulatory sovereignty to frame a more globally competitive and compelling new UK Clinical Trial Framework to continue to attract global life science companies to advance drug discovery.
290. The EU's Clinical Trials Directive and the follow-up regulation Clinical Trials Regulations increased the costs of conducting clinical trials in the EU, and have contributed significantly to the reduction in the number of such trials in the UK.<sup>84</sup> The UK is not obliged to retain this framework: they should be repealed and replaced with a more competitive UK offer.
291. The UK has the opportunity now to develop a forward-looking UK Accelerated Access Translational Clinical Trials framework, updating and expanding on the WHO Good Clinical Research Practice (GCP) of 1995. The MHRA has already made significant progress in areas such as embracing Accelerated Access, The Early Access to Medicines Scheme (EAMS) and their parallel approvals and accelerated protocols developed through COVID-19.
292. The UK has shown its potential to rival the US in regulatory innovation through its groundbreaking Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial, pioneered by the University of Oxford. This was and remains the world's largest clinical trial for COVID-19 treatments, and has now expanded internationally. It was launched rapidly in the UK in March 2020 to investigate whether any existing treatments were effective against COVID-19. It is open to all patients admitted to NHS hospitals with COVID-19, with over 36,000 patients recruited so far. The trial has already delivered results that have changed clinical care, including the findings that the inexpensive steroid, dexamethasone, and the anti-inflammatory treatment,

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<sup>84</sup>[http://vertassets.blob.core.windows.net/download/a78320af/a78320af-1b65-4bbe-b603-bb0540285015/synhcr\\_eu\\_ct\\_regulation.pdf](http://vertassets.blob.core.windows.net/download/a78320af/a78320af-1b65-4bbe-b603-bb0540285015/synhcr_eu_ct_regulation.pdf)



tocilizumab, significantly reduce the risk of death when given to hospitalised patients with severe COVID-19. While such a trial was unusual, it is testament to the UK's skill and agility in clinical trials.

293. The trial's success was dependent on the ability to easily identify potential patients and recruit them into the trial across the entire NHS network. Combined with the use of international partnerships, the trial demonstrated how it is possible to dramatically speed up the assessment of novel treatments, increase the global relevance of the trial results, build capacity, and reduce wasted efforts on small uninformative studies. This best practice must become standard practice.

### *The current UK Framework Architecture*

294. The UK system maintains excellence in many areas of the clinical trials process and has a well-established network of clinical trials expertise and infrastructure. The regulator, the MHRA is world class, widely respected globally, and has once again proven what it is capable of during COVID-19. The new UK regulatory framework should build on the MHRA's strengths to enhance the global competitiveness of the UK's clinical trials sector.

295. The two key problems holding back the UK clinical trials sector are: the slow and costly recruitment of patients; and a lack of system and data integration;

- a. By patient: lack of a single integrated e-medical record for collating all patient data;
- b. By cohort: lack of a single integrated database for different patient cohorts or historic trials data.

296. As we have set out above, there is a huge opportunity for the UK to use the COVID-19 vaccine trials success as a catalyst for a powerful package of reforms to enshrine this best practice into a clinical pathway. This pathway, when implemented, will provide:

- a. Quicker access to patients for trials and cohort study recruitment.
- b. Quicker access for patients to innovative treatments.
- c. UK leadership in Conditional Approval / Adaptive Licensing.
- d. Embrace agile Value Based Pricing based on the actual benefit of a new drug in terms of overall disease cost to the system and medical benefit to patients

297. Building on these proposed reforms, the UK should link up its centres of excellence in life science research and development data – Biobank, Our Future Health, The Health Index, CPRD, and NIHR studies – to create an integrated UK data system would enable the UK to become the best place in the world for:

- a. Citizens and patients to embrace digitalisation of health (which we discuss further in the digital health section below).

- b. Researchers to conduct observational cohort studies for better earlier detection, prevention, and screening.
- c. Recruiting patients into trials.
- d. Evidence based approvals and reimbursement.

298. Embedding best practice from the RECOVERY trial and linking up existing UK centre of excellence needs to be supported by specific reforms in the following areas:

- a. Patient Recruitment.
- b. Trials Approval and Process.
- c. Data and Data Flow.
- d. The role and structure of the MHRA in the global ecosystem.

### *Patient Recruitment*

299. Reform must focus on increasing the speed and reducing the cost of recruiting patients into clinical trials. The success of the COVID-19 trial has demonstrated what is possible, and the MHRA should enshrine the COVID-19 best practice as the norm and set a 60 day target for first patient enrolment in clinical trials.

**Proposal 11.2: Make 60 days to first patient recruitment the new UK standard by replacing the multiple layers of 3rd party 'consent for consent' with a simpler system based on allowing the use of CPRD public datasets and registries by the Health Research Agency to support trial recruitment.**

300. We recommend the establishment of an integrated streamlined best practice recruitment model based on the concept of "Every NHS Patient A Research Patient". The focus needs to expand beyond hospitals and needs to recruit patients from within clinics and patients without disease. Evidence shows that patients who have had a disease diagnosis quickly become very supportive of data sharing for research that will help improve treatment or find a cure. The layers of 3rd party consent need to be replaced with a simpler system, either focussing on direct patient consent, or via the new UK Research Data Registry.

301. For the UK's new Integrated Care Systems (ICS) to work for health promotion, we will need to build a more integrated digital and regulatory pathway for tracking the UK's chronic disease 'co-morbidity' patient base, and especially where mental and physical health problems contribute very adversely to outcomes in long term conditions such as diabetes, COPD and cardiovascular disease. The optimal treatments for these conditions (and hence the necessary clinical trials) are likely to involve multi modal therapies involving a combination of diagnostic, drug and digital devices.

**Proposal 11.3: Develop a network of Our Future Health digital patient portals to encourage engagement and uptake of Clinical Trials by patients with a patient default 'Opt-Out' of medical research process.**

302. The MHRA and Health Regulatory Authority (HRA) should actively work to facilitate patient recruitment by allowing the use of CPRD and all other NHS and public health datasets and registries to support trial recruitment with the overall goal to make 60 days to first patient recruitment the new UK standard.

303. Stakeholder engagement with medical researchers has highlighted an increased pride and support in the UK's medical research following the Oxford / AstraZeneca success. For the UK to capitalise on the 'national spirit' and to drive increased patient interest, we suggest the Government:

- a. Ensure the new regulatory framework actively supports new ways for people to engage in trials through enhancing the '**Our Future Health**' programme with **digital patient portals**: to join up the wellness side of the digital landscape (see Digital Health - section 12) with the "disease" side of the patient journey pathway.
- b. develop a new **patient 'Health Research Opt-Out'** of medical research instead of opt-in, which would immediately boost the number of potential patients available for clinical trials. Stakeholder engagement highlighted that this needs to be linked to the proposed central dataspine and increased data flows (see proposals 11.8 & 11.9). By linking to the dataspine it ensures the system has the ability to proactively identify patients for trials, either through geographic location or disease filters.

304. By combining increased data flow (see proposal 11.8) with the digital portals, this system can give people the chance to enrol in clinical trials. The UK Government needs to support and actively encourage patient engagement as a key part of its 'bottom up' data flow proposal, to enable clinical trial organisers to be able to link directly with patients who volunteer.

**Proposal 11.4: Reform Clinical Trials Units to ensure they standardise patient recruitment across Trusts and incentivise trial delivery through use of the National Costings Template.**

305. Reforming the current Clinical Trials Units within NHS Trusts can also provide an opportunity to increase patient recruitment. There should be a simplified, time-bound and consistent process for the initial assessment of 'capacity and capability' of NHS Trusts to participate in specific research, which are collaboratively developed and then mandated for use.

306. The core elements of the National Costings Template should be the norm, with deviation only in exceptional circumstances. Finally, there should be a standardised process for patient recruitment, which should then also be mandated in every trust which is able to take part in Clinical Trials.

### *Trials Approval Process*

307. The UK should look to incorporate the speed of the Australian model<sup>85</sup> of 'Human Research Ethics' approval by requiring organisations to register and provide transparent reporting supported by specialist professional committees with detailed knowledge of specific areas.

**Proposal 11.5: Simplify and accelerate NIHR adoption and peer review process for trials that are fully funded with standardisation of costing tools across academic and commercial trials.**

308. Improving the approval process to start a clinical trial, and the process and stages of the clinical trial itself, are all vital importance to unlocking the UK's opportunities in this sector.

**Proposal 11.6: Streamline clinical trial set up by HRA adopting automated AI or digital processing of ethical and trials approvals.**

309. The Health Research Authority (HRA) should continue to develop a single combined application system, to improve the administrative process for researchers looking to initiate health and care research, aspiring to a long-term goal of a 15-day approval standard for simple protocols and a 30-day standard for those that involve complex, innovative design.

310. HRA should also look to adopt automated AI/digital processing of ethical approvals where possible to streamline the ease and speed of the clinical trial set up process. This should include simplification of the R&D review processes and approval (e.g. single radiation assessment, single pharmacy review, single costings review). The HRA was designed to do this, however there are still substantial delays between each hospital, repeating local reviews which should be done at a national level.

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<sup>85</sup> <https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees>

**Proposal 11.7: The MHRA and HRA should accelerate the adoption of novel clinical trial processes through better digitising of trials applications and data and use of novel models like UK Trials Acceleration Programme (TAP) and IMPACT with the capacity to deliver registration level trials.**

311. The HRA should also continue to support novel models for accelerated clinical trial delivery. Examples include integrated trials acceleration models, such as the UK disease specific trials network, the Trials Acceleration Programme (TAP) and IMPACT, one of only two transplant trials networks in the world.
312. It should also support the implementation and promotion of digital methods for trial delivery (e-CRFs, electronic Site File Management, e-consent, e-PRO, apps etc) and encourage phasing out of paper-based systems in order to retain speed, efficiency and competitive edge in the UK.
313. Finally, it should invest in novel trials acceleration models (e.g. academic CROs (Hovon, Lysarc etc)) which consist of an enabled hub and linked disease specific UK trials network with embedded and funded research nurses in each major hub.

### *Data and Data Flow*

314. The multiplicity of barriers to the flow of health data across the UK healthcare system is fast becoming the single biggest barrier to the competitiveness of the UK clinical trials sector (it is worth noting that the Recovery trial required the suspension of standard GDPR processes to accelerate the process of vaccine R&D).
315. The fragmentation of healthcare data across various different administrative systems which do not always communicate or allow the sharing of data is acting as a major barrier to clinical trials reform and improvement.
316. Regulatory reform to increase the flow and use of health data for medical research and clinical trials is a core aim of our proposed new UK Regulatory Frameworks for Clinical Trials and post GDPR data regulation. This can be achieved by reforming current organisational and governance data flow restrictions, alongside increased patient engagement of their data.

**Proposal 11.8: Replace the Caldicott data guardians with a HRA Single Data Controller 'One-stop shop' for Health Research Information Governance with harmonised committees to reduce bureaucracy and standardise processes.**

317. GDPR has become a barrier to the use of data for purposes that many people would view as being genuinely in the public interest, such as medical research, improving patient safety and improving standards of care.

318. For example, before GDPR, the Danish Cancer Society analysed 358,403 Danish mobile subscribers by processing Social Security numbers, mobile phone numbers, and the National Cancer Registry. The study proves that mobile phone use is not correlated with brain cancer. The information was not collected for the express purpose of the study, so it is not clear that it would have been possible had GDPR been in place.
319. Under GDPR, organisations must have the ‘consent’ of the data subject to process its data, unless it is processing it as a legitimate or public interest. But it is challenging for private healthcare and research bodies to rely on the public interest legal basis for processing. Equally, to rely on legitimate interests, research organisations would need to show that their interests in processing the data outweighed the rights of data subjects. This is not straightforward and data controllers need greater certainty about when it would be appropriate to rely on the legitimate interests processing condition.
320. GDPR should be reformed to reduce barriers to the use of data in the public interest in areas such as patient safety, drug testing, health research, improved NHS performance and standards of care. What constitutes ‘public interest’ must be defined and should, at a minimum, include data processing and sharing by public authorities, healthcare and research organisations for public good. Data stewardship could help ensure purpose limitation. Respecting individual privacy rights, while protecting broader public health and research needs obviously requires a careful balancing act which the Government would obviously want to consult on. It is vital that there is a strong patient and research charity voice in any consultation so that the interests of the people with the most direct interest in unlocking barriers to improved medicine are at the heart of the new framework.

**Proposal 11.9 Establish a centralised health dataspine, where all data is stored for ease of access by approved users across the health network, with standardised format and approval routes for data collection and curation.**

321. The clinical trials landscape needs to be transformed such that there is a single, well-funded, national online dataspine, which acts as a centralised and organised database, where data can be accessed by multiple systems. This would enable clinicians and researchers to find, recruit and provide follow-up services; incorporating and linking a wide range of existing datasets; and enabling a streamlined approach to identifying individuals and cohorts of patients. In other words, there should be a single location for data providing a longitudinal dataspine from primary care through secondary care to clinical outcomes, covering multiple specialities.
322. This needs to be supported by staff who have up to date digital and information technology skills that potentially don’t come from a direct clinical background. There is a need to drive the digital skill set within the MHRA to support this.



323. A UK health research dataspine would provide a fertile environment for increased use of digital biomarkers and registry based randomised clinical trials, which are highly efficient, easy to set up and much cheaper to deliver.

324. Given the fast pace of medical and technological advancement, any proposed reforms need to be futureproofed. The UK needs to ensure that the NHS Horizon Scanning Unit, which is responsible for identifying future trends and potential medical issues, is connected to the dataspine. The data it provides needs to be available for the life science industry, clinicians and researchers to access.

325. The health research dataspine needs to be embedded in the NHS to ensure benefits for clinical care, research, and trials. The role of the registries in this should not be underestimated. The international collaboration between the CV registry in NICOR and the world-leading group in UCR Sweden has just delivered the first registry based randomised clinical trial, sponsored by AstraZeneca, which is a transformational approach. This a huge opportunity for UK competitiveness in the global trials sector.

**Proposal 11.10: Reform the ICH GCP Guidelines 1995 to embrace the latest novel digital and biomarker end points, and replace 'standard of care' control arms with 'synthetic control arms' derived from RWE (Real World Evidence) and RWD (Real World Data).**

326. Ideally, there should be a single Health Research Data Controller overseeing this dataspine (as discussed in proposal 11.9 above), rather than four currently responsible for health research data. If that is not feasible, then there should be delegated authority for one controller to act on behalf of multiple data controllers and share information as required, taking a balanced approach to risk, building on the work of the HDR UK Data Alliance.

327. This would also support clinical research. Currently researchers need to ask permission from all the data controllers for onward data sharing. A single Data Controller would help speed up research data sharing.

### *Novel biomarkers*

328. Biomarkers are key to translational research, especially in cancer, by bridging basic and clinical research medicine and providing important biological indicators of disease progression. Biomarker methodologies allow hypotheses developed in the basic research environment to be tested in the clinical setting. Conversely, analyses of well-collected and annotated collections of clinical samples, particularly using large series and high-throughput technologies, allow hypothesis-generating research that can reveal new insights into cancer biology.

329. In addition to exploiting and informing basic clinical research, biomarkers are critical to decreasing (for instance) cancer incidence and improving the lives of people who

have cancer. The final stage of biomarker research is qualification, after which a biomarker or test can be used routinely in the general population or clinical setting.

