



Medicines & Healthcare products
Regulatory Agency

Corporate Plan

2018-23



April 2018

Foreword by the Chair

I am delighted to bring forward the five-year Corporate Plan for the Medicines and Healthcare products Regulatory Agency for 2018-23.

There are big changes ahead, not least the impact of the UK's exit from the EU, but I am confident that the Agency, with its globally unique concentration of expertise in data, standards and regulation will continue to offer our customers a full range of services and products which is not replicated anywhere else in the world.

Together, our three centres – the Clinical Practice Research Datalink, the MHRA regulator, and the National Institute for Biological Standards and Control – bring together expertise and evidence so that:

- clinical practice is informed by and contributes to regulatory evidence;
- global standards are underpinned by and enhance regulation; and
- real world data underpins regulation.

All of this collectively brings real benefit to patients across the UK, enabling the Agency to protect public health and improve lives. Our opportunity through this new 5-year Corporate Plan, particularly in the context of the UK's exit from the EU, will be to:

- build further on our unique offer to UK and international customers;
- set out our ambitions on the added value which the Agency brings to improving public health; and
- highlight the Agency's contribution to delivering the Government's Life Sciences agenda, notably in clinical trials, accelerated product licensing and emerging areas like genomics and advanced therapies.

This plan, then, sets direction on what the Agency will do over the next five years, to address proactively the uncertainties we face. It positions us to be agile to meet the changes which we know will lie ahead and to continue to deliver innovative science and first-class research.

As the Agency's Chair, I am excited to take on the challenges which lie ahead of regulating new and innovative products and production methods as scientific advances take us into new areas in medicines and medical devices, and of providing real-time benefit risk information to support patients' and healthcare professionals' decisions.

The Agency has always been at the forefront of innovative science and public health protection and this plan sets out how we will continue to be so over the next five years.



Sir Michael Rawlins GBE
Chairman

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Introduction

The Medicines and Healthcare Products Regulatory Agency (the Agency) is an Executive Agency of the Department of Health and Social Care (DHSC) and a Government Trading Fund, with a mission to protect and improve health through the effective regulation of medicines, medical devices, and blood products underpinned by science and research.

Under its Framework Agreement with the DHSC, the Agency is required to prepare every five years a Corporate Plan which:

- sets out how the Agency will deliver the functions delegated to it by the Secretary of State;
- describes the Agency's longer-term aims and objectives; and
- sets out a strategy for achieving them.

The Corporate Plan provides an agreed basis for detailed annual business planning and an Agency-wide business plan is published each year.



Outcome of the Corporate Plan for 2013-2018

April 2018 marks the start of a new Corporate Plan period which will run to 2023. This plan succeeds the Corporate Plan for 2013-2018 (updated in 2016). In that Corporate Plan period, the Agency set out to:

- embed the synergies from having the UK regulator of medicines, medical devices and blood in the same organisation as the National Institute for Biological Standards and control (NIBSC), and the Clinical Practice Research Datalink (CPRD) - offering a globally unique combination of expertise in regulation, standards and data;
- support innovation and wider UK Government work on Life Sciences and growth;
- better join up activities across the organisation where it makes most sense to do so, notably through a joint vigilance strategy for medicines and medical devices;
- evaluate outcomes of major regulatory actions including effectiveness of risk minimisation;
- assure global supply chains including through stronger links with other global regulators and targeted risk assessment; and
- deepen UK-wide partnerships working across the health and social care and Government sectors of the UK, the third sector, academia and industry both to strengthen the sources of intelligence, information and data coming into the organisation and to improve our contribution from the Agency into networks which influence the quality and safety of care for UK citizens and patients.

We believe that significant progress has been made in all these areas. We would like to express our appreciation and thanks to the many partners with whom we have worked over the past 5 years who have joined us in this work, making this progress truly cross-system.

