Medicines & Healthcare products Regulatory Agency

Corporate Plan Refresh 2016

An update of the Medicines & Healthcare products Regulatory Agency's 2013-18 Corporate Plan



April 2016







This information is also available on the <u>https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</u> website

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Introduction

This is a mid-point update and refresh of the Medicines and Healthcare products Regulatory Agency's Corporate Plan 2013-18¹. It does not replace the 2013-18 Corporate Plan, which remains a sound and valid statement of the Agency's overarching strategy and objectives, but should be read alongside it.

The purpose of the Corporate Plan Refresh 2016 is to review and update the Agency's strategic priorities halfway through the 2013-18 Corporate Plan period and refocus our priorities to end March 2018 in light of the new challenges and opportunities facing the Agency, including the:

- priorities of the new Government;
- recommendations of the the Agency's first Triennial Review²;
- fast-changing scientific landscape in which we work; and
- increasingly competitive European regulatory environment in which we operate.

Being responsive to such changes is crucial to our ability to deliver our public health mission and maximise our positive impact across the UK health and social care system and beyond.

The refresh is the product of extensive discussions with the Agency's core stakeholders across government, including our Department of Health sponsors, as well as our health and social care system partners in England and across the UK as well as representatives of the UK life sciences industry.

Context

Our mission to protect and improve public health remains at the core of what we do. We fulfil this purpose through the effective regulation of medicines, medical devices and blood components for transfusion in the UK. Recognised globally as an authority in our field, we play a leading role in protecting and improving public health and supports innovation through scientific research and development.

The Agency has three centres:

- the Clinical Practice Research Datalink (CPRD), a data research service that aims to improve public health by using anonymised NHS clinical data;
- the National Institute for Biological Standards and Control (NIBSC), a global leader in the standardisation and control of biological medicines; and
- the Medicines and Healthcare products Regulatory Agency (MHRA), the UK's regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness.

The continuing relevance of our Corporate Plan 2013-18 was confirmed by the Agency's first Triennial Review, published in July 2015 by the Department of Health on behalf of the Cabinet Office, which judged that the Agency should continue to operate in its current form. We were pleased with this reaffirmation but see no reason for complacency. The Triennial Review resulted in a number of recommendations for the Agency, which we are taking forward; some of the larger

¹<u>https://www.gov.uk/government/publications/mhra-corporate-plan-2013-to-2018</u>

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/447306/MHRA_Triennial_Review_Report.pdf

recommendations, for example those relating to increased partnership working, also feature strongly in this refresh.

Our aim is to continue to develop the Agency in response to emerging pressures and uncertainties. These include the uncertainties of operating in a competitive regulatory system within the European Union, especially as the regulatory centre moves towards a full cost recovery model. The Agency needs to offer a consistently high-quality service in order to establish itself as a regulator of choice in this environment. We are not immune from the financial pressures with which both public and private organisations are currently faced.

There are also uncertainties about how the EU regulatory system will continue to develop over the coming years, especially regarding pharmaceuticals. Whilst the overall operation of the system, as set out in EU legislation, is unlikely to be subject to fundamental change, there are major discussions on the horizon regarding system financing, fees, and the IT systems for the network; and the balance of work between National Competent Authorities and the centre is open to some level of change. The referendum on the UK's membership of the European Union is, of course, of central relevance to work of the Agency.

Rapid scientific advances are bringing new medicines, devices, and combination products to market in ever more innovative ways, making use of cutting edge science. To continue to function as an effective and flexible regulator, the Agency must anticipate new regulatory challenges, draw on the full range of capabilities of the enlarged Agency, and develop new capabilities to address such challenges.

Our flexibility in responding to change and uncertainty is arguably one of the Agency's greatest strengths. This refresh of the corporate plan aims to help focus our continued efforts to develop the Agency, our role and our operational systems in a way that maintains and builds that capacity to adapt to a changing environment.

Aims and structure

Building on the existing Corporate Plan 2013-18, the refresh seeks to sharpen up and push forward the Agency's priorities, focusing on areas where new goals for the Agency are emerging or where additional work is needed to ensure that our original objectives can be delivered by end March 2018. Consequently, it sets the strategic context for the 2016/17³ and 2017/18 annual Business Plans, which will align with the Department of Health's goals and priorities, as expressed in the Shared Delivery Plan, particularly its public health and innovation objectives.