330. As many medicines move towards the use of targeted therapies, biomarkers will become increasingly important because they:

- a. can help identify the best drugs faster;
- b. help to ensure that the right patients receive the right drug;
- c. provide "proof of mechanism" for drugs in development;
- d. reduce late stage attrition and thus unnecessary cost by enabling those drugs that are likely to be suitable for final stage development to be identified earlier;
- e. support studies of optimal drug combinations;
- f. are key to proving whether existing agents could be used more effectively;
- g. accelerate drug approval by identifying robust correlates of outcome.

331. Consequently, biomarker discovery is complementary to drug discovery in the development of personalised medicine. This needs to be clearly recognised in the MHRA's strategy going forward, and should be a first priority of the newly established Regulatory Innovation Hub (recommended above).

332. Now that the UK is seen as a third country by the EU, there are additional regulatory requirements for the import and export of human tissues and cells. Some developers are reporting having experienced delays due to documentation requirements, the procedural pathway of some EU member states and some authorities insisting that they audit cell collection facilities (which are approved by the Human Tissue Authority - HTA). The UK should ease regulations and engage with the EU to streamline the processes exporters are asked to complete.

333. New and innovative technology and the development of production of human tissues and cells for medical research has been identified as an area where there are future possibilities for medical research that can drive clinical evidence. The UK should look at further support and improvements to the HTA so that it becomes a world leader in any future opportunities relating to tissue and cell development.

334. RWE (Real World Evidence). The complexity of many trials can be reduced and trials themselves can be greatly accelerated, by replacing 'standard of care' control arms with 'synthetic control arms' derived from RWE and RWD (Real World Data). Such an approach has been highly successful in the cancer field and was behind the acquisition by Roche of Flatiron (provider of oncology RWE) for \$1.9Bn in 2018. Such synthetic control arms are not always appropriate, but where they are they can be transformational to the cost and pace of clinical research and patient recruitment. The scale and nature of the NHS makes it well suited to gathering RWE and RWD and being at the forefront of its use to enhance/simplify clinical trials. This could be a serious global opportunity for the UK.

**Proposal 11.11: Accelerate Access to innovation by establishing clear digital framework for Conditional Approvals and Adaptive Licensing of new therapies like gene therapies based on data including from the new Electronic Patient Recorded Outcomes Measure (EPROMs) dataspine.**

335. Having a central dataspine and single data controller must also be supported by increasing the available volume of data and the flow of data to ensure that the correct information reaches the right stakeholders. This will also help patients gain greater benefits from their own data. There are numerous options to support the UK Government to achieve this.
336. Firstly, we propose that to future proof the dataspine and place it at the centre of digital health that we mandate clear interoperability standards for all future digital programmes. This will enable the infrastructure to sit at the core of the digital health economy and provide a future foundation that is not squandered.
337. Secondly to support ease of data flow and use, we propose building on the Community Health Index (CHI) number pioneered in Scotland which has been a powerful illustration of the importance of a centralised patient data system that transcends organisational and governance silos and barriers. The CHI is a unique 10 digit patient number allocated either at birth or when a patient first enters the system, and is kept on the centralised CHI Register to ensure that relevant information pertaining to a patient's health is available to providers of care. Integrating the CHI with the NHS England equivalent and the NHS identifiers in Wales and Northern Ireland to create a UK Health Research Dataspine would be a huge benefit to patients and medical researchers in all parts of the UK and especially in the areas of rare disease where the key barrier to research and trials is lack of access to sufficient patients.
338. As part of populating the dataspine the regulator should look to create a UK equivalent of the Swiss National Clinical Trials Portal (SNCTP) and enable the results from all UK based clinical trials be uploaded to populate the portal. These should be generated by electronic medical notes systems compliant with part 11 of Title 21 of the FDA's Code of Federal Regulations. This will ensure the international acceptability and easy comparability of all UK-based clinical trial results.
339. However, it is vitally important that any proposed centralising of data for health research which includes patient or personal data needs to adhere to the UK's proposed GDPR and data reforms, outlined above in this report, with enhanced rights of ownership control by patients of their own data. If there is any potential negative association of the misuse of personal patient data, then patients will start to withhold their data and in turn undermine the proposed integration via the proposed health dataspine.
340. The UK should standardise all approval routes for how data is collected, curated and collated within the dataspine, so that patients and medical research charities can

have confidence that patients' rights are being properly respected and the patient voice put at the heart of the system.

### **Integrating care records using Northern Ireland's Electronic Care Record Programme (NIECR)**

Prior to 2013, the healthcare data of nearly 1.8 million patients in Northern Ireland (NI) was held in multiple disparate systems spread across the six Health and Social Care trusts in NI (HSCNI). This made the continuity of care and staff access to relevant and up-to-date healthcare information very difficult. To combat this, the NIECR programme, which was fully rolled out in 2013 following a trial in 2009/10, aimed to unite the numerous disparate systems across HSCNI into a single, web-based, easy-to use solution, displaying comprehensive clinically-relevant information that is updated in real-time and accessible from anywhere within HSCNI. The information provided in the Record includes demographics, lab and radiology results, medications, allergies, diagnoses, encounters and clinical correspondence.

In January 2018 the NIECR system recorded 700,000 user logins, and it is currently in use by more than 98% of clinicians, with 95% of NIECR users confirming that the platform has saved them time. As a result of its successful implementation, the NIECR platform won the 2014 HSJ award in 'Enhancing Care by Sharing Data and Information' and in 2016 the 'Building Better Healthcare Award' for best Administration, Information or Data System (eTriage).

### *Role and structure of the MHRA*

**Proposal 11.12: Expand the MHRA remit and Innovation Team to include promotion of UK leadership in innovative trial design, new accelerated access regulatory pathways, standardising format and approval routes for data collecting, curating and collation, and use of novel clinical and digital biomarkers and AI.**

341. Despite the MHRA's world renown and prowess in clinical trials, it has not yet made a substantial long-term investment in regulatory science and innovation in the clinical trials arena. This leaves the UK lagging far behind some of its key international competitors in its regulatory science capacity.

342. We recommend widening the MHRA's role, without in any way undermining its traditional expertise in assessing the efficacy and safety of new medicines and medical devices, to embrace a broader remit to promote UK leadership on Regulatory Innovation. The UK should build on the excellent 'Innovative Licensing and Access Pathway' model that the MHRA has launched in early 2021, and include the wider proposed reforms in this section.

343. **Development of UK skills in clinical research is key.** We have learned through the pandemic how much can now be done online. NIHR already has some online training courses in GCP such as NIHR Learn. However, these could be greatly expanded, supported and promoted, with online qualifications and CPD incentives enhanced. In parallel, online training for administrative, operational and management aspects of clinical trials and clinical research should be established and encouraged. This should be a national programme to spread 'best practice' and build a cross system network of informed and empowered 'champions' of clinical research, at a system level and at a local level, who are recognised, incentivised and empowered.

**Proposal 11.13: Set global Standards in Clinical Research Skills through a UK professional standard for clinical trials research nurses, clinical trial managers, data managers & clinical trials pharmacists**

344. The big opportunity for the UK now is in regulatory innovation. Technological breakthroughs in areas from AI to biotechnologies require innovative and agile regulatory approaches, but many of the UK's current regulatory frameworks were designed decades ago.

345. Stakeholder engagement identified that the MHRA needs to develop a stronger capacity and capability via its 'Innovation Team', which is currently viewed by industry as not reaching its full potential and requiring investment. It needs to develop a stronger capability, have a clear objective and remit to embrace both novel regulatory processes and the proportionate regulation of new technological innovations. To achieve this, we recommend:

- a. Create a standardised National R&D research medicine protocol process that sits within the remit of the MHRA-IT.
- b. Expand MHRA-IT remit, so that it is able to engage with various international trials platforms to help establish variations within drug classes for UK clinical use.
- c. Realign the 'implementation' and 'research' workstreams in the current process by running in parallel, overseen by the MHRA. Stakeholder engagement highlighted that there is a lot of process duplication. A parallel process could reduce a clinical trial by up to 5 years.
- d. Have MHRA-IT support novel Trial Designs and embrace novel approval pathways, embracing multiple staged points throughout the trial, rather than focusing on the current outdated method of one single end point.
- e. Be able to regulate AI as a medical device and set global standards for AI. (see proposal 12.5)
- f. Establish a 'gold standard' for skills training and career progression in clinical trials medicine, as the basis for unlocking global staff training revenues which would also tackle the staff shortages at the National Institute of Health

Research and clinical research facilities. This needs to focus on all staff which support the process, such as nurses, statisticians and data scientists and clinical trial managers.

- g. Establish a joint unit with MHRA-IT, NICE & NHSE to reform NICE Value Assessment and Procurement by integrating the trials, data and evidence to develop a pathway for assessing digital health & accepting digital clinical end points.
- h. Embrace 'digital biomarkers' that can sit alongside the traditional 'pure' biological biomarkers. The pace of health digitisation means these digital biomarkers can now be measured via digital devices such as portable and wearable diagnostic medtech, implantable devices or even ingestibles. These provide a whole new set of data that can support clinical trials and the MHRA-IT should set about developing a set of standards to help support their increased use.

### *Global leadership*

346. In recent years the global benchmark in accelerating clinical trials has been set by the US Food and Drug Administration (FDA). The UK needs to be more closely aligned with the FDA and US regulatory advisers (not just the FDA itself) and determine what clinical trials data that could be generated in the UK could add the most value in a US context.

347. Leaving the EU allows the UK to achieve much closer alignment to the FDA to ensure that UK conducted trials add real value to US regulatory submissions. The UK should have a global collaborative ambition, including working more closely with the FDA Clinical Trials Transformation Initiative to create a parallel process in the UK with huge potential to boost Anglo-US trials collaboration.

348. The UK has real opportunities to lead globally in new areas of medical regulation. For example in the mental health area, the US has no established Outcome Measurement Framework and hence very poor data on 'standard of care' from therapy treatment, which makes it very hard to conduct meaningful trials. Meanwhile the UK (mainly through IAPT) has established a robust 'outcomes framework' making it strongly set up for trials in, for example, depression, where standard of care data is known and consistent and where even synthetic control arms may be possible.

**Proposal 11.14: MHRA to work with stakeholders to establish a UK Regulatory Innovation Hub on the same model as the US Centers of Excellence in Regulatory Science and Innovation (CERSIs).**

349. The US is currently the world leader in regulatory science, with a well-funded network of Centers of Excellence in Regulatory Science and Innovation (CERSIs). These centres are collaborations between its Food and Drug Administration (FDA) and academic institutions, and are purposed with advancing regulatory science through



innovative research, training, and scientific exchanges. They focus on evolving areas of science and new ways to evaluate the safety and effectiveness of FDA-regulated products. This ‘hub-and-spoke’ approach has been shown to increase interoperability between the key stakeholders, and the UK should use it as the basis for its new pathfinder model.

350. The UK needs an equivalent of the USA’s CERSI network. There are a variety of ways this could be established, but a sensible and attractive option is for the MHRA to work with stakeholders to establish a **UK Regulatory Innovation Hub**. This hub would advance regulatory science to speed innovation, improve data informing regulatory decision-making, and accelerate public/patient access to novel healthcare technologies. It would aim to improve safety, helping businesses and accelerate trade, while protecting and promoting the health and wealth of our nation and the global community.

351. Digital access “spokes”: in addition to the central hub, which could cater for all general industry inquiries and needs, flexible and dynamic spokes should be established to explore the opportunities emerging from a subset of complementary key growth markets. Working with institutions with pre-existent clinical trials excellence, such as the research facilities at Birmingham and Oxford, these could include scalable ‘testbeds’ for accelerating validation of regulatory innovation before national delivery. This would have the effect of re-energising the ‘lit runway’ principles originally promoted through the Government’s Accelerated Access Review to support innovators working in the UK and provide proof-of-principle for other market or regulatory settings.

## *Cannabinoid Medicines*

**Proposal 11.15: Regulation of medical cannabinoids and medicinal CBD should move from the Home Office to DHSC / MHRA to create a regulatory pathway for assessment and approval based on patient benefit.**

352. There are two problems with the existing licensing rules.

353. The first is the current regime makes it very difficult for scientists in the UK to conduct pharmaceutical research on potential medical benefits of cannabinoids and medicinal CBD. International examples and leading scientists working in this area have shown that sensible, but limited, reforms to the current licensing process could unlock significant investment into UK medical research into cannabinoids for pain relief.

354. The second is the dichotomy that whilst there is in the UK a fast-growing, legal and well established consumer market for medicinal CBD for a range of pain and neurological conditions, current Home Office rules make it impossible for them to be produced here. This means that domestic consumers are relying on imported products and the UK is losing out on a c£1 billion medicines industry.

355. To resolve these problems, the Government should move the licensing regime for cannabinoid pharmaceutical research and CBD over-the-counter medicines from the Home Office to DHSC/MHRA and create a regulatory pathway for approving these products using an evidence-based assessment of their medicinal effects. At present this is prevented because the rules governing CBD medicines are not properly separated from the criminal law on banned substances derived from cannabis.
356. Our recommendations cover legal-to-use CBD medicinal products only. This report has focused on potential medical usage and does not recommend decriminalisation for recreational use.

## Digital health

**Headline Proposal 12: Establish a clear regulatory pathway for new digital health technology from approved health apps to integrated healthcare ICS system management to ensure the UK is at the forefront of the digitalisation of healthcare.**

357. Digitalisation is transforming healthcare through an array of new technologies with vast potential to help improve healthcare and medicine: from wearable tech and healthcare apps to AI and machine learning for medical research. The promise of Digital Healthcare offers much to our society and economy. Traditionally, healthcare innovation has often resulted in increased healthcare costs with each new drug or test adding costs to the system, slowing down uptake.

### The Benefits of Digital Health

- improved efficiency with costs being taken out of the system, which has proved notoriously difficult in healthcare;
- the opportunity to identify and measure (and monetise) savings as well as outcome improvements;
- the opportunity to quickly identify high-value opportunities like dexamethasone as a Covid treatment;
- the opportunity for incremental (iterative) improvements;
- rapid innovation in business models (as exemplified in other areas of the digital economy) to better share the value (and savings) from digital innovations across multiple contributors;
- the potential to deliver new treatments for health improvements much more rapidly than traditional life science R&D (months instead of years);
- the opportunity to tackle diseases which, whilst costing our society billions, have traditionally not attracted major pharma R&D: hypertension, obesity, depression, anxiety, IBS, as well as disease prevention and population health;
- the ability to measure contributions to improvements in disease outcomes across clinical pathways and eventually at an individual patient level;
- the ability to accurately measure health economic costs and savings across patient pathways, and make targeted interventions to prevent much higher longer-term treatment costs (for instance with mental health);
- the ability to measure savings and outcomes in the real world rather than just in controlled trials, and to share benefits from savings, and better outcomes across all in the system.

358. The health impact for patients can be transformational. One stakeholder roundtable reported a *9 month patient retention rate of 70% using digital health vs a patient retention rate of less than 5% face-to-face*. COVID-19 has shown the potential of

innovative ways of harnessing digital technology and can act as the catalyst for a much stronger engagement with digital health from patients and consumers.