- ✓ **Internally**, we have made good progress in joining up key functions:
 - bringing together medicines and devices vigilance work;
 - CPRD analysis supports an increasing range of the safety and vigilance evidential challenges that the Agency is managing;
 - NIBSC expertise on biologicals has significantly strengthened the regulator's effectiveness in the regulation of the new generation of biological medicines;
- ✓ **Agency work on standards**, now across biological, chemical and herbal medicines, offers a world-class basis of both theoretical and practical safeguards to people across the world; the Agency remains responsible for developing some 90% of global biological standards;
- ✓ **Our Early Access to Medicines Scheme (EAMS)**, the bedrock of our practical support to wider Government work on innovation, has issued 50 designations of promising innovative medicines, and we recently issued our 18th set of advice to support early unlicensed use of these promising products;
- ✓ **Our national, Europe-wide and global regulatory activities** have continued to strengthen:
 - we have concluded bi-lateral regulatory agreements with most of the world's largest regulators, including with China and India;
 - the UK chairs the work of the new International Coalition of Medicines Regulatory Agencies;
 - in 2016/7, the UK led on some 20% of the licensing of the most innovative medicines in Europe, and on the assessment of 50% of the core licensing activities across Europe;
 - we have been active in the reinforced oversight of EU notified bodies in the Devices sector;
 - we have continued to strengthen our safety vigilance work in both pharmaceuticals and devices;
 - CPRD has continued to expand population coverage: 1 in 10 practices across the UK have now signed up to currently contributing near real-time data to CPRD;
 - we have fully operationalised the new EU pharmacovigilance legislation;
 - we have developed and implemented a new regulatory regime for nicotine products as Competent Authority under the Tobacco Products Directive
 - our inspection and enforcement work, as the UK and jointly with others, remains a priority: successive waves of operation Pangea aim to make the UK a highly hostile environment for falsified and sub-standard medicines and our campaigns are changing consumer internet buying behaviour; thanks to the very strong science base in the UK and MHRA's support to innovators of new medicines, the UK continues to be a leading centre for clinical trial work, especially in the early "first in human" trials; and
 - our **Yellow Card** reporting app is being taken up internationally.
- ✓ We have invested heavily in our **partnership working** across the UK, across Europe and globally. The increasing robustness of these links reinforces the resilience of system-wide work to ensure the safety, efficacy and quality of healthcare products used in the UK and is proving central to the Agency's confidence that the global nature of the regulatory systems for pharmaceutical and devices regulation will cope well with the challenges arising from the regional implications of the UK's exit from the EU.

Corporate Plan 2018-2023: Practical challenges

The practical challenges that the Agency needs to address over the period of this Corporate Plan are no less demanding than 2013-2018 and need to be addressed in circumstances of substantially increased uncertainty, not least as negotiations on exiting the European Union, which will have important implications for the European dimension of the Agency's work, will continue over the early stages of 2018-2023. This plan is designed to be a guide through these challenges and uncertainty; and we will keep it under regular review – as we did with the plan for 2013-18.

Key strategic challenges for 2018-2023 are summarised on the next page. These are consistent with the Agency's Corporate Risk Register – including IT, cyber security, the UK's exit from the EU, finance and procurement risks, and risks to the medicines supply chain – and are rigorously managed by the Executive, the Audit and Risk Assurance Committee and the Agency's Board.

This Plan sets out the practical actions which the Agency will take forward over the next 5 years to address these challenges.

Key strategic challenges

Context

- **The UK's exit from the EU**
- **Technological and scientific challenges** including genomics and increased personalisation/specialisation of products
- **New areas of regulation**, including digitally-based products/AI and product development, production processes and novel supply chains

Core Regulatory Products and services

- Development of new processes to **bring new products safely and speedily to market** develop in the next 5-10 years
- Optimising the wide range of data sources in **safety and vigilance** work supported by digital systems and tools, and delivery of safety messages
- The global **inspection and regulatory capacity support challenge** in a post-Brexit world
- **The service levels**, breadth and depth of the Agency's regulatory offer, and the efficiencies and financial/fee base needed to offer this

Specialised products and services

- Business visions for the key Agency specialised products and services (in particular, those delivered by **NIBSC and CPRD**) – and the sum of the parts
- Maintaining/developing **public and clinician understanding and confidence** in the Agency's contribution to patient safety and well-being
- How the Agency **contributes to and benefits from the UK health and care system**

Key enablers

- Agency's **global leadership role**, including in global standards
- Ensuring that **operational transformation** delivers a flexible and efficient organisation to deliver the next 5-10 years of the Agency's work
- The **people strategy**, including talent management, needed to support the next 5-10 years resourcing and development of skills

Addressing the challenge

Overall, the Agency is setting out to build on action and achievement in the last Corporate Plan period and to:

- manage a **transition to operation after the UK's exit from the EU** where the Agency will have a different role in both global and European regional regulatory networks for medicines and devices;
- further **consolidate the Agency's globally unique offer**, combining as it does regulation, standards and data, underpinned by science and research;
- ensure that, as a regulator, **we keep pace with the fast evolution of science** and the new products that will be brought forward in new areas (such as genomics and medical apps/machine learning) and in combined pharmaceuticals/devices products;
- further **strengthen the contribution** we make to, and our engagement with, key patient-focused developments in the UK, notably:
 - work across the UK health and social care system to accelerate access to innovative medicines and medical products in the UK, particularly through the work of the Accelerated Access Collaborative;
 - work across the UK health and social care system to deepen practical (especially data) linkages so as a regulator we can access information about the real world clinical impact of the products we regulate, and can contribute more effectively to informing and influencing clinical practice with our understanding of the risks and benefits of the products clinicians use every day;
 - work to improve how we, as a regulator, work with patients, patient groups, clinicians and the wider health and social care system especially to ensure that the often inevitable risks involved in using some of the products that we regulate can be properly understood by patients and healthcare professionals to manage risks, recognising that more work needs to be done in this area;
- internally, over the period of this Corporate Plan **replace end-of-life IT systems**, which we will do within a wider process of operational transformation; and
- invest in the **recruitment, development and retention of key staff** to meet the challenges of the new world in which we operate.

Exiting the EU

The negotiations on the UK's exit from the EU will be a significant factor in the early stages of this Corporate Plan period. The exact nature of the Agency's relationship with EU regulators after exiting the EU will be determined through the negotiations, but it is the Government's intention to retain a close working partnership with both EU and other global regulators in the interest of ensuring patients continue to have timely access to safe medicines and medical innovations.

Whilst there will be some uncertainty in the early part of the Corporate Plan period, there are also some points of clarity that will help, as we progress towards the operating environment after exiting the EU.

These include:

- there are clear precedents for strong collaborative regulatory working between the EU and non-EU partners: the European Devices regulatory network, for example, includes countries such as Switzerland and Turkey;
- pharmaceuticals is a sector where the UK has made it clear that, in the interests of public health, it wishes to see an on-going active regulatory partnership with the rest of Europe, which was reinforced by the Prime Minister's Mansion House speech of 2 March 2018. This makes sense for all parties:
 - the contribution the UK has made to the European regulatory networks in medicines and devices over the past 20-30 years means the UK has an enormous amount of corporate knowledge from its lead regulator responsibilities;
 - the UK remains keen to make that knowledge and expertise available not only to UK citizens, but to citizens and patients throughout the EU, all of whom have been well served by the close regulatory networks built across the EU and more widely;
- pharmaceuticals and devices are products developed for global markets, and the growing importance of global standards means that regulation of pharmaceuticals and devices is as much a globally-driven as a regional activity;
- a United Kingdom population of 60 million provides a solid basis for safety vigilance work, especially given the strong systems in place – including through the Yellow Card system – to collect signals data; there is real value in two-way data sharing and co-operative working on signal assessment with the EU;
- we estimate that some 40-50% of the medicines used in the UK are of Chinese and Indian origin: our global inspection efforts, and the developing links that we are making with regulators in these key source countries, are core components of our contribution to public health protection.

In common with organisations throughout the UK, the Agency will continue to prepare for all scenarios, including the very unlikely scenario in which no mutually satisfactory agreement can be reached and the UK exits without a deal.

We will explore interest in new global partnerships as well as opportunities for the UK to offer, through closer joined-up working across UK regulators and the NHS, faster access for UK patients to medical innovation.

We will continue to explore the contribution that the Agency can make to regulatory work at the global level, not least to ensure that the UK voice – in support of effective, science-based, proportionate regulation – remains active and influential.

Whatever the outcome of the negotiations, the Government has stated that patients and industry will not be disadvantaged, and the UK will continue to play a leading role in promoting public health. The Agency is fully supportive of this approach.

Strategic vision

We believe it is right, therefore, despite the uncertainties we face in this corporate plan period, to set ourselves an ambitious vision for the next five years. Our vision is that by the end of the Corporate Plan period in 2023, the Agency will:

Strategic vision

continue to play a major role in protecting public health and promoting patient safety by ensuring the safety, efficacy and quality of medical goods on the market;

have managed the outcomes of negotiations on the UK's exit from the EU to enable the Agency to continue to deliver its statutory functions;

continue to support and enhance innovation, horizon scanning for scientific and technological advance, and proactively offer accelerated routes to market to benefit public health and be a magnet for life sciences;

continue to be a full-service regulator, providing high quality robust regulation of medicines and medical devices;

have built an enhanced impact across the health and care system through collaborative working, linking up actively and influencing clinical practice through provision of data/evidence and expertise and embedding vigilance in health care systems;

have maintained its position as a global leader in standardisation and its role in the control of biological medicines, and will have executed a comprehensive underpinning research programme; and

strengthened our global positioning and reach, influencing the safe production and supply of medicines and medical devices, enhancing international partnerships, influencing emerging regulations and strengthening our commercial offering.