The refresh also seeks to identify emerging strategic priorities for the Agency's longer-term future, as a first step towards our next Corporate Plan (2018-23).

³ <u>https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-business-plan-2016-to-17</u>

Our Corporate Plan Refresh is organised by five themes, which also provided the basic structure of the 2013-18 Corporate Plan:



Figure 1 The Agency's five strategic themes

We describe Themes 2, 3, and 4 – shown in the middle of the diagram above – as the 'whats'. Enabling **innovation**, joining up and improving **vigilance** across medicines and devices, and **securing global supply chains** are central to *what* the Agency seeks to achieve.

We describe Themes 1 and 5 – respectively shown at the core and outer circle of the diagram above – as the 'hows'. These are priorities in their own right but also act as enablers for delivering the 'whats'.

Each of these themes is described in more detail in the section below. Across the five themes, the Annex provides an overview of the following:

- 1. Our key achievements since the publication of the Corporate Plan in 2013⁴;
- 2. Our refocused objectives to end March 2018; and
- 3. Emerging strategic priorities for the longer term.

Our focus for 2016-18 and beyond

The 'whats'

Enabling innovation

Enabling innovation in the areas of medicines, devices, advanced manufacturing and biologics (Theme 2) remains a key strategic priority for the Agency. We seek to actively champion safe, swift innovation as a driver for improved public health, giving patients earlier access to safe and effective products. As a pragmatic and responsive regulator, we can also help to position the UK as an attractive location for innovative actors in the life sciences industry. The Agency's work in this area is closely aligned with wider UK and European agendas. Our central role in the

⁴ Further details on our achievements are recorded in the Agency's Annual Reports.

Accelerated Access Review (AAR) on speeding up access to innovative products for NHS patients will remain at the core of our innovation work and the support we can bring to the AAR's vision of better managed access for products of high therapeutic value to the UK care system. Over the rest of the Corporate Plan period and beyond, we will implement the recommendations of the Review in our own regulatory activity, as well as supporting the partnership work that the AAR is promoting. Our aim is to strengthen our service offer for innovative businesses and to further streamline regulatory processes at the UK and European level, building on our ground-breaking work on the Early Access to Medicines Scheme (EAMS), notably through the development of an EU-level priority medicines designation (PRIME) and via our involvement in the European Medicines Agency's Adaptive Pathways pilot. Developing our horizon scanning function will enable us to anticipate new regulatory challenges, and to build the scientific expertise and capacity required to effectively regulate and support standardisation in emerging areas.

Vigilance

In our vigilance work (Theme 3) our central ambition is to deliver world-leading patient safety and surveillance systems, making effective use of enabling IT technologies to join up internal systems and facilitate better integration with the outside world. The implementation of our joint strategy for pharmaceuticals and devices will continue to bring devices and medicines patient safety and vigilance activities closer together and create synergies within the regulatory centre, ensuring that incidents are handled in a consistent way and improving our ability to detect incidents with combination products; having CPRD in the organisation allows us to supplement signals-based vigilance with greater real world/real time evidence. By developing and aligning our data systems and technological capabilities, we will improve the Agency's capacity to manage increasing data flows from a wide range of sources. By strengthening our networks with the wider UK public health and healthcare system and increasing the uptake of tools for digital safety reporting and alerting building on the success of the Yellow Card scheme – the Agency will reinforce its ability to collect relevant data, promptly detect signals of emerging safety issues, and deliver timely, high-quality safety messages with a maximum impact on clinical practice, measuring outcomes. Across both pharmaceuticals and devices, we also will continue to take a leading role in data sharing and vigilance collaboration with European and international regulators, in order to support early detection of emerging issues and ensure their effective management.