359. Because of our integrated single purchaser national health system the UK is better positioned to address many of these challenges than other countries. It requires concerted innovation in our regulatory system.
360. But the digitalisation of healthcare in the UK is also immensely challenging for a myriad of reasons. These include privacy of personal information and medical data, doctor-patient confidentiality, differing professional and clinical responsibilities, standards of different providers across the patient journey, the inevitable politicisation of any debate about unlocking the value of data in the NHS and the complexity and burden of GDPR data protection regulations.
361. The UK's slow uptake in digital health is having a negative impact on the UK's ability to deliver effective healthcare and is restricting the UK medical research and clinical trials sector. It is also hindering investment in the UK's potentially huge business-to-consumer 'wellness' market for digital consumer health products, which is a global high-growth industry.
362. The long awaited and widely welcomed commitment to integration of Health and Social Care through the DHSC Bill will require fundamental digital integration of our hospital, GP and social care management systems. This will need regulatory involvement and leadership. Expanding the role of digital health with sensible reforms will be essential to achieving this.
363. The UK should now set out a new ambitious regulatory framework to support the fast-growing digital health sector to deliver health and care integration and better health outcomes. This needs to cover the current digital health landscape and also anticipate future advancements in AI and future digital technology.
364. Digital Health is a hugely competitive global sector, which the UK is in danger of losing out on: the new UK framework should focus on the areas that offer significant opportunities for the UK and NHS to leverage our existing assets in terms of Biobank, CPRD, Genomics England, Our Future Health, NHSx and the UK hubs of best practice, to maximum health and economic benefit.

## *Health Apps*

**Proposal 12.1: Remove the barriers to adoption of health apps by creating a new digital health regulatory unit within the MHRA, responsible for establishing clear digital interoperability standards and an integrated regulatory pathway for development of Consumer Healthcare Apps.**

365. The pace of digitalisation of consumer healthcare through apps and wearables like Fitbit, and the myriad of other similar products and services, creates a new regulatory reality in healthcare: consumers and patients are now in control of large amounts of their own health data.

366. The scale of the growth of consumer digital health also creates a new challenge for regulators: how to create a regulatory framework which:
- a. encourages greater health empowerment and health monitoring by citizens;
  - b. encourages greater integration of the health and care system;
  - c. balances the privacy requirements of patients with the data interoperability requirements of integration.
367. Reconciling these tensions by closing the gap between the growing digitalisation of personal consumer health and the continuing reliance on faxes and letters in the NHS, and creating a digital pathway for integration, should be a core aim of the new UK Regulatory Framework for digital health we are proposing.
368. Within this 'wellness' sphere there are large numbers of business-to-consumer software apps and wearable technologies, capturing a range of all round health lifestyle and activity data: calorie counting, exercise, temperature, heart rate, oxygen levels, etc.
369. The regulatory rules covering this relatively new and emerging area, including wellness apps, which do not claim to diagnose, treat or monitor a specific illness, are not yet clearly established. This is providing a barrier to integrating them into the health system.
370. Overall, this has created an unregulated grey zone, which has led to a surge in business interest and innovation, yet many may not meet the required technological and clinical standards of the more regulated 'health data'. Recent market studies have shown that some fitness apps and wearable technology are wildly inaccurate.<sup>86</sup> There is also very limited regulation in apps which are advocating potentially unproven health benefits. The UK should expand the current regulation to ensure that appropriate and proportionate standards are set. Discussions with industry have demonstrated some support of a certification of standards which they can advertise to consumers and patients. Clear standards could enhance consumer confidence and unlock further growth in this exciting sector.
371. The NHS has begun publishing<sup>87</sup> apps that people can download to manage their health and wellbeing. These are already screened by the NHSx Digital Technology Assessment Criteria (DTAC) to ensure they meet various standards. This is vital work and we would urge the Government to encourage deeper collaboration between the MHRA and NHSx DTAC to establish a globally competitive UK digital health approval pathway to make the UK a 'go-to' global sandbox for assessment and validation of digital health tools.

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<sup>86</sup> [Most Accurate Fitness Trackers: How Accurate Is Your Fitness Tracker Or Smartwatch?](#) Which? April 2021.

<sup>87</sup> [NHS Apps Library](#), retrieved April 2021.

**Proposal 12.2: Remove barriers to accelerate the integration of business-to-consumer digital health, and create a simple regulatory framework to help new companies develop tools that recruit, diagnose and treat otherwise hard-to-reach patients.**

372. Through the creation of a new MHRA Digital Health Unit the UK regulator should standardise assessment and certification of health apps and wearable technology to the benefit of the consumer; and provide a central point for business-to-consumer use of personal health data, by providing a clear regulatory standard.

373. The single biggest reform to drive UK leadership in digital health would be the linking of regulatory approval of apps to reimbursement – as now happens in Germany through the new digital health application (DiGA) rules which apply there. This puts a whole range of CE marked apps/products on the same prescribable footing as medicines, across multiple therapeutic areas. It legitimises a conversation with GPs, in particular about the benefit of patient engagement in their own care through the monitoring and rapid feedback that flows from apps on the patient's phone. The new UK Regulatory Framework for digital health should combine this level of approval with the UK Digital Technology Assessment Criteria for health and social care (DTAC).

### *Population Health and the Integrated Care System*

**Proposal 12.3: Remove barriers to local health prevention through the new ICS by establishing a digital framework for assessing Disease Cost and Population Health by each local authority area.**

374. Digital health – the integration of data across the patient pathway: from wearable apps monitoring basic personal health stats, to information on the extent and total cost of disease to an area or population – is fundamental to the creation of an effective system of population health management.

375. Digital platforms integrating data from the new UK Health Check are key to tackling the UK's huge chronic disease cohort in 'cardio-metabolic- respiratory' diseases: by offering the chance to drive new and regular interaction with patients in a way that a once a quarter physical check-up will not. This will also support the NHS by contributing to earlier diagnosis and intervention and fewer hospitalisations. Evidence shows big improvements in remote evaluation of patients in oncology and respiratory disease during lock-down which should be continued.

376. At the same time, the Government's long-awaited reform to integrate health and social care via the new Department of Health and Social Care Bill to create Integrated Care Systems (ICSs) will require a fundamental integration of management systems between social care and NHS.



377. This will require a fundamental process of integration of data: for both treatment and patient safety and the effective management and reimbursement of services.

378. At present, provision of both social care by Local Authorities and NHS services in a location is fragmented across various management and delivery organisations:

- a. NHS: GPs, CCGs, Community Care Trusts, Mental Health Trusts, Hospital Trusts and the ICS.
- b. Local Authorities: Adult Social Services, Children's Social Services, Benefits and Housing.

379. The creation of an integrated digital framework for bringing together NHS and Council data in a genuine patient pathway for integrated healthcare will be key to the successful delivery of this reform.

380. Digital health technology provides a platform for accelerating the integration of management systems and health and care diagnosis, treatment and outcomes data. Serious emphasis needs to be placed on the role of digitalisation as the key enabling technology platform for the creation of ICSs.

381. The MHRA should also be supporting the use of this wellness data by linking it with the wider Clinical Trials dataspine and increased data flow reform (see Proposals 11.8 and 11.9). There is an opportunity to have patients and consumers use their health and wellbeing data to help enrol in clinical trials and medical research.

## *System and Data Integration*

**Proposal 12.4: Reform GDPR to improve use of healthcare data by establishing federated models of data sharing and creating a joint sandbox between the ICO and the HRA.**

382. The digitalisation of the NHS has been a core goal of successive governments in the UK, with billions spent in repeated attempts to digitalise the NHS. These initiatives have all approached digitalisation from the top-down, and explained and communicated it to patients and clinicians essentially as a means to improve NHS efficiency, rather than as a fundamental component of better health, diagnoses, treatment and research with clear patient benefits. Embedding the new UK Regulatory Framework for digital health much more profoundly in patient benefit and patient rights (as advocated by patient advocacy groups like Patients4Data) will be key to unlocking the patient support essential for success.

383. Focusing on the patient benefits of digital health should not however reduce the urgency of the "operational" digitalisation of the NHS system to deliver the profound change and efficiencies available, for which several DHSC Ministers have advocated.

384. An example of this is the recently launched AI-based musculoskeletal triage service which uses a machine learning algorithm to triage patients. It helps identify those with

‘red flag’ indicators and those requiring in person treatment, while providing online support and advice for those with low-grade injuries. This technology should be expanded across the NHS to drive targeted access for those most in need and to bring down post-COVID-19 waiting lists. Reforms could also build confidence in patients, clinicians and wider healthcare workers that the UK is committed to the vital digital health sector and has the opportunity to become a world pioneer.

385. Roundtable discussions with stakeholders highlighted that digital health, including AI as a Medical Device (see proposal 12.5), needs to be integrated into the wider clinical pathway and accompanied by the regulatory changes set out above if any of these efficiencies are to be realised. Although regulatory reform is an integral part of advancement of digital health, it also requires embedding in the wider health ecosystem, confidence in use by clinicians, and support of patients to help develop this technology and support innovation.

386. A number of people we heard from proposed the creation of ‘federated models’ in which citizens and patients could sign up for healthcare organisations to have access to citizens data to facilitate learning healthcare systems research and health system improvement. Through a federated model, the different sources of healthcare data would remain on site, unaltered and uncompromised. It is only the final output of the data analysis that is shared within the framework under secure conditions which ensure legal compliance. For example, a Birmingham or Manchester Portal might use local patients data to inform research, clinical treatment, hospital planning and payment models, and influence the effectiveness of the overall healthcare demand and supply value chain. Citizens should remain empowered throughout, so no provider can prevent them from managing or accessing their data.

387. The Information Commissioner’s Office (ICO) and the Health Research Authority (HRA) should work together to provide a new joint test environment for companies to develop innovative ways to use health data for the benefit of both place-based health systems and cohorts of patients with a shared condition.

## *AI as a Medical Device*

**Proposal 12.5: Update regulations on medical devices to represent the latest technological advancements and to licence and adopt AI and AI software as a diagnostic device.**

388. Artificial intelligence (AI) is a term used to describe a range of software applications from the most advanced intelligent software to the application of massive data processing power to make sense of vast silos of data through to the specific definition of software with a level of sophistication that aims to mimic human cognitive functions.

389. Popular AI techniques include machine learning methods for structured data, such as the classical support vector machine and neural network, and the modern deep

learning, as well as natural language processing for unstructured data. Major disease areas that use AI tools include cancer, neurology and cardiology.

390. In all its forms, the application of AI is bringing a paradigm shift to healthcare, powered by increasing availability of healthcare data and rapid progress of analytics techniques. Across healthcare, AI gives us the ability to analyse large datasets of genotypic and phenotypic (disease treatment and outcomes) data across patient cohorts to help dramatically accelerate diagnosis and drug discovery. The use of intelligent software and BigData is a huge tool for patient safety – helping identify ‘outlier’ hospitals, surgeons or drug side effects. But it is perhaps in CNS and neuroscience – our understanding of the biological functioning of the brain and the neural and cognitive role of the central nervous system – that the ability to mimic human cognition has the most transformational application. In mental health, digital health platforms based on gaming software and AI-based neuro-cognitive functional assessment are now being used to create new ways of diagnosing and treating neurological disorders from Parkinsons to dementia to depression.
391. The growing importance of AI in medicine is leading to growing calls for AI to be recognised in its own right as a medical device.
392. Medical devices are defined in regulatory terms as products with a specific medical purpose, such as the diagnosis, prevention or treatment of an illness or injury, which it achieves without the use of drugs. Historically, medical device regulation has focused on hardware devices or devices with minimal software.
393. Recent digital developments in technology have led to a new generation of innovative medical devices that rely heavily, or solely, on software for their function. This has led to various regulatory changes to ensure current regulation reflects the latest developments, including the ‘EU Medical Device Regulations 2017’. In addition, the US FDA has a programme to reimagine the development of medical devices and the International Medical Devices Regulators Forum is leading on harmonising clinical evaluation of ‘Software as a Medical Device.’
394. In establishing our own regulatory framework the UK can now set our own Innovative Medical Devices regime to support this growing sector and anticipate the growing use of software and AI in medical devices. A framework of regulated digital products and devices needs a robust quality system for data management as part of the approval. This could be supplemented with some form of post-marketing surveillance (PMS) as one would see with traditional regulated medical devices.
395. There is a growing opportunity to use advancements in AI, primarily machine learning, to unlock new opportunities and growth. AI as a Medical Device (AIaMD) has the potential to address many large-scale health challenges, support human and manual diagnostics and reduce costs by lowering overheads and boosting efficiency.
396. We have heard a clear call from our sector roundtables that the UK should continue to lead by updating our regulations covering advanced software medical devices, and to pioneer the use of AIaMD to help unlock these potential opportunities and benefits, spurring innovation in the sector.

397. To support these opportunities, the UK should focus its regulatory reform on enabling increased sharing of data across the health economy, and to support companies in the use of available data to feed machine learning and algorithms that underpin current AlaMD. However, any reform must also focus on secure and appropriate use of data (see the section on GDPR above), so that patients can be confident that their personal medical data is being used securely.
398. The new UK 'anticipatory regulatory framework' needs to be forward looking and anticipate the new generation of 'adaptive algorithms' (ones that are regularly or continuously updating based on new data) and the advancements of 'live medical' data, where diagnostic devices provide current patient clinical data that can be used.
399. In other areas of AI use, such as facial recognition, there has been implicit bias against certain sectors of the population. Regulatory reform must be robust to ensure that any AlaMD is equitable, does not discriminate, and ensures confidence in the process to enable public support for its use. This in turn will drive uptake of new technologies and help drive future innovation.
400. The MHRA is already leading in this area with its Software Group Devices. There is the potential to expand this work further and regulatory reform should build on this foundation by resourcing and empowering the team to be at the centre of AlaMD.
401. Similarly, AlaMD needs to be drawn into the wider clinical pathway regulatory changes that are discussed above as confidence in use by clinicians and patient support will help develop this technology and support innovation.

## *Mental Health*

**Proposal 12.6: Remove the barriers to mental health apps by accelerating the integration of business to consumer patient wellness apps like IESO Healthcare with clinical neuroscience research networks like the Case Register Information System and NIHR research databases like Incliseran to create an integrated UK digital health spine for mental health.**

**Proposal 12.7: Extend the IAPT outcome measurement framework (or an IAPT like framework) to Children and Young People and to other therapeutic interventions (e.g. drug treatment) to be able to compare drug and non-drug therapy and conduct multimodal trials.**

402. One of the 'hard-to-reach' patient cohorts in which digital health platforms have been shown to be particularly effective and valuable is in mental health. Digital health advancements can support diagnosis and help with treatment and research in hard-to-reach therapeutic areas like depression, anxiety and a range of psychiatric and neurological disorders. This is a massive area of unmet need in which digital health can play a big part. It is also an area with an increased focus, due to recent advancements in diagnosis and treatment within the sector, and an increased understanding within the population.