Finance and efficiency

The Agency is a Government Trading Fund, substantially funded by fees. Our objectives for this Corporate Plan period include broadening our fees base by putting in place a fee regime for devices safety vigilance work

It is a requirement of statutory fees that the fee charged equates to the cost of providing the service. We recognise that whatever the outcomes of exiting the EU the Agency will be operating in a changed environment. Critically, we recognise that our interest to provide regulatory and scientific expertise across all products and therapeutic sectors, and in improving the customer-focus of our systems and processes, involve major choices for us as a regulator and for the companies (and sometimes tax-payers) who pay for our services.

We recognise, therefore, that we need to transform how the Agency operates and improve/increase efficiency: our operational transformation programme will be the way that we deliver this. The objectives of OT are to:

- deliver superior products and services;
- improve the experience of our customers;
- provide flexibility to meet changing customer requirements; and
- ensure services are delivered giving best value for money.

The OT programme needs to:

- transform our end-of-life IT systems, processes and services into something that better suits our customers and Agency needs; the Agency will take advantage of the digital platforms it has already delivered, making efficiencies through re-use; will standardise the way it manages data and therefore avoid complexity and cost, and develop services in an iterative way with our customers, to improve time, cost and quality of delivery;
- identify ways to drive down the cost base of the organisation and improve efficiency;
- ensure that our systems, but more importantly our regulatory and data experts, are enabled to engage with those we regulate and whose clinical practice we seek to influence in ways that are transparent, supportive but challenging where necessary on behalf of the public whose interests we serve; and
- contribute to the diversification of Agency funding, looking beyond the Agency's current reliance on activities that are funded either through statutory fees or from UK public resources, and explore opportunities to grow new sources of income where this is compatible with our public health mission.

Development of the Corporate Plan

This Corporate Plan is the result of an extensive process over the past year of engagement and discussion inside the organisation and externally with strategic partners across Government, the health sector and industry. These discussions have been significantly strengthened and supported by two other major activities happening at the same time: an extensive set of discussions on the implications of exiting the EU for the organisation; and work to define an operational transformation programme for the Agency, including a complete refresh of the Agency's IT systems.

It has been encouraging to see how much consensus and common ground there has been between the different discussions including:

- a substantial external customer engagement exercise carried out as part of the Operational Transformation programme, the outcome of which has informed the development of the Corporate Plan;
- an extensive set of discussions, including under the Life Sciences task force, on the implications of exiting the EU for medicines and medical devices regulation; and
- a series of structured discussions in the regular partnership meetings that the Agency has established over the past 5 years with a range of external partners including the Devolved Administrations.

These discussions have helped the Agency to identify the key functions, requirements and practical expectations that others have of the Agency in terms of:

- our key statutory functions and contractual obligations;
- activities and actions that, as an Agency, we recognise that we must do over the Corporate Plan period; and
- more aspirational/ exploratory work that we intend to carry out over the Plan period, and that we expect will become firmer commitments either for later stages of this period, or for the next Corporate Plan.

These are articulated in the detailed plan below.

