National Audit Office

From COVID-19 to Net Zero: How can regulation respond to change?

21 September 2021

NAO good practice guide: Principles of effective regulation

From COVID-19 to Net Zero: How can regulation respond to change?

Today's programme and speakers

1. Keynote speakers:
   - **Gareth Davies**, Comptroller & Auditor General and head of the National Audit Office
   - **Dame Glenys Stacey**, Chair Designate, Office for Environmental Protection & Chief Regulator, Ofqual
2. Q&A with Gareth and Dame Glenys

3. Panel member introductory remarks:
   - **Chris Carr**, Director of Better Regulation, Department for Business, Energy and Industrial Strategy
   - **Rachel Arrundale**, Deputy Policy Director, Medicines and Healthcare products Regulatory Agency
   - **Will Hayter**, Head of the Digital Markets Unit, Competition and Markets Authority
   - **Tim Johnson**, Policy Director, Civil Aviation Authority
   - **Martin Lodge**, Professor of Political Science and Public Policy, London School of Economics
4. Panel discussion and Q&A

Housekeeping

- Please feel free to ask questions for our speakers using the chat function, which will be visible to all of today's presenters. We will try to answer as many as we can.
- The event is being recorded, and we plan to make the video available on the NAO website.
- We will write up a note summarising the key themes from the event and make this available online.

How can regulation respond to change?

Chris Carr, Director, Better Regulation Executive, BEIS

NAO Webinar 21 September 2021

Department for Business, Energy & Industrial Strategy

Introduction

There are four main ways in which BRE helps UK regulation respond to change:

- **Having the Right Metric** - Measuring and scoring regulatory impacts and – important! – keeping the methods up-to-date.
- **Horizon Scanning** - Keeping abreast of changes in technology and society.
- **Promoting best practice among regulators** - Making sure regulators are at the cutting edge of change.
- **Unlocking the benefits of technology** - Using technology to make navigating regulation easier for government, regulators and the regulated.

In addition, we also look for **outcomes-based regulation** where sensible; we build on the **anticipatory approach,** identifying regulatory problems before they become critical; and **learn from our international peers**. This may include international collaboration, to ensure we take account of best practice.

Having the Right Metric

We are reviewing the Better Regulation Framework. As part of this review, we are exploring how the Government could change the metrics it uses to measure the impact of regulation. These metrics are used to decide whether to implement a regulation, to evaluate its effectiveness and to report on the impact of the Government's intervention on business.

The right metric:	A less effective metric risks:
• Enables Government to **understand the impacts** of its regulation; • Can be **calculated consistently** across different sectors; • Is **clear in scope,** so that decision-makers understand what it does (and does not) measure; • **Measures impacts that are important** to Government and stakeholders.	• Creating perverse incentives for decision makers (e.g. a metric that does not differentiate between **small costs affecting many businesses and large costs affecting a smaller number**, could lead to disregarding the needs of the majority of businesses, in favour of impacts with a higher OIXO score affecting few businesses.); • (When used as part of a decision-making process.) **Impeding action on important societal issues**, particularly where the benefits are financially difficult to quantify (e.g. curbing the gambling industry, addressing net zero, may be expensive); and • **Misrepresenting costs to business**, for example by not taking into account the indirect costs brought about by behavioural changes caused by a policy.

Horizon Scanning

REGULATORY HORIZONS COUNCIL

- In its 2019 White Paper "**Regulation for the Fourth Industrial Revolution"**, the government recognised the need for regulation to unlock new innovations.
- The **Regulatory Horizons Council** was established as an independent expert body to identify the implications of technological innovation and advise on the regulatory reform needed to support its rapid and safe introduction.
- To match the pace of technological change, the Council works in an agile way, identifying areas for change, quickly engaging with sector experts and producing timely reports. It has recently published recommendations on the future regulation of: fusion energy; genetic technologies; and medical devices; with a report on drones to follow.
- In its next wave of work the Council is considering: Pro-Innovation Regulatory Principles; AI in Healthcare; Neurotechnologies; and the Hydrogen Economy.