403. New digital service providers in mental health such as IESO Health (formerly Psychology Online) which has incorporated novel games based technology platforms and user interfaces; and business-to-business ventures like SilverCloud Health, a provider of mental and wellbeing programmes, illustrate the growing opportunity for UK leadership in digital mental health services. These services support patients by using self-reported data and guidance. A simple regulatory framework is needed to support these innovative companies in their efforts to diagnose and treat otherwise hard-to-reach patients.
404. To establish an integrated framework for digital health we need to extend the Improving Access to Psychological Therapies (IAPT - the service that provides cognitive behavioural therapy to NHS patients - outcome measurement framework (or an IAPT-like framework) to Child and Adolescent Mental Health Services (CAMHS) - mental health provision for children and young people - and to additionally apply the assessment methodology to other therapeutic interventions (e.g. drug treatment) to be able to compare drug and non-drug therapy and conduct multimodal trials.
405. Crucially, we need to measure engagement levels of mental health app therapy and create a framework that supports public and patient engagement. We should aim to be in the vanguard of this, especially in relation to mental health comorbidities with long-term conditions (diabetes, IBS, COPD, CHF, Hypertension, cancer) which have a major impact on outcomes.

## Agri-environmental innovation

*Unlocking UK leadership in clean, green modern farming to produce food to the highest standards and protect rural biodiversity and habitats*

**Headline Proposal 13: Replace EU rules with an integrated agri-environment framework which better supports the development of more environmentally sustainable agriculture, with proportionate and evidence-based, outcomes-focussed regulation.**

406. Our departure from the Common Agriculture Policy (CAP) creates a major opportunity for the UK to be a pioneer in agri-environmental innovation: developing and exporting to the world the innovative approaches to agri-environmental best practice on which the UK is already leading, and which the challenges of climate change, habitat loss and falling UK agricultural productivity make even more urgent.

407. We believe the UK has a major opportunity now to develop bold global leadership in agri-environmental policy based on a number of key principles:

- a. Not only honouring our environmental commitments in the EU Withdrawal Agreement, but seeking to go further faster than the EU in showing how commercial agriculture can put habitat and environment at its heart.
- b. Accelerating UK leadership in carbon sequestration and low input and high output agriculture.
- c. Harnessing the power of the market and consumer power through clearer metrics and labelling.
- d. Building on the Government's new Environmental Land Management framework.
- e. Reforming the way agri-environmental regulations are implemented on farms so we focus more on outcomes, rather than input.
- f. Creating a framework which encourages greater private investment in biodiversity.

408. Our departure from the EU and the establishment of a new post-EU system of farm support framework for UK farming is the biggest change to UK agriculture since 1947. The combination of rising global food demand, the urgency of the need to reduce carbon emissions, growing consumer interest in food and farm welfare standards, provenance and food labelling, and the urgency of habitat and species conservation make this a generation-defining moment for reform.

409. Having rightly guaranteed that Brexit would not involve reducing UK food or farm standards, the Government should be bold in putting in place a better system of integrated agri-environmental regulation, to replace the EU framework. The new approach should incentivise and attract private sector investment in innovative agri-tech, biodiversity gain, habitat, landscape, whilst ensuring the highest safety and environmental standards.

410. The Environment Bill, which is currently making its way through Parliament, provides powers which will enable the Government to review and consolidate the number of



environmental regulations with which businesses must comply. It will also enable the Government to make other important regulatory improvements, particularly with regard to licensing. Once the Bill has been passed the Government will be in a position to make progress on reforms to environmental regulation that operate more efficiently but continue to promote ecological outcomes and maintain high standards.

411. The Environment Bill makes provisions for Defra to develop and publish a suite of indicators and metrics to measure environmental change to track long-term progress. While the Government's 25 Year Environment Plan refers to the ongoing work to define and create these metrics,<sup>88</sup> we need progress on a robust system of metrics for both the environment and agriculture. Once established, this can provide data to enable consolidation of regulatory requirements, and even deregulation.

412. These metrics should draw on existing work on indicators, taking into account sustainable agriculture and ecological standards, and should be developed in conjunction with stakeholders across the sector, including consumers, retailers, academics, farmers, agri-environment investors and environmental groups. The 2020 report from the Agricultural Productivity Working Group to the Food and Sector Drink Council<sup>89</sup> made a number of sensible recommendations for key performance indicators which should be seriously considered.

413. The Government should promote these metrics through international engagement on global standards for agrimetrics, for example in discussions of reform of the Food and Agriculture Organization of the United Nations Sustainability Assessment of Food and Agriculture systems (SAFA).

#### **Proposal 13.1: Promote a flexible, market-based trading system for biodiversity offset credits.**

414. As we leave the European Union, we have a significant opportunity to change the UK's approach to managing land so that we provide better protection for nature and wildlife, as well as boosting our efforts to combat climate change and pollution. Development for housing, commercial, industry, and infrastructure makes a significant contribution to land use change and to the loss of natural habitats that reduces biodiversity. The State of Nature Partnership<sup>90</sup> rates development as one of the greatest pressures on biodiversity, with significant losses in biodiversity, including the extent and quality of habitat, over the past 50 years. Furthermore, habitat loss often occurs most rapidly near urban populations, where natural capital is most valuable.

415. Biodiversity offsetting can, if properly created and managed, be a useful mechanism to better protect nature and help the UK meet its Net Zero targets.

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<sup>88</sup> [Measuring environmental change - draft indicators framework for the 25 Year Environment Plan](#), December 2018.

<sup>89</sup> [Agricultural Productivity Working Group, report to the Food and Sector Drink Council](#), February 2020.

<sup>90</sup> 2019 report from the [State of Nature Partnership](#) group of conservation and research organisations.

416. The biodiversity net gain (BNG) initiative is due to be introduced by the Environment Bill.<sup>91</sup> This will mandate around 10% net gain through the use of a specified biodiversity metric, based on both the area and quality of habitat which is disrupted by development. Developers will have the option, once mitigation hierarchy has been demonstrated, to pay for the offset of remaining units through a biodiversity units market. It is important that there are sufficient biodiversity credits in circulation before their use is mandated, to ensure that building work is not delayed.

417. We welcome the BNG initiative and urge the Government to look for ways to refine this scheme. They should avoid leaving this all to Natural England licensing. Instead a more dynamic market based model should be embraced, creating a market for BNG credits (based on quantifiable metrics), unlocking innovation and investment.

418. The right flexible and market led system in this space could see the UK both pioneering sustainable agriculture and the global leadership in financing, metrics, standards and environmental agri-tech innovation.

## Australia

In Australia, offsetting frameworks are encouraged at the federal level under the Environmental Protection and Biodiversity Conservation Act 1999, and reinforced by planning and conservation laws in a number of States and Territories.

In 2002, the Victorian government introduced BushBroker®, a system to establish, register and trade native vegetation credits. Under this framework, landowners register their interest in being credit providers. Developers subsequently approach BushBroker® when they need to find an offset. BushBroker® registers all transactions and creates the initial credits by recruiting landowners and conservation bank investors on payment agreement or land surrender schemes.

In the State of Victoria, there is no explicit legislation for habitat banking but offsets are a legal requirement to protect native vegetation as a prerequisite of planning approval. In New South Wales, a 'biobanking' scheme is regulated by the Department of Environment and Conservation (DEC), allowing developers to voluntarily buy credits to offset the adverse ecological impacts of their development as an alternative to existing threatened species approval schemes.

## Proposal 13.2: Implement with urgency the data sharing provisions in the Agriculture Act 2020 to unlock data silos in agriculture and the environment.

419. To address transparency in the agri-food supply chain, the Government should introduce reform to support data sharing in the agri-food sector, to open up data silos, so that different parts of the supply chain can share more data more easily. This is key to the development of integrated metrics for sustainability needed to help manage risk, promote traceability, minimise farm waste, and increase recycling. The

<sup>91</sup> [Biodiversity net gain and local nature recovery strategies](#). Impact Assessment from Defra and Natural England, October 2019.

Agriculture Act 2020 is a welcome step forward in this regard, and we would urge Defra to move swiftly in implementing the data sharing provisions it contains.

420. Wider sharing of data within the supply chain has the potential to deliver efficiencies in the agriculture sector. It would of course be important to ensure such sharing did not facilitate any anti-competitive practices, however these proposals were agreed by Parliament as part of the Agriculture Act 2020, and we believe that any stakeholder concerns over implementation can be worked through.

**Proposal 13.3: Develop a comprehensive system of environmental metrics for sustainable agriculture, incorporating the environmental impacts of a production system from field to fork, to support clearer food labelling.**

421. The agri-environmental policy agenda has historically been dominated by an incorrect presumption that productive farming cannot be environmentally sustainable. This is changing fast with a growing recognition and major investment by the agricultural and food sectors in 'farm to fork' metrics to properly measure the environmental impact of a crop or food product line. This is key to helping consumers make enlightened choices, by ensuring that these metrics are able to be clearly displayed on food labels.
422. However, these sustainability metrics are also an important part of a modern regulatory framework that incentivises industry to develop more sustainable supply chains. The UK has a huge opportunity to lead this next agricultural revolution by using our post CAP freedom to pioneer a new farm support regime which rewards genuine environmental enhancement and empowers consumers to make informed choices about the food they buy. In the UK Agri-Tech Strategy 2014 the UK made a big move towards this with the funding of a UK Agrimetrics Data Hub at Rothamsted. However, progress needs to be accelerated.
423. The Agriculture Act 2020 provides a legislative framework for replacement of the EU Common Agricultural Policy in England. It includes a range of powers to implement new approaches to farm payments and regulation that should work better for the UK than the restrictive CAP. In England, this will be based on the principle that farmers will be paid to produce 'public goods' such as environmental or animal welfare improvements. The Act also includes wider measures, on fairness in the agricultural supply chain and on the operation of agricultural markets which we believe will be implemented to provide a more effective, proportionate and efficient regulatory framework than the one we have inherited from the EU.
424. Unnecessary regulations are already being removed from the agriculture sector in England. For example, CAP 'greening' requirements have been lifted, as has the 'three crop rule'. However, the UK agriculture regulatory picture is still too complex, with multiple non-departmental public bodies responsible for the oversight of numerous regulations. As Defra noted in the November 2020 report, The Path to

Sustainable Farming: An Agricultural Transition Plan 2021-2024<sup>92</sup>, there is a need for better strategic and operational join-up between agencies. Defra should give urgent consideration to consolidating some of these regulatory functions, both in agriculture and the environment.

**Proposal 13.4: Develop a supportive regulatory environment to enable the development of and increased use of agri-tech to promote sustainable agriculture.**

425. In parallel to implementing the Agriculture Act, any system of support for agriculture must ensure that the regulatory environment is equally promoting and actively supporting the development of agri-tech. The UK Agri-Tech Industrial Strategy 2014 was a ground-breaking step: the first time in 40 years that a UK Government had recognised UK agriculture explicitly as a major strategic industry with a key role to play in tackling the wider UK productivity challenge.

426. The agri-tech sector is harnessing technological innovation across a range of sectors to increase the sustainable productivity of agriculture, producing “more with less”. The sector is rapidly growing globally as an investment class, with venture capital and companies investing in a whole range of agricultural innovations from GPS guided drilling rigs, SatNav guided tractors, variable pesticide spray applications (ie. only spraying where needed), to agri-robotics, carbon sequestration, hydroponics, nutraceuticals and gene editing. We go into further detail about the potential for drone technology in the transport and mobility section of this report above.

427. A number of these areas are whole industrial growth sectors in their own right, which, with a properly integrated regulatory environment that uses metrics to police and reward outcomes, can accelerate UK leadership in clean green sustainable agriculture. They can also create substantial exports and industrial synergies (for example the harnessing of synthetic biology and cell science for intracellular carbon sequestration).

428. With the right regulatory framework, the UK could be a leader in agri-robotics to help to reduce the sector’s reliance on seasonal labour that has been traditionally sourced from overseas. Greater use of inexpensive, reliable robotics for certain routine farm tasks could drive innovation in agriculture and create a new skilled sector.

**Proposal 13.5: Simplify compliance with environmental licensing and permitting requirements, with the aim of moving from a mechanistic compliance-based system toward outcome measurement.**

429. The existing environmental licensing and permitting regime, inherited from the EU, is complex, siloed in a range of government agencies, and costly to comply with. If we are to take the opportunity of making Brexit a moment for pioneering UK leadership

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<sup>92</sup> [The Path to Sustainable Farming: An Agricultural Transition Plan 2021-2024](#), Department for Environment, Food & Rural Affairs, November 2020.

in agri-environmental innovation we need to simplify regulation, moving from a system based on multiple “tick-box” compliance by multiple agencies to each farm, to a more streamlined and integrated approach which regulates for the desired outcome rather than input process.

430. The UK has an opportunity to streamline this system outside the EU, reducing the costs of compliance for business, but also maintaining environmental protection and driving environmental improvement. This simplification can be achieved in part by the streamlining of existing licensing and permitting requirements.
431. Defra are currently looking at how to streamline environmental licensing and permitting (ELP) to reduce the burden of compliance on business based on three principles, of flexibility (considering risk), clarity (making clear to regulators and business what regulations they need to comply with), and funding (reducing the costs of compliance where possible).
432. Consideration could be given to a requirement for larger entities to move towards corporate natural capital accounting (including for their supply chains), to inform business decision-making, and provide greater transparency on nature dependencies and impacts. Corporate Natural Capital Accounting has been trialled within a number of businesses and organisations, such as the National Trust, Crown Estate and United Utilities. This type of assessment uses ecological units (principally habitats) to appraise a range of benefits (ecosystem services) provided by the natural environment such as flood risk reduction, carbon sequestration and recreational opportunities.
433. The approach we have set out would help us to put a value on desired environmental outcomes (such as the number of recorded bird or flower or insect species). This can create the foundation for a new market for biodiversity investing and innovation in which it becomes commercially viable to buy low quality habitat and enhance it. Thus regulatory reform in this area has the potential to create a new substantial source of capital for agri-environmental investment and innovation.

**Proposal 13.6: Deliver a common-sense solution to transitioning chemical registrations from EU to the UK REACH.**

434. UK REACH is a new part of the chemicals regulatory regime for Great Britain and retains the aims and principles of EU REACH. Industry has long argued that EU REACH is prescriptive, bureaucratic and costly. UK companies have now sunk significant cost into compliance, estimated at £500 million.<sup>93</sup>
435. The UK proposed mutual exchange of data with the European Chemicals Agency (ECHA) database as a foundation to build an independent UK regulatory system, but the EU refused. This means that some 23,000 substances already in the EU REACH database are due to be re-registered with full data dossiers, in the new UK REACH

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<sup>93</sup> Analysis from the Chemicals Industry Association, provided to the Taskforce.



database. Industry estimates indicate that it might cost as much as £1 billion to do this.

436. We recognise too, that, without access to the ECHA database, industry's proposal that the UK should accept on to its market existing EU REACH registered chemicals, with a further process for substances of interest, has drawbacks. The UK's regulatory approach would be dependent on the limited data we can now access from EU REACH.

437. We believe that the Government needs to look again at this issue. As a temporary transitional measure, chemicals already approved under EU REACH could be accepted, but with a requirement to submit data when new evidence or substances emerge in the future. That would avoid imposing the considerable cost of re-verification of well-established chemicals, but also give time to carry out further work on a long term UK solution which avoids the obligation to duplicate data collected for EU REACH purposes. That could involve either streamlined new approval procedures or further discussions with the EU on accessing data held in their systems.

**Proposal 13.7: Introduce further exemptions to Annex XVII of UK REACH to allow the reuse of products in support of the UK's circular economy ambition.**

438. Increasing the life of products and incentivising their re-use where possible will be critical to achieving a circular economy.<sup>94</sup> Regulation must support this ambition. Annex XVII of UK REACH contains restrictions on the use of certain substances in products that are "placed on the market". These restrictions apply every time a product is made available to consumers, including when second hand. While sensible in principle, this restriction can make the re-use of products more difficult.