Safe and secure global supply chains

We will strive to maintain our excellent track record in ensuring safe and secure global supply chains for medicines and devices (Theme 4). In the face of increasingly complex global supply chains, this will require us to strengthen intelligence sharing and regulatory collaborations with our European and international partners. We will notably focus on working towards smarter inspection regimes, regulatory harmonisation and standards in order to both reduce burdens on compliant businesses and allow for a more efficient use of regulatory resources. Our continued efforts to build regulatory capacity and compliance in key supplying countries also will contribute to ensuring the safety of UK supply chains. Moreover, we will support the effective implementation of the safety features introduced under the Falsified Medicines Directive and of the EU Unique Device Identifier system to improve traceability. This is linked to our commitment to work with the Department of Health to define and secure the wider benefits of the digitalisation of the UK supply chain.

The 'hows'

Vision, scope and partnerships

The strategic priorities proposed under Theme 1 reflect our commitment to maximising the Agency's public health impact both within the UK public health and healthcare systems and through our active engagement with European and global regulatory networks. In particular, there is a renewed focus on establishing strong, effective and purposeful partnerships, as highlighted under 'cross-cutting themes'.

Organisational excellence

Likewise, elements of achieving organisational excellence (Theme 5) - through transforming how we work and continue to grow our business - are covered under 'cross-cutting themes'.

More generally, organisational excellence covers our operational objectives – *how* we will work to ensure we operate in the most efficient manner possible in pursuing our strategic objectives and serving our stakeholders' needs. Achieving organisational excellence is a key precondition for the Agency's ability both to innovate internally and to support innovation in the UK life sciences sector. It is also central to the delivery of the core work arising from our statutory obligations and our commitment to delivering an efficient and high-quality service to our stakeholders across all our core roles and functions.

Cross-cutting themes

As previously highlighted, there are a few cross-cutting themes underpinning this Corporate Plan refresh:



Figure 2 The Agency's cross-cutting themes

Optimising synergies across the Agency

Through its expansion at the beginning of the Corporate Plan period (bringing NIBSC into the organisation and growing the CPRD), the Agency has acquired a unique combination of expertise. The integration of the regulatory centre, NIBSC and CPRD under one roof has strengthened our capabilities and will allow us more effectively to realise our strategic objectives and public health mission. The global leadership of NIBSC in the standardisation and control of biological medicines is key to keeping the Agency at the cutting edge of scientific advances in areas like biologicals and genomics. This has strengthened our ability to function as an effective regulator and facilitate innovation in these growth areas, as well as helping us to respond to fast-emerging global health threats like Ebola and Zika. The launch of the CPRD provides us with unique access to real-world data, enabling us to become a more effective and pragmatic regulator and to facilitate innovation by supporting innovative late-phase clinical trials and novel interventional studies. Equally importantly, we are committed to optimising synergies within the regulatory centre, by further developing joined-up working on medicines and devices and developing cross-cutting activities in areas like combination products, precision medicine and early access. The Agency will also seek to develop ways to better communicate our unique range of expertise to ensure we remain a regulator of choice, and to raise the scientific profile of the Agency. We recommit ourselves, in this refresh, to fully exploit the potential synergies across the enlarged Agency: we daily discover that, working together, we are more than the sum of our parts.

Partnerships

Building partnerships across the UK health and social care system and government – as well as with international regulators, industry, the third sector and the public and patients – is essential to maximising the Agency's public health impact across the UK and internationally.

The value of establishing strong and effective partnerships is continuing to increase. Strengthened partnerships and structured, purposeful engagement will contribute to the Agency's work to support innovation along the entire pathway to the patient. Strong links with our health and social care system partners also maximise our access to safety data and the impact of our safety information. By growing the CPRD and developing collaborations with academia and other partners, we will make a significant contribution to the use of data for research, benefiting the UK health and social care system as a whole. Through our engagement with partners at the European level and through the Agency's bilateral and multi-lateral relationships, we will continue to promote data sharing, regulatory harmonisation and capacity building, increasing the security of our global supply chains and contributing to a more effective use of regulatory resources. We will also continue to play a recognised leadership role in setting the strategic direction of the EU regulatory network for medicines and devices.

Transforming our organisation

Continuing to pursue ways to support the efficient and effective delivery of an excellent service notably through the Agency's IT and digital strategy, our work to develop a strong customer service orientation across the Agency and our efforts to recruit and retain an outstanding workforce – will transform our organisation.

