Medicines and Healthcare Products Regulatory Agency

Corporate Plan 2013-2018

CPRD NIBSC MHRA

Medicines and Healthcare Products Regulatory Agency

2013-18 Corporate Plan

The Medicines and Healthcare Products Regulatory Agency is an Executive Agency of the Department of Health and a government trading fund, with a mission to protect and improve the health of millions of people every day through the effective regulation of medicines and devices, underpinned by science and research.

April 2013

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Foreword

As the newly appointed Chair of the Medicines and Healthcare Products Regulatory Agency, it is an honour to introduce our five year Corporate Plan for 2013-18.

Some big changes to the Agency mark the start of this, our second decade. We are delighted that the National Institute for Biological Standards and Control will become part of the Agency from April 2013. This will reinforce our capabilities in regulating the new generations of biological products, and thereby our role in an area of science of central importance to the health and wellbeing of the public and patients whose interests we serve. The period of this Corporate Plan will also see the further development of the Clinical Practice Research Datalink, which the Agency launched in 2012. The CPRD provides a world-class link into the unique healthcare datasets of the NHS, offering unprecedented opportunities to link regulation to clinical practice in the real world.

The enlargement of our functions and capabilities through NIBSC and CPRD is central to the strategic direction mapped out in this Corporate Plan.

The plan sets out how we will embrace the key opportunities and meet the challenges that we have identified for the next five years. These start with the changing expectations from society about what it wants from the regulator. As always, the regulator must continue carefully to assess the relative benefits and risks of products and determine which enter, and remain on, the market.

But there is also an increasing role for regulation to help inform and influence individual clinical decisions: our work with patients, the public and healthcare professionals will contribute importantly to this. Acting in the best interests of individual and public health also means supporting innovation in the development of useful new medicines and devices. We are committed to this, and the plan sets out our approaches to getting innovation into clinical use as quickly as is safely possible, to improving the oversight and vigilance of products once they are in use, and to protecting UK citizens from threats in the supply chains of the two highly globalised industries that we regulate. Lastly, the plan sets out the actions we will take to build a strong, resilient organisation focused on offering a high quality, good value service.

We are very conscious that, as well as the opportunities of the next five years, we face some major challenges. The period of this Corporate Plan will see further integration of medicines regulation across the European Union: we want, and intend, to continue to be a key, constructive contributor to the EU regulatory networks in both medicines and devices. In common with all parts of the public sector, we will need to deal with rising demands and pressures to control and reduce

budgets, including in the industries we regulate: we remain committed to offering the cost-effective and efficient service that industry has consistently said is highly valued.

Our Corporate Plan sets out our ambition to seize the opportunities from our enlarged role to build a world-class organisation in all aspects of the work we do.
We regulate global industries and must continue to develop a global outlook.
We have an unusual, if not unique, set of activities encompassing regulation, standards, research and information; we work at a critical juncture between science, industry and clinical practice.
However, that uniqueness is not, in itself, enough to deliver our vision for the next stage of the Agency's development: a key commitment underlying our plans for the next five years is for reinforced collaborative working with other partners in the new health and social care system, the EU and global regulatory networks, healthcare professionals, the industries we regulate and the patients and public whose interests we serve.

I hope you enjoy reading the plan, and that it might inspire you to join us in working towards the strategic objectives set out within it.

Professor Sir Gordon Duff
Chairman
Medicines and Healthcare Products Regulatory Agency

1. Purpose of the Corporate Plan

This Corporate Plan sets our strategic direction for 2013-18. It does this by describing:

- our **mission and aims**
- key **challenges and opportunities** that we will face over the next five years
- **objectives** that will enable us to deliver our mission and aims in the face of these challenges and opportunities
- key **activities and outputs** through which we will meet our strategic objectives, and the **outcomes** that these will achieve or to which they will contribute
- **supporting strategies and programmes** to help ensure that we deliver our work efficiently and effectively, and can communicate clearly with our stakeholders.

This plan focuses on how we intend to respond to the challenges and opportunities facing us. It is a plan for an enlarged organisation. From April 2013 our functions – notably relating to the regulation of medicines, devices and blood products – will include the Clinical Practice Research Datalink (CPRD)[1] and the National Institute of Biological Standards and Control (NIBSC)[2].