439. It is virtually impossible for charities and other economic operators to know or determine if a second hand product might contain restricted substances (e.g. certain phthalate plasticizers). These operators might therefore, for compliance reasons, abstain from engaging in re-use programs that promote the reuse of second hand products, or from accepting and selling certain goods. A good example of this can be found in the donation and reuse of some toys, which despite posing no hazardous threat and being rigorously tested to be made available on the market in the first place, are restricted by REACH regulations.

440. There are already exemptions for some second hand products. For example, entry 72 of Annex XVII of REACH contains exemptions for second hand textiles and clothing). To cut waste and drive the move towards a more circular economy, the Government should consider introducing similar exemptions for other products that do not present a risk to users.

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<sup>94</sup> Department for Environment, Food & Rural Affairs, [Circular Economy Package policy statement](#), July 2020.



**Proposal 13.8: Reform landfill surrender requirements to accelerate diversification away from landfill.**

441. The Government has set out the ambition for the UK to produce zero avoidable waste by 2050.<sup>95</sup> A crucial part of delivering on this ambition will be transitioning away from landfill. However, there is currently a lack of certainty over requirements for the 'surrender' of landfills. Environmental permits issued to landfill operators set conditions that are designed to prevent pollution and minimise human health and environmental impacts. 'Surrender' is the process by which a landfill site operator demonstrates through data that a landfill site, which they plan to close, no longer represents a threat to human health or the environment; and therefore does not need to be covered by the permit conditions once closed. Lack of regulatory certainty is tying up resources and inhibiting diversification away from landfill. The hazard-based approach contained in the provisions of the Landfill Directive is so restrictive that it is apparently discouraging any meaningful progress towards surrender for non-hazardous sites.

442. Clearly there needs to be a process to ensure that the environment is not significantly harmed by historic landfills and the Environment Agency should not surrender its control lightly. However, under the current requirements it is difficult to see how a non-hazardous landfill will ever surrender a permit with the current framework in place – none have to date. Instead operators continue to make permit subsistence payments to the EA on an ongoing basis, whilst the process for site surrender is too onerous and costly to be attempted, let alone completed.

**Proposal 13.9: Adopt a risk-based approach to waste regulation to drive greater re-use of waste products.**

443. The current regulatory approach to the classification of waste can be prescriptive and resource-intensive and can lead to unintended negative environmental outcomes, for example hindering the reuse and recycling of wood waste and incinerator bottom ash. Similarly, the re-use of waste materials is currently being hindered and entrepreneurs discouraged by an overly bureaucratic, prescriptive and confusing approach to the process for demonstrating that a material is no longer a waste and can therefore be sensibly used to minimise the reliance on virgin raw materials. Examples include:

- a. The reuse of incinerator bottom ash as a replacement for construction aggregate – in excess of 2 million tonnes per annum.
- b. The re-use of waste soils and aggregate for restoring quarries, used in developments e.g. noise bunds, landscaping – tens of millions of tonnes per annum.
- c. The re use of waste oils – circa 300 thousand tonnes per annum.

<sup>95</sup> Department for Environment, Food & Rural Affairs, [25 Year Environment Plan](#), January 2018.

444. The UK currently takes a hazard-based approach when determining what to classify specific waste materials. This process involves assessing substances based on their natural properties and determining what risks they could potentially pose on either people, the environment or both. This risk-based approach works by factoring in the exposure you would likely have to the substance. In the case of most products, exposure can generally be assessed in advance based on how the product will be used. If the risk is deemed to be great, it can be restricted under REACH regulations. A risk-based approach to product safety is common and generally seen as the most efficient and safest process.
445. A key waste challenge is uncertainty about final destination and use. This uncertainty means that we should exercise caution in any changes to hazard-based classification. However, there is scope for flexibility to be introduced, which continues to deliver on our environmental and safety objectives but adopts a more risk-based approach to how waste is managed. For example, the Environment Agency is already working with the waste wood sector on the reuse of incinerator bottom ash. This work should be accelerated, and other similar projects pursued.
446. The approach to regulating the re-use of such materials needs to be clarified and simplified, providing a path from the 'waste control regime' to the 'product control regime', while maintaining environmental protection to ensure its vital role in enabling re-use of resources and delivering the circular economy is fully realised.

**Proposal 13.10: Remove burdensome EU regulation on the animal feed industry, whilst maintaining rigorous safety standards.**

447. The UK currently follows a series of burdensome EU legacy regulations for animal feed which do not promote safe, environmentally friendly, or cost-effective feed. There are a number of suggested changes, supported by the Agricultural Industries Confederation, which could support the growth of the animal feed sector, including promoting novel technologies. Rigorous high standards must be retained for food safety but we believe that there is scope for reform which maintains and enhances food safety whilst also delivering a more efficient and proportionate regulation.
448. Retained EU legislation is currently a barrier to bringing innovative feed additives to the market. Additives include products such as vitamins, amino acids, and trace elements. There is considerable potential for UK livestock farmers to use additives that have proven environmental benefits (such as methane mitigation etc) in their feed. While it is right that there are clear standards about what constitutes animal feed, domestic legislation should be developed that would permit simplified efficacy requirements for claims made on animal feed. This could allow businesses to make data-supported environmental claims on labels, so farmers know the benefits of what they are buying. Such a change would require the amendment of retained EU legislation (Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition).

449. There is also an opportunity for the UK to regulate to allow innovative new proteins to be used for animal feed. There is already a great deal of interest in insects, algae and other single cell proteins that have huge potential for the bioeconomy. If UK based research on these proteins suggested they were not harmful to animals or humans (and many of these are already available for human consumption) some of these Single Cell Proteins could then be used as feed material for livestock. In order for the potential of these novel protein sources to be realised and innovation to be driven forward, retained EU legislation (Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001) should be amended to allow insect protein to be fed to pigs and poultry. It is currently only authorised for pets and fish. In addition to this the rules around what insects can be used as feed would also need to be reviewed.
450. Similarly, the classification and segregation of food waste should be reviewed to consider whether it should be updated to potentially include more categories of human food waste as feed materials. Again, the safety of humans and animals should be paramount, but we judge that this is the right moment to consider whether changes can be made. This review could consider the existing standards put forward by the European Commission's Product Environment Footprint Category Rules (PEFCR) methodology and the Global Feed LCA Institute (GFLI) database and consider what changes, if any, should be applicable to the UK.

## Agricultural genomics

451. The world faces the Grand Challenge of increasing global food production by 70% by 2050<sup>96</sup>, using the same land area but only half as much water and energy. There will be huge growth in the demand for bioscience solutions to improve agricultural productivity and secure a transition to biological, rather than chemical, methods of disease control. Developing new systems of agriculture which better preserve habitats, minimise energy use and methane production, and maximise carbon sequestration is a priority.
452. Breakthroughs in genomics, and our understanding of how the genetic code controls the characteristics of biological systems, are transforming healthcare. Delivering a COVID-19 vaccine in less than 12 months would have been impossible without the UK's world class genomic capability. There is a huge potential for us to grow our economy through research, commercialisation and regulatory standards in this bioscience revolution.
453. Genomics can deliver higher crop yields, improved plant health and better protection for the environment. It can promote naturally occurring characteristics, such as drought and disease resistance, reducing the need for expensive, environmentally undesirable (and often carbon intensive) plant protection treatments. Outside the EU we should harness the UK's long-standing strengths in agricultural science to lead in this new field.
454. The key elements of agricultural genomics (both gene editing and genetic modification, considered further below) are subject to a de facto ban in the European Union. Retained EU law has imported this ban on to the UK statute book. This locks our world class agricultural science sector out of big opportunities. Carefully calibrated regulatory reform could enable the UK to tap into a global market for agricultural genetics that is already estimated to be worth £17 billion a year. This technology has the potential to:
- a. increase crop yields, supporting the rural economy at home, promoting sustainable agriculture in the developing world, and making it easier to feed a growing global population;
  - b. reduce the environmental impact of farming by improving plant resilience and health, decreasing the need for harmful pesticides, and supporting nature recovery;
  - c. help tackle climate change, for example through cutting edge technology such as intracellular carbon sequestration;
  - d. develop a new range of industrial bio-energy crops;
  - e. develop foods with enhanced benefits for human health, for example through increased vitamin and nutrition content (as discussed in the nutraceuticals section below).

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<sup>96</sup> Global Agriculture towards 2050, [How to Feed the World 2050](#). October 2009.

455. Over the past two decades, there has been extensive public debate about agricultural genomics and any new post-Brexit system of standards and regulation must reflect this. In this context, it is important to distinguish between gene editing and gene modification. Gene editing (GE) is the novel process of altering small sections of existing DNA within an organism, resulting in changes to plant traits which could have occurred through traditional breeding. This new technology means changes can be delivered much more quickly than would be possible using the conventional approach. By contrast, genetic modification (GM) involves transferring genes from one organism to another, or around the same organism, and produces results which would not always be possible to achieve by natural breeding.

456. The EU's hostility to virtually all agricultural genetics has had some unintended consequences. Take, for example, the blight-resistant potato plant developed at the Sainsbury laboratory at the Norwich Research Park through the identification and transfer of a blight resistant gene sequence from a wild strain of potato to the cultivated potato species we grow today. The EU's very restrictive rules meant that the modified potato was banned, even though it would deliver important environmental and economic advantages: avoiding the need to spray each field with up to 15 applications of fungicide.

457. The EU's restrictive approach has had a significant economic impact. For example, in 2012 BASF, the leading German agrochemicals company, wanting to transition from chemical pesticide to biological pest control systems, moved its entire agricultural science division from Germany to the USA: a circa £10bn divestment.

458. The UK Government and the devolved administrations now have the power to create a new framework for agricultural genomics. The aim should be rules which maintain and strengthen consumer and environmental protections, and which are based on rigorous scientific assessment of any risk to health or the environment; but also enable us to seize the opportunities presented by this technology.

**Headline Proposal 14: The UK Government should actively support research into and commercial adoption by UK farmers and growers of gene edited crops, particularly those which help the transition away from agrochemicals to naturally occurring biological resilience.**

459. Outside the EU we should reform our regulation of innovative genetic techniques to help domestic agriculture reduce its dependence on chemical pesticides and cut its carbon footprint; and to grasp the economic and environmental opportunities set out in the preceding section.

460. The UK's world-leading food, environmental and animal welfare standards must be maintained. But we believe we can do that and still allow for a vibrant and successful gene edited crop sector, not least because the changes this technology delivers are ones which could potentially have been produced using traditional breeding methods which have been deployed for centuries. We believe GE technology can be used

safely and that the benefits it offers are so great that we should no longer keep the EU ban on it in place.

461. Crop innovation in the EU is severely hindered by the European Court of Justice 2018 ruling which makes no distinction between genetic editing (GE) and genetic modification (GM), de facto banning both. Now that we have left the EU, the UK should ensure that it is not bound by this ruling. Instead, we should adopt the Cartagena protocol definition which allows the interpretation that simple GE is not considered to be GM. This would mean that new plant strains that incorporate GE could be regulated as any other new variety.
462. Defra have recently consulted on agricultural breeding and genetics in plants and animals. The consultation mainly focuses on the regulation of GE organisms. Depending on the results of this consultation, Defra is considering whether to amend the definition in section 106 of the Environmental Protection Act 1990 to disapply this legislation to organisms produced by GE. We recommend that this work is progressed rapidly to encourage growth in the GE sector.
463. GE crops have the potential to deliver major benefits to human and animal health, by the promotion of traits such as increased vitamin and nutritional content. This can significantly increase the value of crops sold, bringing economic gains, as well as wider health and social benefits to consumers.
464. Allowing GE crops in the UK would signal the UK is back as a leader again in agricultural science and biotechnology. For many decades, the UK has been a powerhouse in agricultural science, with significant centres of deep scientific expertise in both the public and private sector, across the UK: from Aberystwyth to Roslin, Rothamstead, Norwich and East Malling in Kent. Allowing GE science in these centres to be commercialised would set the UK apart from the EU as a biotechnology innovation hub, and it would promote substantial inward investment. The export opportunities to countries already using gene technology could be huge.
465. Small businesses often struggle to compete with major plant breeding companies because current regulation disincentivises investment. A better, more flexible regulatory system could open the way for small businesses and start-ups to genetically edit crops which produce niche traits, presenting a big growth opportunity for UK farmers and growers, and UK global technology transfer.
466. There are some potential benefits for animal welfare in applying agricultural genetics in the UK livestock sector. However, given the understandable public and consumer sensitivity in this area, our proposals in this section relate solely to plant science which we recommend should be the Government's priority at this present time.

**Proposal 14.1: Interpret current GM rules on a case-by-case basis, to permit specific crops with proven benefits and which are consistent with the UK's rigorous standards on food safety and environmental protection.**

467. In our view, the future of agricultural genomics is in gene editing rather than genetic modification. GE is where the biggest growth potential lies. That is why the key



change we are advocating in this report is the liberalisation of the rules on GE crops set out in the preceding section. The issues relating to GMO genetic 'modification' are more divisive, complex and contested. Therefore, our recommendations in this area are more targeted and cautious.

468. Nevertheless, there may sometimes be circumstances justifying an exemption from the GM ban where an existing GM crop is able to offer significant environmental, health, or economic benefits. One such example could be the blight resistant potato, to which we refer above. This is ready for commercial use and would deliver significant environmental and economic advantages, through reduced pesticide use. Blight is estimated to cost farmers worldwide in excess of £3.5bn and is particularly prevalent in the UK.
469. Where there are specific crops like this which offer major environmental and/or health benefits (and for which there is not yet a GE alternative), we suggest that regulators in the UK should take a case-by-case approach to exemptions from the inherited EU ban. Clear and tough criteria would need to be established to determine when such exemptions could be made. A thorough evidence-based assessment, led by Defra, should be carried out in relation to the safety and environmental impact of the product. Any changes to the way such crops are regulated must be mindful of consumer concerns. They must be based on rigorous science and evidence, and they must ensure that the highest environmental and consumer safety standards are maintained.
470. This report has not considered the use of GE or GM with regard to livestock or animal health and welfare. We therefore make no recommendations regarding changes to the rules that currently apply in relation to animals and this area of science.