Developing the Agency's IT and digital capabilities, and giving the organisation the capacity to run our own IT, will allow us to generate efficiencies, break down silos, and pursue opportunities to reduce burdens on business. It also will enable us to consider more fundamentally how we can transform our operations, demonstrating that we are running an efficient and high-quality service. A key element of this organisational transformation is linked to the Agency's efforts to embed a customer-service orientation across the organisation. Most importantly, we are committed to developing the people across our organisation so we establish ourselves as an employer of choice who is equipped to proactively respond to the evolving world around us.

Continuing to grow our business

The Agency is committed to exploring opportunities to grow our business in a way that is rooted in, and contributes to, our public health mission, thereby advancing our leading position in an increasingly competitive international context and strengthening the resilience of our financing both at home and abroad. Over the remainder of the Corporate Plan period, we will be taking forward a programme of work to identify projects that will allow us both to generate external revenues and to increase our public health relevance and wider positive influence further. This may include activities in areas such as global standards, the use of CPRD data, and IT and training services, which could contribute to capacity building along the global supply chain and constitute a new source of income for the Agency.

Conclusion

Read in conjunction with the 2013-18 Corporate Plan, this refresh reconfirms the Medicines and Healthcare products Regulatory Agency's strategic priorities for the remainder of the Corporate Plan period, and sets out ambitions for the longer-term future. We will continue to be responsive to emerging challenges and opportunities in our operating environment, and to strive for excellence in delivering our public health mission and maximising our positive impact across the UK health and social care system and beyond.

The agency's key achievements since the publication of the Corporate Plan 2013-18 in March 2013

1. Vision, scope and partnerships

Successfully worked with partners on

 Accelerated Access Review
 Vigilance reporting and patient safety alerting
 Provision of advice to companies with NICE Established a new infrastructure for stronger patient involvement in regulatory decision making (Patient Consultative Forum) Established the infrastructure for more structured engagement with partners across the wider public health and healthcare systems, including by identifying priority partners and creating a stakeholder database

Reinforced partnership working with NICE and Devolved Administrations (DAs) to facilitate shared understanding and dayto-day collaboration Developed a positive collaboration between CPRD and both Public Health England and the Health & Social Care Information Centre Expanded academic collaborations and developed new partnerships with universities in key areas of emerging importance (e.g. advanced therapies)

2. Enabling innovation

Actively supported the Accelerated Access Review on speeding up access to innovative products for NHS patients Launched the Early Access to Medicines Scheme to give patients with serious conditions access to novel medicines earlier, with 13 PIMs and 5 opinions delivered so far Devised and progressed improvements to EU/EMA regulatory processes to support innovation, including the Adaptive Pathways pilot and the EU Priority Medicines (PRIME) designation

Launched the Innovation Office, providing one-stop shop advice to companies wanting to bring innovative products to patients Built awareness and understanding of the agency's support to innovation, including through publishing a series of innovation case studies

Laid the foundations for the innovative use of electronic health records by CPRD to increase efficiency of clinical trials in real world settings

Progressed and / or completed substantial EU negotiations on Clinical Trials, Falsified Medicines, and Medical Devices and ensured the new legislation supports growth and innovation

Successfully reinforced the horizon scanning capability of the agency

Relaunched joint MHRA/NICE scientific advice, with supporting website information and seminars/workshops

3. Vigilance

Developed a joint patient safety and vigilance strategy for pharmaceuticals and devices to align activities and create synergies within the regulatory centre

Strengthened the use of CPRD's real-world / real-time data to support enhanced vigilance capability for medicines and devices

Demonstrated the success of strengthened European cooperation on vigilance in addressing emerging risks

Furthered EU-level pharmacovigilance collaboration through the SCOPE Joint Action, delivering 10 reports on the current EU situation and contributing to the development of European best practice

Formed networks of medicines and medical devices safety officers and updated the Central Alerting System to ensure that patient safety information is embedded in healthcare services Introduced new channels for reporting adverse drug reactions by the general public via the Yellow Card App, successfully using digital technologies in vigilance reporting