The strategic direction set out in this plan will ensure that the whole organisation achieves the full benefit from its enlargement, securing our future capability with the new generation of biological products and building our capacity to use clinical data and information. At the same time, the plan demonstrates how we propose to develop further our extensive range of continuing regulatory and wider public health roles and functions. In dialogue during the development of this plan, stakeholders stressed the importance of continued delivery of an efficient and high quality service in all our core work. Thus, while the plan has an emphasis on areas where we have identified a particular need for strategic change and development, we also have a total commitment to the achievement of excellence in all our continuing roles, functions and services.

Our operating and financial context

After a long period in which our operating environment has been relatively favourable, particularly for medicines regulation, the operating environment for the timeframe of this plan will be much more challenging. Further increases over the next five years in the amount of regulatory activity conducted within the EU network rather than at purely member state level should improve the overall efficiency of the regulatory system, but at significant risk to the financial income of individual agencies.

In relation to medicines, there is some evidence that the total amount of licensing activity is falling. In addition, new pharmacovigilance functions established in EU law may reduce the amount of vigilance activity carried out at member state level, but the new functions have yet to be accompanied by an EU fee regime to pay for them. In relation to devices, we are managing a significant reduction in the money we receive from central Government funds for our regulatory functions. This is set against an increase in devices activity – including rapid growth in the number

[1] CPRD is the new English NHS observational data and interventional research service, jointly funded by the MHRA and the NHS National Institute for Health Research (NIHR). Its services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research, and deliver research outputs that are beneficial to improving and safeguarding public health.

[2] NIBSC is the global leader in the field of biological standardisation, responsible for developing and producing over 90% of the international standards in use around the world to assure the quality of biological medicines. It is the UK's Official Medicines Control Laboratory (OMCL), responsible for testing biological medicines within the framework of the European Union.

and complexity of invasive and implantable devices; an increase in adverse incident reports; and the scope of regulation expanding into areas such as cosmetic devices, free-standing software and greater scrutiny of Notified Bodies.

We took steps two years ago to reverse the increase in staffing that had helped us respond to a growing amount of medicines licensing activity. In many of the key areas of our work, including that delivered by NIBSC and CPRD, we operate in an environment where the industries we regulate have a choice about whether to use us. The consistent feedback from these industries is that they value the quality and the speed of the services that we provide. We will continue to deliver our services as efficiently as possible, while exploring options to reinforce the financial resilience of the organisation in key areas, notably devices regulation.

The challenge of regulating two industries – medicines and devices – with highly globalised supply chains will remain for the period of this Corporate Plan. We will continue to prioritise our contribution to the successful operation of the EU regulatory networks for both industries, mindful of the reality that national agencies and national Ministers remain, in the first instance, accountable for the appropriate regulation of medicines and devices.

Over the next five years, a number of factors will create challenges for us as a Trading Fund:

- Being a ‘three centre’ organisation with quite distinct but complementary functions, pursuing very different development paths. These centres will operate within quite different financial opportunities and constraints and need collectively to deliver our statutory obligation to earn a 3.5% return on our assets.

- The competitive position of our regulatory functions in relation to other national agencies. This will continue to affect volumes of remunerated activity, but with an increasing proportion of medicines-related regulatory income being derived from activity on behalf of the EU network. These EU fees are not cost-based, are not within our control and are designed to satisfy the UK’s needs within the wider EU community.

- The expectation of greater efficiency in the delivery of medicines and devices regulation, as it becomes an increasingly collective and networked activity between national agencies.

- The cost recovery basis of our regulatory functions, with fees seeking just to cover the associated costs incurred. To illustrate the fragility of this model, and the potential for significant change during the period of this plan, three out of four of the enlarged Agency’s staff will be funded from regulatory fees. Any fee reduction from lower volumes of work, lower fee levels or changes in the functions delivered would require immediate and proportionate reductions in costs and reprioritisation of effort.