## The UK as a leader in satellites

**Headline Proposal 15: Through reform of the Space Industry Act, the Government should address the indemnity and liability issues currently holding back investor confidence in the UK as a satellite launch and operations hub.**

471. With more and more use of satellites for global transmission of data, the global space market is expected to more than double in size in the next 10 years, and be worth £400 billion by 2030.<sup>97</sup> The UK's space sector, which has trebled in size in real terms since 2000, currently captures between 6.3% and 7.7% of this global market, and now generates over £15bn in income. Space data and services alone underpin more than £300bn of our GDP. The Government has set a target with industry to grow our share of the global space market to 10% by 2030.
472. The UK has led the way for the 'NewSpace' industry.<sup>98</sup> However the field is now being exploited by other countries due to a combination of UK regulatory constraints and inadequate financial investment. Industry is clear that action is needed now to preserve, and build on, the UK's role as a pioneer in space technologies, including through regulation.
473. The UK's current policy, philosophy and machinery is seen by industry as a major impediment to growth in international trade in space hardware (satellites) and services (e.g. Earth observation for collecting data on weather and flooding, as well as communications). The balance the UK is currently making between protecting key capabilities (such as those relating to national security) and pursuing commercial exploitation is unduly cautious and risk averse. Without a change in approach, we risk losing the ability to influence markets and the associated loss of export value, which would reduce the UK's potential in this sector.
474. The UK has a strong position in the small satellite market and a laudable Government ambition to be a launching nation.<sup>99</sup> However, a key issue highlighted by industry is the liability requirements in legislation for satellite and launch operations in the UK. These requirements are viewed as discouraging investment and making the UK uncompetitive. Given the international nature of the space sector, businesses will simply look elsewhere for places to invest. This needs to be addressed. The Government has already acknowledged these concerns as part of a recent consultation of the Space Industry Act 2018. To address this, and unlock the full potential of this sector, the Government should consider amendments to this Act and additional guidance as detailed below.

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<sup>97</sup> [Space Sector](#), House of Commons Select Committee on Exiting the European Union. June 2017.

<sup>98</sup> NewSpace generally refers to the recent commercialisation of space operations by private companies such as SpaceX, when historically this was the preserve of sovereign states.

<sup>99</sup> [LaunchUK](#) is the UK Government's spaceflight programme with the stated aim to establish commercial small satellite launch facilities in UK spaceports from the early 2020s.

**Proposal 15.1: Amend the Space Industry Act 2018 to cap liability and indemnity requirements for licence applicants to launch and operate satellites from the UK.**

475. Section 36 of the Space Industry Act 2018 requires applicants for licenses to indemnify the Government for claims brought against it in respect of spaceflight activities. The terms of a license may specify a cap on this liability and, as we understand it, the Government intends for liability to be capped in this way,<sup>100</sup> with a limit on liability for standard missions set at €60m. However, businesses need to raise funds before a license is issued. Industry is clear that unless this provision is amended to introduce a mandatory cap on liability, UK license holders will struggle to attract sufficient investment or obtain insurance. Certainty that a cap on liability will apply, ideally by amending section 36 of the Act would give investors confidence and help in raising finance before licenses are granted. If a change to section 36 is not possible in the short term, guidance should make clear that all granted licenses will provide for a cap on liability and how this will be applied should be published.
476. Industry has also raised concerns about the strict liability for operators carrying out spaceflight activities provided for in Section 34 of the Act. This created a new liability to third parties compared with licences issued under the Outer Space Act 1986. In our view it was unnecessary to extend this liability to established satellite operators holding orbital licensees. It is a barrier which makes the UK less attractive as a base for orbital license holders.
477. Concerns were also raised with us about the third party liability insurance requirement of €60m per satellite for standard missions being disproportionate for small satellite launches. The Government should ensure that other models of covering third party liabilities can be used as an alternative to traditional insurance, such as a discretionary mutual fund, which can be owned and controlled by and for the small satellite industry. The goal should be to ensure third parties are sufficiently protected rather than to specify the way in which this should be done. This will enable greater competition in the market by making smaller launches more viable, which is good for businesses, and for the UK.
478. In addition to addressing the liability issues in the regulation, the Government should accelerate efforts to introduce secondary legislation, licensing and a regulatory framework to implement the Space Industry Act. The UK has already set a goal of becoming a launch nation. Getting the associated regulatory framework in place could mean the first launches from the UK take place as early as 2022.

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<sup>100</sup> [Unlocking Commercial Spaceflight for the UK, consultation on draft insurance and liabilities requirements to implement the Space Industry Act 2018](#). UK Space Agency, July 2020.

**Proposal 15.2: Ensure the Civil Aviation Authority has the expertise to fulfil its new and additional responsibilities as a regulator for the space sector.**

479. The decision that the Civil Aviation Authority (CAA) is the UK's space regulator<sup>101</sup> creates challenges because of the CAA's historic focus on civil aviation, which risks holding back the Government's correct priority of getting a UK launch sector established. We propose that serious consideration should be given to whether the previous regime of air navigation orders should be grandfathered. In addition, the Government must ensure the CAA is properly resourced and has sufficient expertise to carry out its new responsibilities in addition to those it has as the regulator for civil aviation.

**Proposal 15.3: Develop an Earth Observation (EO) data regulatory policy framework.**

480. The Government should develop and publish an Earth Observation (EO) data regulatory policy. Currently, each export of EO data is regulated on a case-by-case basis, which industry say is lengthy and inefficient, putting them at a disadvantage to those in other countries. By creating a regulatory policy for EO, industry believe this would increase investment and increase the UK's competitiveness. Such a policy would need to be developed by the Government, and then enforced by the CAA.

481. The CAA and Ofcom should work together to ensure joined up and streamlined processes for companies in the space sector that need a license from both regulators, for example where a company needs a spectrum license from Ofcom and frequency approval from the CAA.

482. Finally, the Government should seek to make the UK the first country in the world to champion the 'space environment', namely: sustainability of space, sustainability in space and sustainability from space. The upcoming COP26 will provide an opportunity for the UK to show regulatory leadership in this area.

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<sup>101</sup> [Giant leap for UK spaceflight programme as consultation launches](#), press release as part of a Government consultation on Space Industry Act Regulations, July 2020.

## Nutraceuticals and the consumer health sector

**Headline Proposal 16: Create a new regulatory framework for the fast-growing category of novel health enhancing foods and supplements to promote investment in the UK as a leader in the nutraceutical sector.**

483. The pace of life science and broader bioscience research progress is driving huge growth in our understanding of the systems of both disease and health, and delivering a range of new products in the prevention and 'consumer wellness' space.
484. We are now seeing the emergence of an active 'nutraceutical' sector generating an expanding range of non-pharmaceutical 'over the counter' nutritional products with health benefits. There is also a growing understanding of the physiological basis for traditional herbal or plant based remedies and the development of innovative foods, from cholesterol reducing yoghurt like Benecol to Beneforte broccoli, and foods engineered to have specific health enhancing properties,<sup>102</sup> such as chia seeds engineered to be richer in  $\alpha$ -linolenic acid. In addition, there are food products sold as a supplement, and demonstrated to have physiological benefits or provide protection against chronic disease, such as pomegranate supplements intended to support DNA integrity and promote overall cell health.
485. Our traditional silos of regulatory classification (food / medicine / diagnostic / device) are being challenged by the pace of bioscience and technological convergence of biological and digital platforms.
486. Whilst an increasing number of GPs and specialist consultants have long supported this sector, nutraceuticals, supplements and herbal medicine have traditionally been viewed with scepticism by the mainstream medical and pharmaceutical establishment. As a result, the regulatory environment has tended to focus on pharmaceutical grade medicines, which are tested and approved through the full clinical Randomised Control Trial (RCT) process, while nutraceuticals and supplements are treated outside of any medical framework. However, science is starting to point the way to a new sector of nutritional products with increasingly explicable and/or verifiable medicinal benefits, which needs to be reflected in our regulatory framework.
487. Nutraceuticals are a huge and rapidly expanding economic sector led globally by corporate giants like Unilever and Danone and a growing ecosystem of smaller specialist suppliers. The sector is estimated to be worth £275bn globally<sup>103</sup> and £4bn

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<sup>102</sup>Lackie, John. 'nutraceutical' in *A Dictionary of Biomedicine*, edited by Nation, Brian. : Oxford University Press. 2nd edition (2019).

Bender, D. 'nutraceutical' in *A Dictionary of Food and Nutrition*: Oxford University Press. 4th edition (2014).

<sup>103</sup> [Nutraceutical Market Size, Share & Trends Analysis Report By Product \(Dietary Supplements, Functional Foods, Functional Beverages\), By Region, And Segment Forecasts, 2020 - 2027](#), Grand View Research, April 2020.

in the UK<sup>104</sup> at its broadest definition. In recent years we have seen increasing pressure for regulatory reform to create a much clearer, more consistent and reliable landscape for investors.

488. Currently, nutraceuticals are regulated, via retained EU law, to protect the consumer from fraud and false claims, and to ensure scientific standards are met.<sup>105</sup> The primary objective of this regulation is consumer protection. It is designed to stop businesses making spurious claims on products often sold at a premium price, that have minimal or no medical benefit. Regulation also sets standards to stop the sale of products which cause harm, such as unapproved additives, colourings or E Numbers.

489. Where a product like a food or a herbal remedy makes 'medicinal' claims, i.e. it claims to help cure or mitigate a disease, it is regulated in the UK by the MHRA. Where a food product makes 'health' claims, i.e. it claims to benefit your health more generally, it is regulated by the DHSC in England, by the FSA in Wales and Northern Ireland, and by Food Standards Scotland in Scotland. Industry experts have highlighted that this patchwork of regulators creates additional costs and uncertainty for businesses. They would like to see the relevant functions brought together in a central regulatory body and a clearer UK landscape. We are mindful that this is a devolved matter, and we are not advocating the creation of a new quango, but we urge the Government to find a common sense solution which creates greater certainty for businesses by tackling the complexity of the current regulatory landscape.

490. The pace of scientific progress, the rapid growth of the consumer health wellness market, growing consumer demand and health system pressure for increased focus on prevention is creating a number of problems. This has led to confused terminology, inappropriately polarised regulatory silos, a lack of consistency between UK/EU and other international standards, and the lack of a clear regulatory framework for assessing, verifying and authorising medicinal claims.

491. Leaving the EU presents the UK with the opportunity to explore the potential benefits of regulatory reform in the nutraceuticals and emerging consumer wellness market, to enhance health promotion & disease prevention. This will help create a stronger research evidence base on which to develop a more proportionate, permissive and innovative approach to regulation, with the goal of providing better protection for consumers and enabling the UK to develop a stronger industrial base in this new sector.

### **Probiotics**

492. Probiotics are foods containing live bacteria with beneficial properties for health. The value of the sector was globally over \$49.4bn in 2018 and is forecast to reach about \$69.3bn by 2023. In the UK the sector currently stands at only around £750m. As

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<sup>104</sup> [Europe Nutraceutical Market: growth, trends, covid-19 impact and forecasts \(2021-2026\)](#), Mordor Intelligence.

<sup>105</sup> Directive 2002/46/EC.



European regulation of food health claims has tightened, probiotic manufacturers have been required to provide stronger scientific evidence to support health claims. In July 2012 the European Food Safety Authority (EFSA) rejected health claims made by the probiotics industry, and made labelling extremely restricted. Despite its current limited size, according to Global Industry Analysts, Europe is the largest and fastest growing probiotics market, with Germany and the UK accounting for around 45% of the total EU market with annual growth rates of 10-12% quoted by various analysts.

### ***Enriched (Beneforte) Broccoli***

493. A number of leading global companies now see nutritionally enriched food like Beneforte broccoli as key to their growth plans. For example, Bayer, the agrochemical plant protection company, has made a strategic commitment to this sector seeking to deliver consumer benefits directly through food rather than simply focusing on increasing yields of commodity crops for growers. This whole area has significant implications for future nutrition and healthcare. Although Beneforte sales so far are modest, market penetration for a new variety can be relatively swift if it becomes the adopted standard. Seminis, owned by Bayer, supplies around 40% of world broccoli seed. Apio Inc, one of the largest North American growers and distributors of fresh vegetable produce, anticipates 100% replacement of conventional broccoli within five years.

### ***The Global Bone and Joint Ingredients Market***

494. The market size of the bone health ingredients market in the United States and Europe is projected to reach a value of over \$4bn by the end of 2024. DSM Nutritional products, ADM, BASF, Huber Engineered Materials, and Verdure Sciences are key players in the bone health ingredients market. In terms of market size, the joint health ingredients market is larger than the bone health ingredient in the United States and Europe earning \$600m in sales per annum. The most important ingredients represented in this market segment are glucosamine and chondroitin. Companies like InterHealth Nutraceuticals and Biocell Technology are active in the collagen peptides market.

**Proposal 16.1: Establish clear regulatory standards and definitions for 'nutraceutical products and create a permissive environment for regulation of products with accepted science outcomes, to form a new easier nutraceutical product regulation pathway.**

495. Despite good intentions, regulation as it stands is imperfect, with confusion and ambiguity over the terms used. 'Nutraceutical' (sometimes spelt 'nutriceutical') is a marketing neologism formed from combining 'nutrient' and 'pharmaceutical'.<sup>106</sup> The definition used above is only indicative as there is no industry-accepted, standard definition. It is both differentiated from and used interchangeably with a variety of

<sup>106</sup> The term was invented in 1989 by Stephen DeFelice. Aronson JK. Defining 'nutraceuticals': neither nutritious nor pharmaceutical. Br J Clin Pharmacol. 2017;83(1):8–19. doi:10.1111/bcp.12935.

other terms including 'dietary supplement', 'bioceutical', 'supplement', 'phytochemical', 'functional food', 'health food', 'medical food', food for 'special dietary use' or 'special medical purposes'.<sup>107</sup> Despite its wide use, the term is not referred to anywhere in current UK or EU regulations. This is an international issue and there is an opportunity for the UK to lead the way in setting clear, comparable standards for these terms.

496. Clear regulatory pathway and accepted, standard terminology needs to be established for foods of vegetal or animal origin which claim to perform a specific medicinal role in the prevention and treatment of pathological conditions. Some herbal medicines and remedies have a long and validated medicinal benefit. Currently the lack of official recognition of medicinal foodstuffs limits research, meaning they are in some cases under-scrutinised (depending on how they are categorised), which makes the UK an unfavourable destination to pursue development.

497. There needs to be a clearly linked pathway to market for foodstuffs making more generalised health claims. The importance of linkage is vital as currently regulation either recognises something as a food or a medicine, but not both. This disconnection causes innovation-stifling uncertainty, given the regulatory burden associated with crossing that barrier. The disconnection is currently embedded into the system because food regulations (overseen by the FSA and DHSC) only go as far as officially recognising food supplements with health claims, and the MHRA only officially recognises medicines (which stop being perceived as foodstuffs as soon as they achieve that recognition). This leaves a large, ambiguous grey area between food and pharmaceuticals which is hard to navigate. Current regulation fails to recognise the relationship between the two categories is more of a sliding scale than a binary split between two separate entities.

**Proposal 16.2: Encourage NIHR to gather data to support claims and enable research into products medicinal and health properties, lead on international standardisations and ensure a pathway to market, so that consumers are aware of the health benefits and better able to make informed choices.**

498. There needs to be a clear join up between the functions currently performed separately by the FSA, DHSC and MHRA. They need to work together to provide a single place of contact for companies interested in investing in this sector. We propose a new cross-organisational innovation office (which would link into the MHRA proposals in section 11) to provide a clear regulatory pathway for this sector. In addition, it could include guidance as to which category their suggested products would fall within, depending on their desired claims and pre-existing evidence. This could be linked to the central registry of Patient Recorded Medical Outcomes to inform the regulatory process with up-to-date evidence from consumers to help validate medical benefits.

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<sup>107</sup> Borchers AT, Keen CL, Gerswin ME. The basis of structure/function claims of nutraceuticals. *Clin Rev Allergy Immunol* 2016; 51: 370– 382.