Developed a new Yellow Card reporting strategy and extended the scope of the Yellow Card portal to include devices, counterfeit/falsified and defective products Developed tools for analysing social media data through the WEB-RADR (Recognising Adverse Drug Reactions) project to explore how such data can be used to support pharmacovigilance activities Conducted initial studies evaluating the outcomes of the agency's regulatory action, resulting in the implementation of a new strategy for embedding outcomes research through the benefit risk assessment process

4. Secure global supply chains

Achieving a secure regulated supply chain in the UK

Merged the devices and medicines enforcement functions and developed a control strategy informed by a comprehensive strategic threat assessment

Collaborated with international regulators on inspections, regulatory harmonisation and standards

Moved towards a risk-based approach to inspections to further secure supply chains, reduce burdens on compliant industry and ensure a more efficient use of regulatory resources

Supported regulatory compliance and competence in key supplying countries (e.g. via Memoranda of Understanding with India and other partners)

Strengthened Medical Devices Notified Bodies across the Union via its involvement in the Joint Audit programme

Successfully participated in measures to combat the illegal internet trade of medical products, including Operation Pangea

Played a central role in product standardisation via NIBSC / British Pharmacopeia Increased public awareness of the dangers of buying medicines and medical devices through unregulated supply chains

5. Organisational excellence

People	 Launched an employer branding drive to support recruitment, with a particular emphasis on hard-to-recruit roles Strengthened internal talent management and development including a focus on leadership capability, as reflected in increased employee engagement across the agency
IT / Digital	 Reformed the operating model of the agency's IT services, delivered a series of accelerated enhancements to existing systems and strengthened the agency's internal capabilities and procedures Critically reviewed current operating models to understand the opportunities of digital transformation and identified relevant technology platforms
Finance	•Developed a new plan for income generation to align income and expenditure related to fees while continuing to generate surpluses from other activities
Regulatory Excellence	 Met cross-government objectives on burden reduction (e.g. Red Tape Challenge) and regulatory improvement Successfully concluded EU negotiations on key legislation, influencing outcomes to achieve proportionate regulation Made well-received contributions to key government initiatives such as the Accelerated Access Review
Customer service	 Strengthened the agency's responsiveness to customers' needs by introducing new feedback mechanisms and a cross-agency Customer Services User Group Achieved external accreditation from Customer First for our main customer services function
Comms	 Successfully handled a range of high profile medicines and medical devices issues, ensuring that key safety messages and advice were communicated effectively and in a timely way

The agency's goals for next two years, until the conclusion of the 2013-18 Corporate Plan period

1. Vision, scope and partnerships

Extend our collaboration with wider public health and healthcare system partners on areas of shared concern: actively supporting the implementation of the recommendations of the Accelerated Access Review for both pharmaceuticals and devices, working closely with other UK partners to support innovation

Develop further partnership work with healthcare professionals and health system leaders to ensure that our safety information and regulatory action is embedded in clinical practice

Extend effective mechanisms for structured engagement to new partners (Care Quality Commission, NHS England, Public Health England) and further strengthen engagement with the Devolved Administrations and NICE

Provide stakeholders with further opportunities for dialogue with the agency and strengthen their engagement and involvement early on in our projects and decision making

Actively engage in global partnerships, especially for the purpose of exchanging vigilance data and inspection information, incident reporting, and taking coordinated action, and in European and global discussions about the future of the regulatory environment for both pharmaceuticals and devices

Continue working in partnership with the Health & Social Care Information Centre to streamline processes where possible, in order to maximise the use of health data in clinical and public health research

Continue to build academic partnerships and scientific capability to support the safe and effective development of key innovative medicines and technologies (e.g. precision medicines, advanced therapies) and collaborate with partners to develop talent for the UK public health arena (e.g. lectures, secondments, joint working)

2. Enabling innovation

Actively support the implementation of the recommendations of the Accelerated Access Review

Further develop and improve the Early Access to Medicines Scheme to improve patient access to innovative medicines in areas of unmet clinical need in the NHS

Continue to work towards streamlining EU regulatory processes by contributing to the development of an EU-level priority medicines designation (PRIME) and the Adaptive Pathways pilot

Increase uptake of CPRD's real world data services to support innovative late phase clinical trials and novel intervention studies