Delivering Agency core functions

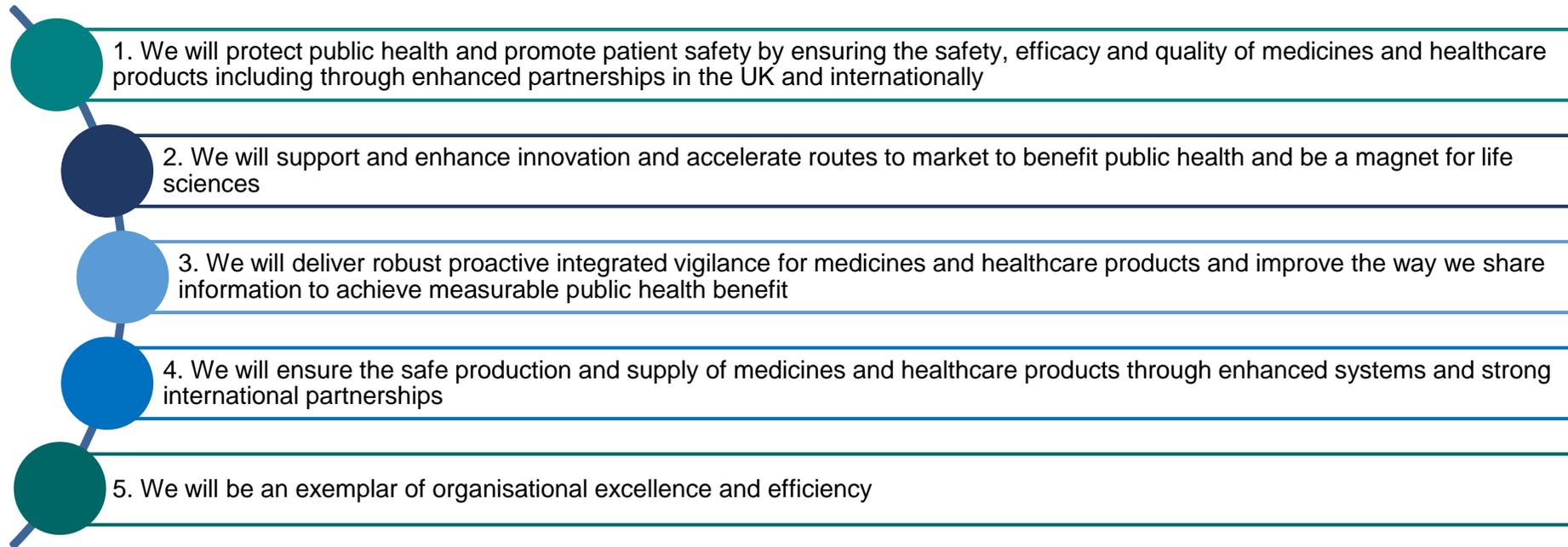
The priority actions and activities which the Agency will take forward over the Corporate Plan period set out in the detailed plan below will ensure the delivery of the statutory role and functions of the Agency including:

- our **regulatory role** in authorising and regulating clinical trials; licensing medicines; acting as the UK competent authority for medical devices and monitoring the performance of notified bodies; post marketing surveillance of medicines and medical devices; enforcement action on safety issues and breaches of regulations; inspections including partnerships with other regulators; regulating the safety and quality of blood and blood components; good laboratory practice monitoring authority for the UK; regulating e-cigarettes; implementing EU legislation;
- our role in **assuring standards** including standards for biological medicines and test procedures; laboratory testing for biological medicines; British Pharmacopeia;
- our role in **research and information** including provision of real world longitudinal data and facilitating patient recruitment to trials;
- our responsibility to **account to Government** for delivery of statutory requirements; and
- our role to **advise** on medicines and health care products safety and public health.

Corporate Plan structure

The structure of the 2013-18 corporate plan has served us well: it is simple and clear and relates directly to our core legal functions and to the key products and services that we provide. As we intended this structure has encouraged cross-Agency working and helped in outward-facing partnership work.

We have decided to retain the five areas of the 2013-18 plan and to turn these into clear objectives for 2018-2023 as below:

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1. We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products including through enhanced partnerships in the UK and internationally
 2. We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences
 3. We will deliver robust proactive integrated vigilance for medicines and healthcare products and improve the way we share information to achieve measurable public health benefit
 4. We will ensure the safe production and supply of medicines and healthcare products through enhanced systems and strong international partnerships
 5. We will be an exemplar of organisational excellence and efficiency

In the next section, we provide an “at a glance” summary of the contents of the **operational parts of the corporate plan** followed by the detailed operational corporate plan – with specific actions, activities and projects set out to deliver these five objectives.

Actions, activities and projects are broadly distinguished between those that are firm commitments to specific activities, deliverables or outcomes, and more exploratory work. These activities, many of which will be delivered through practical projects and activities under the Operational Transformation programme, will be tracked through the Agency’s annual business plans.

The whole Corporate Plan will be kept under review; we envisage the first review will be in April 2020.