499. A clearer framework and process to support innovations in this nutraceutical space would enable the UK to take advantage of and attract investment into this fast growing sector. Based on our engagement with academia, current regulators and businesses, it is apparent that there is significant opportunity for sensible targeted reform to enable the UK to maximise the benefits of the fast emerging nutraceutical and medical supplements sectors. Not only would the UK benefit from the medicinal and health outcomes, but reform would also encourage investment, innovation and growth.
500. These recommendations are not a call for lowering or weakening consumer protections or standards. By acknowledging a category of products which are not pharmaceutical grade medicines, but foods and nutritional supplements with health benefits, these reforms are designed to reduce barriers for genuine “nutraceuticals”. These health benefits must be either rooted in good science and/or verified by better evidence from a dedicated regulatory centre of excellence. In addition, better use of patient recorded outcomes would make the UK a leader in this sector, attract significant inward investment and growth to the UK, and improve population health.

## Further important reforms

**Headline Proposal 17: Deliver other targeted regulatory reforms to reduce the regulatory burden on businesses.**

501. This section of the report covers a number of targeted reforms that would remove unnecessary burdens on business, but which do not fit neatly into any of the various sectors we have considered. Whilst the proposals in this section are more limited in scope than some of the transformative changes we recommend for key growth sectors, they could nevertheless provide important economic benefits, for example where retained EU law can be removed and replaced with an approach more suited to UK's specific circumstances. As set out above, we urge government departments to conduct a thorough review of the enormous body of retained EU law to establish what further changes and repeals need to be made across the whole of the domestic regulatory landscape.

**Proposal 17.1: Amend the Weights and Measures Act 1985 to allow traders to use imperial measurements without the equivalent metric measurement.**

502. It is currently an offence under the 1985 Weights and Measures Act to use imperial measurement as the primary indicator of measurement without an equally prominent metric measurement for trading. This has long been identified as an example of overly prescriptive EU regulation, with notable prosecutions of small traders in the early 2000s.<sup>108</sup> This change would require amendment of the 1985 Weights and Measures Act through primary legislation.

**Proposal 17.2: Develop an optional e-labelling system for devices with screens or that can be connected to a screen, to display compliance information.**

503. E-labelling (or electronic labelling) is an alternative to physically marking devices to indicate market compliance. Many countries, including the USA, Australia, Singapore and Japan - together representing over 56% of the world's economy and 46% of the world's population - have already adopted e-labelling schemes.<sup>109</sup> In the EU, on the other hand, physical marking on devices is mandatory for most products.

504. Outside the EU, the UK has an opportunity to join other major economies by embracing e-labelling, reducing the cost of compliance with regulation for business and demonstrating how technology can be used to make regulation smarter.

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<sup>108</sup> See *Thoburn v Sunderland City Council* 2002.

<sup>109</sup> [E-labelling for Europe](#). Digital Europe, June 2018.

#### **Potential savings as a result of adopting e-labelling:**

In total, companies in the computing, multimedia and telephony sectors across Europe pay c. €4bn p.a on compliance. Indicating compliance information represents around 20% of that cost (c. €800m).

Digital Europe has estimated that the introduction and uptake of e-labelling could reduce the cost of indicating compliance by c. 15%, representing a saving of €112mn p.a.

505. This change would require primary legislation, and action from BEIS, the Office for Product Safety and Standards and market surveillance authorities. We recommend the relevant parts of government, working with industry, go ahead with a transition to e-labelling.

#### **Proposal 17.3: Repeal the Port Services Regulation 2019 (SI 2019 No. 575) to remove unnecessary, EU-derived regulatory burdens on UK ports.**

506. The 50 major sea ports of the UK are a successful and competitive private sector industry. In 2017, up to 70% of the UK's goods imports and exports flowed through sea ports, valued at £822bn in 2017.<sup>110</sup> Outside the EU, we have an excellent opportunity to ensure that the regulation of ports is tailored to reflect the UK's circumstances, rather than continuing to retain an onerous EU regime.

507. At the end of the Transition Period, the UK retained the Port Services Regulation (Regulation EU 2017/352, the 'PSR'). This is a prime example of EU regulation that is not appropriate for the UK's economic circumstance.

#### **Provisions of the Port Services Regulation:**

The PSR is designed to address transparency and competition issues arising from state ownership or significant funding of Member State Ports (e.g. Rotterdam, Antwerp and Hamburg).

The PSR applies to larger port operations in 43 areas of the UK. The PSR introduced requirements on port service provision and restricts how ports provide or allow for services such as towage, waste reception and bunkering. The Regulation also sets out rules on financial transparency and infrastructure charges.

The Government argued that the application of the PSR to the UK's ports was unnecessary as the PSR was being prepared. The UK voted against adoption of the PSR – the only Member State to do so.

508. UK ports already operate in a competitive environment and receive very little public funding. Competition between UK ports means that there are open and accessible service provision opportunities for suppliers, unlike some European nations where publicly owned ports do not have the same focus on a competitive tendering process.

<sup>110</sup> [Prospects for trade and Britain's maritime ports](#). Policy Exchange. July 2018.

509. The regulations establish rules on financial transparency which already exist elsewhere in the UK regulatory framework, and create issues for shipping companies, ports and port services providers. The rules require the Government to have a level of oversight which it has not needed in the liberalised industry. Current UK ports policy is very much one of market-led competition.

510. The cost to businesses created by the PSR is difficult to quantify. That is partly because some of the costs of the PSR, to the Government as well as businesses, would depend on the nature of any complaint being made under the PSR (to date none have), and whether a decision on a complaint were to be challenged. At the time the PSR was adopted, the Department for Transport, working with industry, estimated costs to be in the range of £2.2m to £8.4m per year. What is clear, however, is that an administrative burden is created by the regulations for no clear benefit.

511. The PSR therefore does not take account of the UK's market-led, largely private ports sector and commercial ports industry. It should be a candidate for repeal as an example of retained EU regulation that is not suitable to the UK's circumstances. To do so, primary legislation would be needed to repeal the 2019 UK regulations.

**Proposal 17.4: Liberalise parallel import laws to reduce prices and increase choice for consumers.**

512. 'Parallel imports' take place when traders who are not part of a manufacturer's official distribution system obtain the manufacturer's genuine products in a foreign market and import them 'in parallel' to products which are distributed through the official system. This is normally because that product is available at a lower price than the price at which the manufacturer makes its goods available in the UK.

513. As a result of EU regulation and subsequent judicial interpretation, IP right owners became entitled to prevent the importation of their own genuine goods into the EU where they had been placed on the market elsewhere in the world, in the absence of explicit consent to their being re-sold into the EU. This has allowed brand owners to maintain differential pricing structures to the disadvantage of consumers.

514. The UK retained the position in EU law at the end of the Transition Period. However, historically, the general position under UK law was that genuine goods placed on the market in foreign countries by owners of intellectual property rights could be imported into and sold in the UK by traders in the same way as goods placed on the market within the UK - so-called "global exhaustion of rights".<sup>111</sup>

515. The Government should explore returning to the historic UK position by liberalising parallel imports from the rest of the world. This will likely produce substantial benefits in terms of lower prices, and in some areas increased choice, for consumers in the UK. There may be some limited areas where it is justified to restrict parallel imports for example when drug companies make drugs available in less developed countries

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<sup>111</sup> See *Revlon v Cripps & Lee* [1980] FSR 85.



at low prices compared with their prices in wealthier countries - but in general protectionist use of IP rights should be resisted.

516. Similarly, where parallel importation of services is feasible, the Government should not allow intellectual property laws to be used as a barrier. The increasing importance of parallel imports of services should not be ignored, for example where ECJ case law allowed the cross-border importation and use of satellite decoder cards.

**Proposal 17.5: Urgently review guidance on hand sanitisers so that tested, effective non-alcohol based sanitisers can be used.**

517. Hand hygiene (washing and sanitising) has been a crucial part of the global response to the coronavirus pandemic. Current guidelines in the UK on non-alcohol based hand sanitisers are unclear. As a result, there is confusion in industry and among consumers as to what products are safe and effective to use, and we may be unnecessarily limiting the range of sanitising products available.

518. While alcohol-based sanitisers will continue to play a key role, non-alcohol based products can provide an important alternative to those with skin conditions aggravated by alcohol-based products. Government should review current guidance to place alcohol- and non-alcohol-based on a level playing field. But this should only be done where non-alcohol-based products can be shown to be as effective at killing the coronavirus on hands through rigorous, independent testing.

519. In the medium term, the Government should also consider the introduction of a conformity mark for hand sanitisers, to ensure only safe, effective products are available to consumers.

# Annex A: Full list of recommendations

## A BOLD NEW REGULATORY FRAMEWORK FOR THE UK

### **1. Promote productivity, competition and innovation through a new framework of proportionate, agile and less bureaucratic regulation.**

- 1.1. Reimpose the 'one in, two out' regulatory duty on all government departments.
- 1.2. Make the UK a global pioneer and leader in agile, adaptive regulation to increase productivity, competition and innovation.
- 1.3. Create a lead Cabinet Minister and ensure there is a Cabinet Committee responsible for the implementation of regulatory reform.
- 1.4. Mandate a new "Proportionality Principle" at the heart of all UK regulation.
- 1.5. Use digital sandboxes to test innovations more quickly and ensure regulation is based on evidence of impact.
- 1.6. Regulators should introduce 'scaleboxes' to provide agile regulatory support to high growth innovative scale-up companies.
- 1.7. Give regulators statutory objectives to promote competition and innovation in the markets they regulate.
- 1.8. Delegate greater flexibility to regulators to put the principles of agile regulation into practice, allowing more to be done through decisions, guidance and rules rather than legislation.
- 1.9. Give the Regulatory Reform Committee a remit to scrutinise all regulators and regulatory reform proposals. Bolster its resources, including with seconded experts, to carry out this expanded function.
- 1.10. Include consideration of the wider effects of proposed policies in Regulatory Impact Assessments, including on innovation, competition, the environment, and trade.
- 1.11. Establish a framework for regulators to report publicly on how they have promoted competition and innovation in the markets they regulate.
- 1.12. Produce a simple annual innovation scorecard to assess departments and regulators on the markets they are responsible for.
- 1.13. Embed our recommendations in the UK Innovation Strategy, use non-legislative and existing regulatory powers where possible and make use of targeted primary legislation.
- 1.14. Set a UK standards strategy to promote the use of British standards internationally as a way to boost UK influence and promote trade and exports.

## SECTOR PROPOSALS

### UK PENSIONS AND INVESTMENTS

### **2. Reform regulations limiting UK pension and insurance funds to enable greater investment in UK domestic growth.**

- 2.1. Enable Defined Contribution (DC) pensions schemes to diversify their investments into venture capital and businesses that drive Net Zero and levelling up commitments.
- 2.2. Amend matching adjustment and risk margins in Solvency II to release significant capital for investment in the UK.
- 2.3. Attract private investment to help regenerate local infrastructure and support the UK's levelling up agenda.

## **UK START-UP AND SCALE-UP FINANCE**

### **3. Amend the Seed Enterprise Investment Scheme (SEIS) and the Enterprise Investment Scheme (EIS) to maximise Private Equity and Venture Capital investment in growth industries.**

- 3.1. Amend the age eligibility requirements for companies to access investment through EIS and SEIS to ensure businesses outside London and the south east benefit equally.
- 3.2. Increase the maximum level of SEIS investment.
- 3.3. Commit to the continuation of EIS beyond 2025.

## **FINANCIAL SERVICES**

### **4. Restore a common law principles based approach to financial services regulation.**

- 4.1. Amend inherited MiFID II Position Limits to introduce greater flexibility while preserving protections on critical contracts.
- 4.2. Introduce a more discretionary and judgment-based approach to calculating Central Counterparty Clearing House (CCP) margins.

### **5. Deliver a regulatory framework that supports UK global leadership in FinTech and digitalisation of financial services infrastructure.**

- 5.1. Mandate the expansion of Open Banking to Open Finance quickly, and take a more market-led, Australian-style approach.
- 5.2. Increase competition in the banking sector by adopting a graduated regulatory approach for challenger banks.
- 5.3. Reducing Anti-Money Laundering (AML) burdens for new Open Banking/Fintech services, which have been caught in the scope of the EU AML Directive.
- 5.4. Accelerate UK plans to develop a Central Bank Digital Currency (CBDC) and launch a pilot within 12 - 18 months.

### **6. Amend disclosure and transparency requirements for financial services products to make them more proportionate and less burdensome.**

- 6.1. Remove the requirement to provide costs and charges reports to professional investors and eligible counterparties from MiFID II.

- 6.2. Remove the “investment recommendation” disclosure requirements from MAR for wholesale clients.
- 6.3. Confine the key information document disclosure requirement in PRIIPs to genuinely complex packaged products.

## DATA

- 7. **Replace the UK General Data Protection Regulation 2018 with a new, more proportionate, UK Framework of Citizen Data Rights to give people greater control of their data while allowing it to flow more freely and drive growth across healthcare, public services and the digital economy.**
  - 7.1. Reform GDPR to give people meaningful control of their data.
  - 7.2. Reform GDPR for artificial intelligence, including by removing Article 22 of GDPR and focussing instead on the legitimacy of automated decision-making.

## SMART GRID

- 8. **Create the ‘smart’ energy grid of the future, through interoperable data standards, reforms to the energy retail market, regulation, and licencing, and a new regulatory framework for smart appliances.**
  - 8.1. Support the deployment of low-carbon technologies on to the National Grid, by accelerating creation of a platform to facilitate data-sharing across the energy sector, through shared data standards and interoperability.
  - 8.2. Create clear consistent technical and regulatory standards for ‘energy smart’ appliances to support their roll out - creating a more stable energy network in response to growing demands for energy.
  - 8.3. Modernise energy retail regulation to support novel and innovative participation in the energy market and improve consumer protections by using activity-based regulation rather than supply licenses.
  - 8.4. Reform the regulation framework for the retail energy market to enable innovative approaches to tariff pricing and new products.
  - 8.5. Prioritise investment in infrastructure in pricing negotiations with energy market operators.

## NET ZERO

- 9. **Reform the current UK regulatory framework governing energy generation and distribution to match the Government’s ambitions for green growth and Net Zero.**
  - 9.1. Fully implement the short-term findings of the Offshore Transmission Network Review, reforming offshore transmission connections to support disruptive ‘pathfinder’ projects in the industry.
  - 9.2. Reform the regulatory framework for offshore wind to simplify responsibilities across government, and create a more coordinated offshore network that uses standardised designs and can link with interconnectors at scale.

- 9.3. Reform OFTO regulations to unblock industry coordination of offshore wind projects.
- 9.4. Review the Grid Code and other relevant technical codes and standards, to ensure they adequately support innovative net-zero and decarbonisation technologies.
- 9.5. Design and deliver an energy network 'blueprint' to support further delivery of offshore wind power.
- 9.6. Create a new regulatory framework for hydrogen via a new Office for Hydrogen in BEIS, encouraging investment and innovation in the sector.
- 9.7. Increase the legal limit on hydrogen blending by amending the Gas Safety (Management) Regulations 2016.
- 9.8. Create a testbed UK airport to act as a first-in-the-world location for trialling future Net Zero transport technologies.