Expand the support offered to innovative businesses, especially SMEs, and academia via the Innovation Office and increase awareness of our innovation support work

Further develop the agency's horizon scanning function to identify new products and ideas that may require investments in new regulatory capacities and expertise, and explore the potential benefits of linking up with other organisations' horizon scanning activities

Build scientific expertise and capacity within NIBSC and across the wider agency to support key innovative areas of product development (e.g. genomics, advanced therapies, cancer immunotherapy)

Ensure the proportionate and effective implementation of key EU legislation on Clinical Trials and Medical Devices, and influence wider thinking, including on ATMPS

Operationalise a new regulatory area on consumer e-cigarettes under the revised Tobacco Products Directive

Reinforce our efforts to promote access to innovative self-care products, facilitate applications for switches to self-care, and work with industry to identify how regulatory approaches adapted to the specificities of the self-care market could deliver public health benefits

3. Vigilance

Position MHRA as a key patient safety partner embedded in the healthcare system and recognised for its joinedup approach to patient safety, vigilance and post market surveillance across medicines, devices and blood safety

Develop and implement the strategy for joint vigilance for medicines and medical devices based on real-world data in order to exploit synergies within the regulatory centre

Embed the agency's unique access to the real-world data and analytic expertise of CPRD into our work on vigilance/market surveillance, transforming the MHRA into a 'real-world regulator'

Bring together the agency's data systems and develop Business Intelligence tools to enable us to more effectively manage vastly increasing data flows from multiple channels and optimise safety messaging

Take a leading role in strengthening mechanisms for effective data sharing with national and international partners in order to obtain access to wider vigilance data pools and support early detection of emerging issues

Work effectively with other regulators in Europe and globally to manage decisions that need to be taken as a result of vigilance and to maximise regulatory resources

Further strengthen our engagement with UK practitioners to ensure we transmit timely, high-qualify information with a maximum impact on clinical practice

4. Secure global supply chains

Increase the use of intelligent, targeted risk management based on intelligence sharing with other regulators

Play a recognised leadership role in European and international regulatory collaboration on inspections, regulatory harmonisation and pharmacopoeial standards in order to secure supply chains, reduce burdens on compliant businesses and ensure a more efficient use of regulatory resources

Continue to strengthen relationships with international partners - especially India, China and USA – and build regulatory capacity, competence and compliance in key supplying countries

Exploit synergies across the agency in biological medicines and develop measurement and quality assurance standards to support competition in the market for high quality biological medicines

Support the implementation of the Unique Device Identifier system and work with partners along the devices supply chain to fully exploit its potential for effective postmarket surveillance and crisis management across the health and social care system

Seek to exploit fully the benefits of the Falsified Medicines Directive to increase the integrity of supply chains, and prepare for the use of the new Unique Identifier to strengthen pharmacovigilance and pharmacoepidemiology, particularly for vaccines

Implement a major new communication campaign to increase public awareness of the dangers of purchasing medicines and medical products outside of the regulated supply chain

5. Organisational excellence

People

• Develop and implement an overarching people strategy for the agency based on a lifecycle approach, to improve all aspects of people resourcing, leadership and management and advance the people contribution to meeting our challenges and aims

IT / Digital

- Produce a digital transformation plan to manage the introduction of flexible, modern applications and a shift to digital platforms that will enable new revenue streams, continuous service innovation and an enhanced customer experience
- Integrate and transform business and data management systems, processes and applications across the enlarged agency to reduce burdens on staff, increase capabilities and break down internal silos

Finance

• Readjust our fees regime for medicines licensing and introduce new fees regimes for the FMD logo scheme, consumer e-cigarettes and devices, commencing the move towards cost recovery

Growth

• Develop a programme of activity to identify and test business cases for growth and development that support the public health mission of the agency

Regulatory Excellence

 Refresh our Regulatory Excellence programme and continue to champion proportionate regulation to maintain effective assessment of all products and bring innovative products to market safely and quickly, making a demonstrable contribution to the Government's deregulatory target

Customer service

• Develop feedback systems and customer service capabilities across the agency in order to increase our customer focus and responsiveness, and use the opportunities of digital investment to provide more customer-focused and easy-to-access services