Corporate Plan summary

| | | | |
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|  <p>Public health and partnerships</p> | 1 | <p>We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and health care products in the UK and internationally, including:</p> | 1a: with Government and strategic partners, we will prioritise action to deliver our statutory functions in response to the challenges of exiting the EU |
| | | | 1b: with Government and strategic partners, we will deliver our statutory functions to protect public health and ensure the safety and quality of medicines and health care products in the UK |
| | | | 1c: we will enhance our public health impact through building stronger partnerships, collaboration and engagement across the UK healthcare sector to improve clinical practice and protect public health |
| | | | 1d: we will enhance our public health impact through building stronger partnerships, collaboration and engagement including through further development of our international strategy |
|  <p>Enhancing innovation</p> | 2 | <p>We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences including:</p> | 2a: we will support innovation and growth in Life Sciences |
| | | | 2b: we will develop and deliver innovative regulatory and legislative measures including through our offer to research and clinical trials |
| | | | 2c: we will be responsive to priority areas of scientific development including new products, product types and production methods and methodologies |
|  <p>Proactive, robust surveillance</p> | 3 | <p>We will deliver robust proactive surveillance for medicines and medical devices to achieve measurable public health benefit including through:</p> | <ul style="list-style-type: none"> ● improved use of real world data |
| | | | <ul style="list-style-type: none"> ● enhanced information sharing |
|  <p>Secure global supply chains</p> | 4 | <p>We will ensure the safe production and supply of medicines and medical devices through:</p> | <ul style="list-style-type: none"> ● enhanced systems |
| | | | <ul style="list-style-type: none"> ● strong international partnerships |
| | | | <ul style="list-style-type: none"> ● educating consumers |
|  <p>Organisational excellence / efficiency</p> | 5 | <p>We will be an exemplar organisational excellence and efficiency:</p> | 5a: through our operational transformation programme, we will deliver a flexible and efficient organisation able to respond effectively to market and customer requirements |
| | | | 5b: we will build staff resilience and deliver a people strategy to ensure the Agency has the skill mix to adapt to changing regulatory models across the next five years and beyond |

Detailed Corporate plan

1a: With Government and strategic partners we will prioritise action to deliver our statutory functions in response to the challenges of exiting the EU

We will:

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| 1a(i) | plan to deliver a smooth exit from the EU under any scenario, in line with all other Government Departments and Arm's Length Bodies |
| 1a(ii) | participate in preparations for the future economic partnership the UK hopes to negotiate with the EU |
| 1a(iii) | deliver plans for the very unlikely scenario in which no mutually satisfactory agreement can be reached and the UK exits the EU without a deal |

1b: With Government and strategic partners we will deliver our statutory functions to protect public health and ensure the safety and quality of medicines and health care products in the UK

We will continue to deliver our core statutory functions including to authorise and regulate clinical trials, license medicines, act as competent authority for medical devices, and monitor the performance of notified bodies with a focus on continuing to improve regulatory excellence. In addition, we will progress plans for:

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| 1b(i) | implementing the EU medical devices regulations by May 2020 and In Vitro Diagnostic (IVD) regulations by May 2022 subject to EU exit |
| 1b(ii) | implementing the new clinical trials regulations (expected to come into force by March 2020) so that the UK continues to be an excellent place to do research |
| 1b(iii) | ensuring resilience of funding for devices safety work |
| 1b(iv) | identifying opportunities for regulatory simplification and lighter touch approaches |
| 1b(v) | exploring opportunities to develop a joined up clinical trials authorisation process with other health sector partners |
| 1b(vi) | developing better real world evidence data links into the NHS for vigilance and safety monitoring |

1c: We will enhance our public health impact through building stronger partnerships, collaboration and engagement across the UK healthcare sector to improve clinical practice and protect public health

We will:

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| 1c(i) | build on existing partnerships and develop new agreements and ways of working with key NHS and health care bodies to increase understanding and impact of our contribution to public health |
| 1c(ii) | improve the way we share information with, and communicate safety messages to, clinicians and patients |
| 1c(iii) | enhance relationships with strategic partners to support speedy access to new products |
| 1c(iv) | improve the way we deliver information to the right people and organisations at the right time |
| 1c(v) | optimise licensing pathways |
| 1c(vi) | enhance strong partnerships with partners to help build an information governance environment |
| 1c(vii) | explore opportunities to develop more agile, transparent and joined up approvals procedures and simplify processes, in particular health technology assessment, to improve access to innovative medicines |
| 1c(viii) | explore opportunities to increase the Agency's influence on clinical practice through improved partnerships, vigilance data building on real world evidence, information exploitation capacity, targeting of safety information and take up of safety reporting |
| 1c(ix) | explore opportunities to adapt our regulatory approach to support innovators |