Our planning process

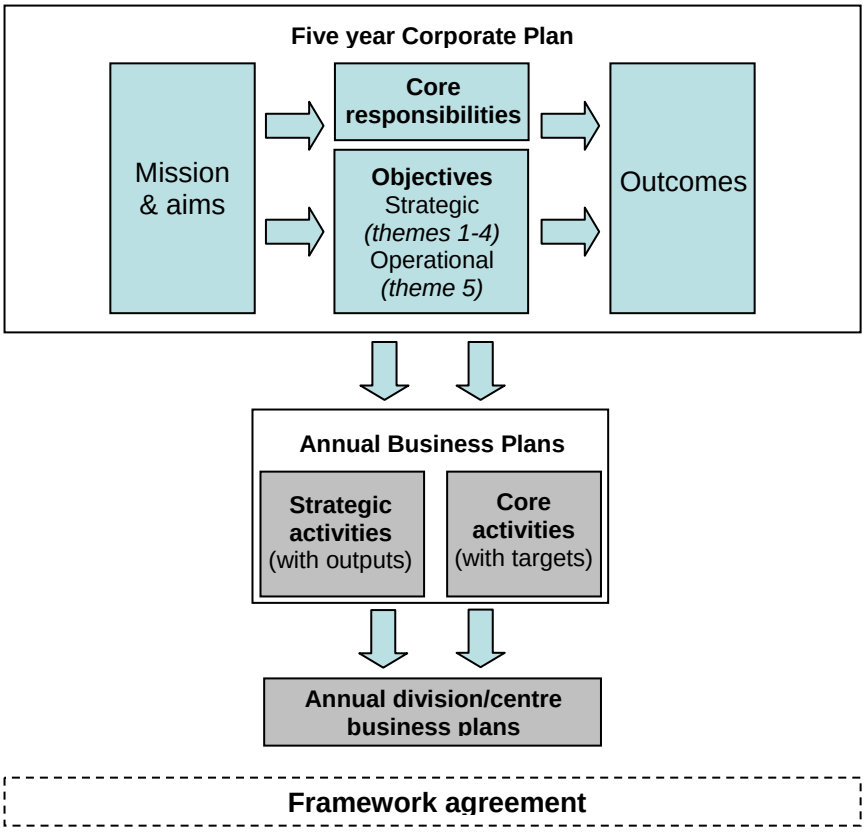
This plan has a generally high-level and broad focus, providing a structure for our work over the next five years. It will feed into our annual business plans, which will be published at the start of each financial year. The business plans will set out activities that will contribute to delivery of the Corporate Plan in each given year. They will be ‘SMART’ (specific, measurable, attainable, realistic, timely) and contain targets that will enable us to monitor and report on our progress, and allow stakeholders to see the key work we will be undertaking. They will provide further and more quantitative substance to the Corporate Plan, which is an inherently broad and high-level document.

Our business plans will also be particularly important in ensuring that we deliver our core responsibilities as effectively and efficiently as possible, and provide a high quality service to our customers. They are a core component of a wider planning process involving internal business

plans for different parts of the organisation. These internal plans ensure that Agency-level activities are managed effectively alongside our core functions.

The Agency is an Executive Agency of the Department of Health and a government Trading Fund. As such, we work in close partnership with the wider Department and other parts of Government (for example, with the Department for Business, Innovation & Skills on the Life Sciences and Growth agenda) to deliver common objectives. These relationships and our governance and accountability structures are set out in a Framework Agreement.[3]

The following diagram shows how our planning process functions:



[3] The Framework Agreement is available at www.mhra.gov.uk.

2. Our mission, aims and values

Our mission

We protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research.

Our aims

Through science-based regulatory work and the contribution of the Clinical Practice Research Datalink and the National Institute for Biological Standards and Control, we aim to:

- ensure that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality, efficacy and effectiveness
- ensure that the supply chain for medicines, medical devices and blood components is safer and more secure
- promote international standardisation and harmonisation to assure the efficacy and safety of biological medicines
- promote increased understanding of the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- promote and support innovation, research and development beneficial to public health
- influence the shape and operation of the UK, EU and international regulatory frameworks in which we operate, to achieve risk-proportionate and effective public health protection
- achieve national and international recognition of the excellence of our work in protecting and promoting public health, thereby contributing to the success of the UK economy.