The agency's strategic aims for the future, beyond 2018

1. Vision, scope and partnerships

Strengthen links with academia and research to engage with evolving areas of innovation

Actively support the implementation of the recommendations of the Accelerated Access Review to support innovation, collaborating with other health system partners

Play a recognised leadership role in setting the strategic direction of the EU regulatory network

Be a constructive partner in global regulatory networks, in sharing vigilance information and inspection information and coordinating decisions on vigilance and incident management

Further strengthen mechanisms for sharing vigilance information and managing incidents in collaboration with wider UK public health and healthcare system partners

Build MHRA global influence through bilateral and multi-lateral relationships and through engagement with ICMRA, IMDRF, WHO and other key players

2. Enabling innovation

Aim to be recognised for our ability to think flexibly and make bold regulatory decisions in justified circumstances, especially where there is an unmet clinical need or unserved population

Strengthen the agency's internal infrastructure for supporting innovative companies through the regulatory process, notably the organisational structure, resources and internal expertise of the Innovation Office

Plan and focus our efforts on upskilling/resourcing in selected areas of innovation, based on the conclusions of horizon scanning, and embed them in innovation networks

Build on existing partnerships throughout the public health and healthcare systems and with industry to develop clear drug and device development pathways for getting innovative products safely and swiftly to market

Work to provide better guidance on areas of innovation, by providing access to expertise and working with European partners

Enable safe access to innovative products with prospective risk/benefits monitoring

Support the role of regulated medicines and devices in the development of personalised medicine

3. Vigilance

Having drawn together the joint strategy, the next step will be to review and test the agency's activities against the following:

Further increase patient safety by strengthening post-market clinical follow-up and market surveillance activities for pharmaceuticals and devices

Build on its full range of scientific and technical capabilities to capture adverse events and incidents from all sources, including based on real-time data, and develop leading signal detection and surveillance systems

Pursue the integration / standardisation of data collection by clinical practitioners and in emerging technological areas to facilitate signal detection

Ensure that the regulator is equipped to proactively address the challenges related to emerging technologies and develop new approaches to regulation where required

Continue to play a leading role in national and international collaboration to obtain access to wider vigilance data pools and exploit them more effectively to increase patient safety, coordinating activities to maximise regulatory resources

4. Secure global supply chains

Work to maintain our record in preventing the penetration of the regulated supply chain in the UK by counterfeit / falsified or substandard products

Engage in assessments of risk in order to ensure we can take timely action to safeguard consistency and continuity of supply

Continue to address issues arising from unregulated supply chains and challenges arising from new modes of supply (e.g. distance sales, direct-to-consumer sales of diagnostics)

Build upon our strategic partnerships with key supplier countries in order to develop their capacity and increase our ability to rely on their regulatory activity

Continue to identify opportunities for smarter regulation and to move towards more mutual reliance/recognition on inspections with international partners

Reduce the burden on industry through a reduction in the number of inspections for compliant companies and the promotion of internationally harmonised standards

Continue our work to alert the public to the dangers of procuring products through unregulated channels

5. Organisational excellence

People	Seek to establish ourselves as an employer of choice, with a complement of people and a sustainable pipeline to meet the needs of an expert, innovative organisation and adapt to changing requirements
IT / Digital	Consider digital technology as an enabler for a transformation of the agency's business models, services and ways of working
	Use new digital platforms to provide existing services via self-service and to speedily deliver innovative digital services, enhancing customer service
Finance	To continue to invest in the agency's public health influence and impact across regulation, science and the use of real-world data
Regulatory	Respond to the Business Impact Target to reduce regulatory burdens on industry
Excellence	Influence the regulatory agenda in the UK, Europe and globally, which includes identifying / proposing changes to our legislation and enforcement frameworks to encourage growth and innovation
Customer service	Continue work on putting the customer at the heart of our businesses, increasing our customer responsiveness and customer feedback, and using the opportunities offered by our digital investments to transform the way customers interact with us
Comms	Maximise the opportunities to market, promote and develop our products and services so they continue to meet changing customer needs and exceed expectations
	Continue to build the agency's reputation and profile as a leading global regulator, and for science and research