1d: We will enhance our public health impact through building stronger partnerships, collaboration and engagement including through further development of our international strategy

We will:

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| 1d(i) | strengthen our global positioning to continue to influence the development and marketing of safe effective product |
| 1d(ii) | establish and utilise the Agency's international office to support global reach and impact not least through the International Coalition of Medicines Regulatory Authorities chair and our membership of other international bodies e.g. International Medical Device Regulators Forum |
| 1d(iii) | build further a pragmatic risk and science-based approach to regulation and enforcement, working with international partners |
| 1d(iv) | build on the Agency's reputation to enhance impact and engage in international research and control collaborations |
| 1d(v) | build on NIBSC and British Pharmacopeia reputation to maintain and further expand our leading global role in standardisation and control of biological medicines, working closely with international collaborations to improve public health |
| 1d(vi) | build on existing key UK relationships e.g. with India and China |
| 1d(vii) | explore opportunities to build on existing links with foundations and international bodies (e.g. WHO) to strengthen opportunities to influence emerging markets and enhance our global reach |
| 1d(viii) | explore opportunities for new international regulatory links |
| 1d(ix) | explore opportunities to develop further the scientific reputation and reach of the Agency's regulatory centre. |

2a: We will support innovation and growth in Life Sciences

We will:

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| 2a(i) | work with the Office for Life Sciences and the Accelerated Access Collaborative to deliver the Government’s Life Sciences Industrial Strategy |
| 2a(ii) | further enhance the Early Access to Medicines Scheme (EAMS) |
| 2a(iii) | further enhance the work of the innovation office to support development and marketing of new innovative medicines and healthcare products |
| 2a(iv) | develop processes and maximise expertise in dealing with special/small populations, pragmatic trials and real world data |
| 2a(v) | explore opportunities to make the UK a magnet for life science innovation |
| 2a(vi) | explore opportunities for redesigning the way in which the Agency provides advice to developers of innovative products |

2b: We will develop and deliver innovative regulatory and legislative measures including through our offer to research and clinical trials

We will:

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| 2b(i) | increase efficiency of clinical trials and intervention studies by facilitating patient recruitment to trials |
| 2b(ii) | underpin cost effective research using real world data |
| 2b(iii) | engage with industry on innovative methodologies and deliver comprehensive research to underpin standardization, control and innovation of biological medicines |
| 2b(iv) | explore further opportunities for reclassification of medicines |
| 2b(v) | explore further market and expand our interventional research offerings to conduct national trials and to participate in international trials |

2c: We will be responsive to priority areas of scientific development including new products, product types and production methods and methodologies

We will:

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| 2c(i) | build on our horizon scanning including developing expertise on advanced genomics |
| 2c(ii) | explore new technology projects on digital products, artificial intelligence/machine learning, |
| 2c(iii) | support the development of Advanced Therapies Medicinal Products (ATMPs) and novel biologicals by providing useful standards and all-stage expert scientific advice |
| 2c(iv) | develop reference materials to help genomic diagnostics |
| 2c(v) | develop new standards e.g. for biologicals including biosimilars, advanced therapies |
| 2c(vi) | optimise access in healthcare to advances in genomics by listening to developers and regulatory guideline development etc |
| 2c(vii) | become an integral part in the UK health system response to emerging pathogens |
| 2c(viii) | support innovative strategies to reduce the use of antibiotics, e.g. implementation of novel vaccines and therapies |
| 2c(ix) | engage with the clinical diagnostics community to enhance reliability of disease diagnoses and commutability of results |
| 2c(x) | explore innovative ways of using real world data to assess clinical effectiveness in routine clinical settings |
| 2c(xi) | explore developing more agile regulatory approvals processes for novel and generic products |
| 2c(xii) | explore developing standards for new areas e.g. digital health, artificial intelligence, machine learning |
| 2c(xiii) | explore supporting opportunities in vaccines, combination products, software algorithms, remote site reporting and additives |

3: We will deliver robust proactive surveillance for medicines and medical devices including improved use of real world data and enhanced information sharing

We will:

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| 3(i) | continue to develop systems and processes for integrated medicines and devices surveillance |
| 3(ii) | develop enhance analysis of data to link reporting and information tools to relevant digital platforms |
| 3(iii) | further expand CPRD UK population data coverage to enhance the data base for vigilance |
| 3(iv) | optimise signal and risk assessment functions to respond to risks in real time |
| 3(v) | develop professional expertise and systems to improve market surveillance of medical devices using the new regulations and its new data sets |
| 3(vi) | develop and expand use of medical device electronic data standards with partners |
| 3(vii) | encourage reporting of adverse incidents from patients and health care professionals |
| 3(viii) | systematically evaluate effectiveness of risk minimisation and impact |
| 3(ix) | develop and implement a strategy on the safety of medicines in pregnancy taking into account implementing the recommendations from the Report of the Expert Working Group on Hormone Pregnancy Tests |
| 3(x) | explore action to optimise the use of CPRD data in vigilance to become a real world regulator proactively monitoring medicine and medical devices safety in real time |
| 3(xi) | explore action to increase the focus on life-cycle market surveillance |
| 3(xii) | explore actions to develop processes and IT solutions which allow us to draw on information to inform market surveillance action |
| 3(xiii) | explore opportunities to enhance public understanding of our role and how to raise safety concerns, and to enhance patient engagement in safety decision-making |
| 3(xiv) | enhance the role of pharmacovigilance in enabling the introduction of innovative medicines |

4: We will ensure the safe production and supply of medicines and medical devices through enhanced systems, strong international partnerships and educating our consumers

We will:

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|---------|---|
| 4(i) | redevelop risk-based inspection methodologies using ICMRA and key regulatory partner concepts |
| 4(ii) | continue to develop intelligence-gathering & dissemination processes to inform and direct resources and activities to areas of greatest threat/harm |
| 4(iii) | further develop shared global inspection and enforcement data and resources |
| 4(iv) | work closely with key source countries to assure safe production and supply |
| 4(v) | continue to cooperate with global partners to share intelligence and information |
| 4(vi) | continue to develop biological medicines through production and supply of WHO international standards and via our established and emerging links with key bodies, pharmacopoeias and regulators |
| 4(vii) | continue to influence consumers to change their buying behaviour through campaigns highlighting the risk of buying products through the internet |
| 4(viii) | explore new methodologies for detecting data integrity issues associated with regulatory studies |
| 4(ix) | explore the role of service providers in the delivery of key IT platforms to ensure regulatory compliance |
| 4(x) | explore opportunities to develop collaborations and information sharing with key global regulators |
| 4(xi) | develop further international partnerships with WHO and other key players e.g. the Gates Foundation |

5a: Through our Operational Transformation programme we will deliver a flexible and efficient organisation able to respond effectively to market and customers

We will:

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|----------|---|
| 5a(i) | invest in improving information management and replacing critical IT systems by March 2020 so we can continue to deliver statutory functions |
| 5a(ii) | implement best practice ways of working to drive effectiveness |
| 5a(iii) | ensure effective financial management and control |
| 5a(iv) | deliver effective enterprise management |
| 5a(v) | transform the way we do business and optimise staffing through operational transformation |
| 5a(vi) | implement change and improvement capacity |
| 5a(vii) | explore opportunities to transform our organisation through operational transformation to: <ul style="list-style-type: none"> • fix critical IT systems • embrace digital technologies • improve automation of processes where possible • respond to customers • create an environment to maintain world-leading scientific capability including investing in our facilities |
| 5a(viii) | explore opportunities to deliver improved efficiencies of the Agency cost base |
| 5a(ix) | explore opportunities to put in place a fee regime for devices safety vigilance work |
| 5a(x) | explore opportunities to increase our non-statutory income through commercial and revenue generation opportunities (especially CPRD and global standards) |

5b: We will build staff resilience and deliver a strategy to ensure the Agency has the skill mix to adapt to changing regulatory models across the next 5 years and beyond

We will:

| | |
|---------|---|
| 5b(i) | identify future capability needs and ensure we have the right skill mix to support innovation and deliver priority programmes and core functions across the next five years |
| 5b(ii) | identify opportunities to recruit, retain and develop staff with the key skills we need including through increased range of employment models, new opportunities for training and development, and options for improving the overall rewards package |
| 5b(iii) | work in partnership with colleagues and develop workforce analytics to identify key risks to staff resilience and ensure that our People Strategy and related plans seek to address these |
| 5b(iv) | continue to prioritise and invest in scientific capabilities to meet emerging needs, investing into our staff and their specialist skill sets, and in our facilities to deliver state of the art regulation and services |
| 5b(v) | focus on identifying and developing talent and on the importance of leadership, in the context of organisational development in an environment of scientific advance and environmental change |
| 5b(vi) | explore further opportunities for making the Agency the employer of choice for those who have the skills we need |

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