Enabling innovation by getting regulation right

- The Regulators' Pioneer Fund (RPF) helps regulators develop new ways to reduce regulatory barriers to innovation and help businesses get their innovative products and services to market faster.
- During 2018-20, the RPF invested ~£10 million in 14 regulator-led projects. Examples of positive advances from this include:
  - **Medicines and Healthcare products Regulatory Agency** developed unique synthetic datasets, which mimic real patient data with very high fidelity. These datasets will help researchers and firms develop and validate their innovative AI and medical devices.
  - **Civil Aviation Authority** used RPF funding to establish a regulatory sandbox, working with innovative companies to explore regulatory barriers and test innovations in a safe environment.
- On 16 September 2021, BEIS confirmed the 21 projects selected for a new £3.7 million round of the RPF.

Unlocking the benefits of technology

A key challenge for HMG is to improve business access to regulation and simplify paths for innovators to create new products and services. Technology can help to deliver these outcomes, with a range of RegTech solutions already emerging. To provide these types of solution at scale, access is required to the structure and operation of UK regulation as data. The Better Regulation Executive is developing new tools to enable these outcomes:

- An **Open Regulation Platform (ORP)** will publish UK business regulations as enriched machine-readable data and making it available through an open-access API.
  Using the ORP, government, businesses and third parties will be able to develop tools to help navigate and comply with regulatory obligations in smarter and less burdensome ways.
- A **Digital Regulation Navigator (DRN)** will be the first consumer of ORP data. It will help businesses (especially Small and Medium-sized Enterprises and microbusinesses) to navigate the complex regulatory landscape and aid compliance.
- A **Smart Regulation (Smartreg) tool** will provide a digital service for policy makers, lawyers and analysts using Natural Language Processing (NLP), to help them understand better the individual and cumulative burden of the stock of regulation.

Thank you.

Chris Carr, Director, BRE

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Medicines & Healthcare products Regulatory Agency

NAO Regulation Event – MHRA Panel Session

Rachel Arrundale, Deputy Director, Policy: Tuesday 21 September 2021



CPRD NIBSC MHRA

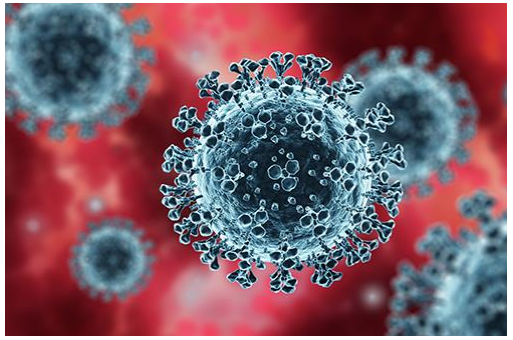
The change environment

Science and technology advances – realising the potential for transformative new treatments

The IMMDSR highlighting serious lessons and areas for improvement in standards

EU Exit, establishing MHRA as a standalone Agency, making most of opportunities

… **Covid 19 Pandemic**



Covid 19 Flexibilities

Guidance

MHRA regulatory flexibilities resulting from coronavirus (COVID-19)

Guidance for industry on flexible approaches to regulation we are taking during the COVID-19 outbreak

https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19

Covid 19 Vaccine development

Rapid reviews of clinical trials applications to support manufacturers and researchers on potential treatments for COVID-19. Clinical trial approval time reduced from c19 to 8 days

Rolling reviews of applications for authorisation: and open invitation for those developing Covid 19 vaccines to come for early regulatory advice