## MOBILITY AND FUTURE OF TRANSPORT

- 10. Create a new regulatory framework to support UK leadership in the future of transport, promoting UK transport R&D, digital sandboxes, and agile, anticipatory regulation that sets global standards.**
  - 10.1. Create a world leading regulatory framework for autonomous vehicles and other disruptive mobility solutions.
  - 10.2. Develop and support sandboxes for autonomous vehicles, and other advanced trials of zero-emission passenger and logistics services.
  - 10.3. Create a micromobility regulatory framework for the regulation of e-scooters and other emerging forms of micromobility on the road.
  - 10.4. Empower the Civil Aviation Authority to better regulate the use of remotely piloted air systems (RPAS) (i.e. drones and UAVs), specifically to enable the use of RPAS beyond visual line of sight (BVLOS) by 2024.
  - 10.5. Reconsider regulation to allow the spraying of plant protection chemicals from drones.

## CLINICAL TRIALS

- 11. Establish a new UK Clinical Trials Regulatory landscape to build on the success of the COVID-19 RECOVERY trial and UK leadership in genomics, novel trial design, faster patient recruitment and use of disease cohort data to make the UK a world leader in clinical trials.**
  - 11.1. Repeal the EU Clinical Trials Directive, and develop a replacement UK Accelerated Access Translational Clinical Trials framework to restore global UK leadership in clinical trials.
  - 11.2. Make 60 days to first patient recruitment the new UK standard by replacing the multiple layers of 3rd party 'consent for consent' with a simpler system based on allowing the use of CPRD public datasets and registries by the Health Research Agency to support trial recruitment.

- 11.3. Develop a network of Our Future Health digital patient portals to encourage engagement and uptake of Clinical Trials by patients with a patient default 'Opt-Out' of medical research process.
- 11.4. Reform Clinical Trials Units to ensure they standardise patient recruitment across Trusts and incentivise trial delivery through use of the National Costings Template.
- 11.5. Simplify and accelerate NIHR adoption and peer review process for trials that are fully funded with standardisation of costing tools across academic and commercial trials.
- 11.6. Streamline clinical trial set up by HRA adopting automated AI or digital processing of ethical and trials approvals.
- 11.7. The MHRA and HRA should accelerate the adoption of novel clinical trial processes through better digitising of trials applications and data and use of novel models like UK Trials Acceleration Programme (TAP) and IMPACT with the capacity to deliver registration level trials.
- 11.8. Replace the Caldicott data guardians with a HRA Single Data Controller 'One-stop shop' for Health Research Information Governance with harmonised committees to reduce bureaucracy and standardise processes.
- 11.9. Establish a centralised health dataspine, where all data is stored for ease of access by approved users across the health network, with standardised format and approval routes for data collection and curation.
- 11.10. Reform the ICH GCP Guidelines 1995 to embrace the latest novel digital and biomarker end points, and replace 'standard of care' control arms with 'synthetic control arms' derived from RWE (Real World Evidence) and RWD (Real World Data).
- 11.11. Accelerate Access to innovation by establishing clear digital framework for Conditional Approvals and Adaptive Licensing of new therapies like gene therapies based on data including from the new Electronic Patient Recorded Outcomes Measure (EPROMs) dataspine.
- 11.12. Expand the MHRA remit and Innovation Team to include promotion of UK leadership in innovative trial design, new accelerated access regulatory pathways, standardising format and approval routes for data collecting, curating and collation, and use of novel clinical and digital biomarkers and AI.
- 11.13. Set global Standards in Clinical Research Skills through a UK professional standard for clinical trials research nurses, clinical trial managers, data managers & clinical trials pharmacists.
- 11.14. MHRA to work with stakeholders to establish a UK Regulatory Innovation Hub on the same model as the US Centers of Excellence in Regulatory Science and Innovation (CERSIs).
- 11.15. Regulation of medical cannabinoids and medicinal CBD should move from the Home Office to DHSC / MHRA to create a regulatory pathway for assessment and approval based on patient benefit.

## **DIGITAL HEALTH**

- 12. Establish a clear regulatory pathway for new digital health technology from approved health apps to integrated healthcare ICS system management to ensure the UK is at the forefront of the digitalisation of healthcare.**



- 12.1. Remove the barriers to adoption of health apps by creating a new digital health regulatory unit within the MHRA, responsible for establishing clear digital interoperability standards and an integrated regulatory pathway for development of Consumer Healthcare Apps.
- 12.2. Remove barriers to accelerate the integration of business-to-consumer digital health, and create a simple regulatory framework to help new companies develop tools that recruit, diagnose and treat otherwise hard-to-reach patients.
- 12.3. Remove barriers to local health prevention through the new ICS by establishing a digital framework for assessing Disease Cost and Population Health by each local authority area.
- 12.4. Reform GDPR to improve use of healthcare data by establishing federated models of data sharing and creating a joint sandbox between the ICO and the HRA.
- 12.5. Update regulations on medical devices to represent the latest technological advancements and to licence and adopt AI and AI software as a diagnostic device.
- 12.6. Remove the barriers to mental health apps by accelerating the integration of business to consumer patient wellness apps like IESO Healthcare with clinical neuroscience research networks like the Case Register Information System and NIHR research databases like Incliseran to create an integrated UK digital health spine for mental health.
- 12.7. Extend the IAPT outcome measurement framework (or an IAPT like framework) to Children and Young People and to other therapeutic interventions (e.g. drug treatment) to be able to compare drug and non-drug therapy and conduct multimodal trials.

## **AGRI-ENVIRONMENT**

- 13. Replace EU rules with an integrated agri-environment framework which better supports the development of more environmentally sustainable agriculture, with more proportionate and evidence-based, outcomes-focussed regulation.**
  - 13.1. Promote a flexible, market based trading system for biodiversity offset credits.
  - 13.2. Implement with urgency the data sharing provisions in the Agriculture Act 2020 to unlock data silos in agriculture and the environment.
  - 13.3. Develop a comprehensive system of environmental metrics for sustainable agriculture, incorporating the environmental impacts of a production system from field to fork, to support clearer food labelling.
  - 13.4. Develop a supportive regulatory environment to enable the development of and increased use of agri-tech to promote sustainable agriculture.
  - 13.5. Simplify compliance with environmental licensing and permitting requirements, with the aim of moving from a mechanistic compliance-based system toward outcome measurement.
  - 13.6. Deliver a common-sense solution to transitioning chemical registrations from EU to the UK REACH.
  - 13.7. Introduce further exemptions to Annex XVII of UK REACH to allow the reuse of products in support of the UK's circular economy ambition.

- 13.8. Reform landfill surrender requirements to accelerate diversification away from landfill.
- 13.9. Adopt a risk-based approach to waste regulation to drive greater re-use of waste products.
- 13.10. Remove burdensome EU regulation on the animal feed industry, whilst maintaining rigorous safety standards.

## **AGRICULTURAL GENOMICS**

- 14. The UK Government should actively support research into and commercial adoption by UK farmers and growers of gene edited crops, particularly those which help the transition away from agrochemicals to naturally occurring biological resilience.**
  - 14.1. Interpret current GM rules on a case-by-case basis, to permit specific crops with proven benefits and which are consistent with the UK's rigorous standards on food safety and environmental protection.

## **SPACE AND SATELLITES**

- 15. Through reform of the Space Industry Act, the Government should address the indemnity and liability issues currently holding back investor confidence in the UK as a satellite launch and operations hub.**
  - 15.1. Amend the Space Industry Act 2018 to cap liability and indemnity requirements for licence applicants to launch and operate satellites from the UK.
  - 15.2. Ensure the Civil Aviation Authority has the expertise to fulfil its new and additional responsibilities as a regulator for the space sector.
  - 15.3. Develop an Earth Observation (EO) data regulatory policy framework.

## **NUTRACEUTICALS**

- 16. Create a new regulatory framework for the fast-growing category of novel health enhancing foods and supplements to promote investment in the UK as a leader in the nutraceutical sector.**
  - 16.1. Establish clear regulatory standards and definitions for 'nutraceutical products and create a permissive environment for regulation of products with accepted science outcomes, to form a new easier nutraceutical product regulation pathway.
  - 16.2. Encourage NIHR to gather data to support claims and enable research into products medicinal and health properties, lead on international standardisations and ensure a pathway to market, so that consumers are aware of the health benefits and better able to make informed choices.

## **OTHER TARGETED REFORMS**

- 17. Deliver other targeted regulatory reforms to reduce the regulatory burden on**

**businesses.**

- 17.1. Amend the Weights and Measures Act 1985 to allow traders to use imperial measurements without the equivalent metric measurement.
- 17.2. Develop an optional e-labelling system for devices with screens or that can be connected to a screen, to display compliance information.
- 17.3. Repeal the Port Services Regulation 2019 (SI 2019 No. 575) to remove unnecessary, EU-derived regulatory burdens on UK ports.
- 17.4. Liberalise parallel import laws to reduce prices and increase choice for consumers.
- 17.5. Urgently review guidance on hand sanitisers so that tested, effective non-alcohol based sanitisers can be used.

## Annex B: Stakeholder engagement

520. This project was a rapid review of the opportunities for regulatory reform. It is not a comprehensive picture of the opportunities across all areas of the UK economy. Instead it focuses on a smaller number of areas that could see disproportionate benefit from regulatory reform and meet our original objectives as set out in our Terms of Reference.<sup>112</sup> In particular, we have focused on those areas that could see change happen quickly and have an economic impact within the next few years.
521. The project has been carried out by the Taskforce with civil service secretariat support from the Cabinet Office.
522. We have held meetings and roundtables with approximately 125 experts from across the country - from SMEs to global leaders - as well as academia and think tanks. The full list of stakeholders we have met with can be found at Annex B. We have separately received numerous written contributions from think tanks and the general public, and in total generated over 200 ideas.
523. We considered these ideas based on our terms of reference, especially the need to focus on opportunities for driving innovation and the commercialisation and safe adoption of new technologies, or reduce barriers to entry and scale-up.
524. Many of the interesting and likely beneficial proposals we received were outside of the scope of this project, or even just out of our capacity to consider. This does not mean that these ideas were without merit, and we have collated these inputs and shared with the Government where appropriate. We recommend that the Government gives these ideas the consideration that we were unable to.
525. Our thanks go out to all those that shared proposals and contributed to discussions; it has given us the assurance and confidence that there is considerable scope for beneficial regulatory reform in the UK. We have seen firsthand the level of expertise on the cutting edge of innovation in this country. If the Government takes forward the recommendations set out in this report, we have no doubt that they will play a big role in the UK flourishing in the bright post-EU future.
526. To note, while many of our proposals cover reserved matters, some of the proposals discussed fall under devolved competence. Therefore it would be for the devolved administrations to decide whether to take forward proposals in those areas.

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<sup>112</sup> Taskforce on Innovation, Growth and Regulatory Reform (TIGRR), [terms of reference](#), February 2021.

## Engagement List

### Financial Services and investment

- Association of British Insurers (ABI)
- British Growth Fund (BGF)
- Bank of England (BoE)
- British Business Bank
- British Private Equity and Venture Capital Association (BVCA)
- The Cambridge Angels
- City of London Corporation
- Competere
- Financial Conduct Authority (FCA)
- Institute of Chartered Accountants in England and Wales (ICAEW)
- International Regulatory Strategy Group (IRSG)
- InvestUK
- Legal and General
- Payment System Regulator (PSR)
- Politeia
- Prudential Regulation Authority (PRA)
- Revolut
- Shearman and Sterling
- The CityUnited Project
- The Coalition for a Digital Economy (Coadec)
- The Kalifa Review of UK FinTech
- The Pensions Regulator (TPR)
- True Capital Ltd.
- UK Finance (UKF)
- Venture Capitalist Trust Associator (VCTA)

### Data, life sciences and Space

- AI Council (BEIS/DCMS)
- Alden
- Apex Healthcare Partners
- Biobank
- Birmingham Institute for Translational Medicine
- Closed Loop Medicine
- Coadec
- CogX
- Clyde Space
- Digital Catapult
- Gallaghers
- GlaxoSmithKline
- Global Network on Sustainability in Space Board
- Harwell Oxford Partners
- IESO Digital Health
- Inmarsat

- Interel
- OcQuila Therapeutics
- OneWeb
- Oxdynamics
- Oxford Entrepreneurs Network
- Oxford Nanopore Technologies
- Oxford Sciences Innovation
- Oxford University Astra Zeneca Trials team
- OcQuila Therapeutics
- PUBLIC
- QinetiQ
- RegulAltion
- Regulatory Horizons Council (BEIS)
- Rosalind Franklin Institute
- Satellite Applications Catapult
- Satellite Finance Network
- SatixFy
- Skyrora
- Surrey Satellite Technology Ltd
- The Birmingham Health Partners Centre for Regulatory Science and Innovation
- The House of Lords Science and Technology Committee
- UK Parliamentary Space Committee
- UKspace

## Transport and Net Zero

- Aurigo Driverless Technology
- British Marine
- British Ports Association (BPA)
- Cadent
- Centrica Storage Ltd
- CoMoUK
- EDF
- Edinburgh Centre for Robotics
- Emitwise
- Energy Networks Association (ENA)
- Energy Systems Catapult
- EnergyUK
- ERM
- Greyparrot
- Liftshare Ltd
- Moixa
- National Grid
- Octopus Electric Vehicles
- Oxbotica
- RenewableUK
- Scottish Gas Network (SGN)



- Siemens Mobility Ltd
- Terrapraaxis
- Topolytics
- Transport for London (TfL)
- Uber
- Xampla

## Environment and Nutraceuticals

- Aldersgate Group
- Barclays Agriculture
- Bio Potatoes Ltd
- Bouncing Bear
- Brains Bioceutical
- Britannia Life Sciences
- Emmac Life Sciences
- Food and Drink Federation
- FrontFoot Communications Ltd.
- GD NatCap Ltd
- Grow Group PLC
- Hanway Associates
- Harper Adams University
- Innocan Pharma
- Innogen Institute
- Naturecan
- Niras Consulting
- Orsted
- Public First
- Rothamsted Research
- RSK Biocencus Ltd.
- Sativa Wellness
- The Centre for Medicinal Cannabis
- The Ellingham Partnership
- The Environment Bank
- The Environmental Services Association (ESA)
- The John Innes Centre, Norwich Research Park
- The Raynham Estate
- The Roslin Institute
- The Sainsbury Laboratory
- Town and Legal
- Vitacress

## Manufacturing & Retail

- Apple Inc.
- Association Of Convenience Stores (ACS)

- British Electrotechnical and Allied Manufacturers' Association (BEAMA)
- British Retail Consortium (BRC)
- Chemicals Industry Association (CIA)
- Ford UK
- Make UK
- REIDSteel
- The Society of Motor Manufacturers & Traders Limited (SMMT)

### Cross-cutting

- AECOM
- AVIVA
- Alliance for Intellectual Property (AIP)
- British Chamber of Commerce (BCC)
- British Educational Suppliers Association (BESA)
- British Standards Institute (BSI)
- The Cambridge Angels
- Confederation of British Industry (CBI)
- Catapult
- Entrepreneur First (EF)
- Federation of Small Business (FSB)
- Institute of Directors (IoD)
- Institute of Economic Affairs (IEA)
- KPMG
- Legal and General
- NHSA
- Onward
- Porterbrook
- Regulatory Horizons Council
- Rothesay
- The Association of Independent Professionals and the Self-Employed (IPSE)
- The Centre for Social Justice (CSJ)
- The Scale Up Institute
- Trade Union Congress (TUC)
- True
- UK Regulators Network (UKRN)