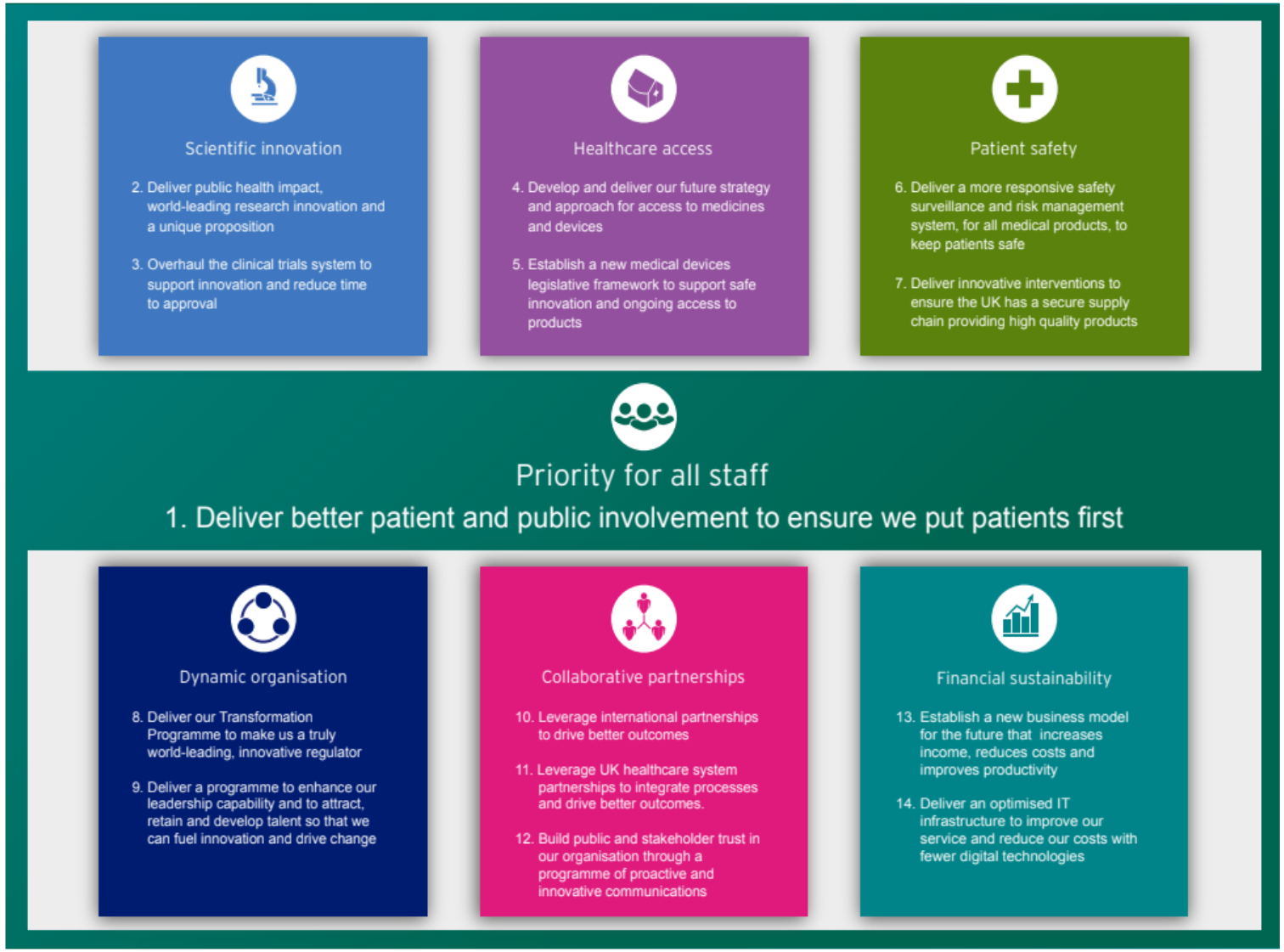
Regulatory development: use of R174 emergency authorisation – and new Statutory Instrument to “back up” use of that regulation.

Everything ready for the time a vaccine could be approved:

- Pharmacovigilance and surveillance plans and mechanisms in place
- Inspections: advance consideration of GxP issues, ensuring relevant inspections carried out in advance
- Readiness for batch testing - tech transfers completed and ready to go
- Communications and policy advice prepared …

The Future – Our Delivery Plan

Our goals



Contact

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Thank you

National Audit Office

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