We seek to deliver these aims successfully by being a well-run, cost-effective organisation that has excellent relationships with stakeholders and regulates proportionately and efficiently.

Our values

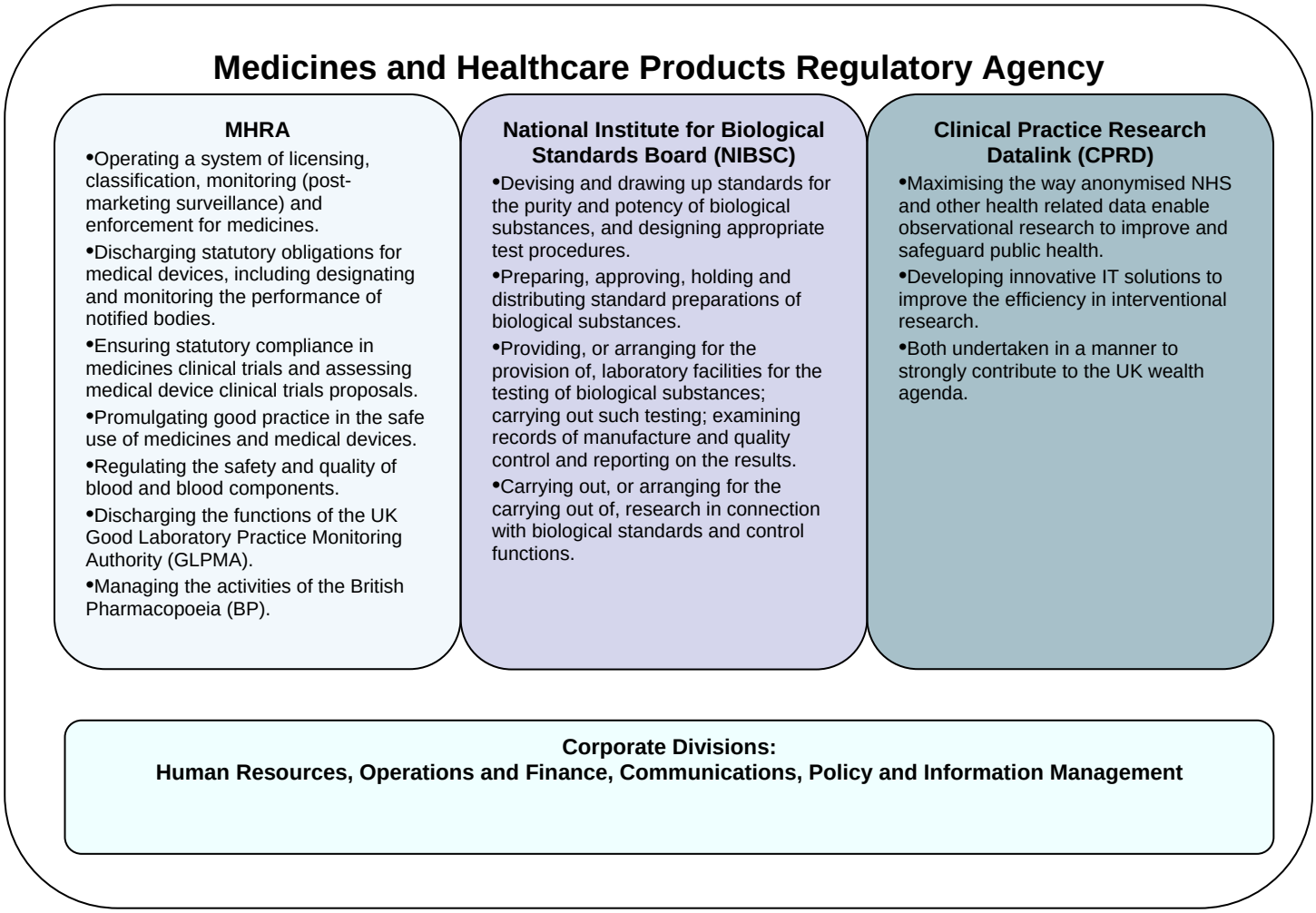
We are:

- innovative
- proactive
- impartial
- evidence-based
- open
- trustworthy.

3. Our core work

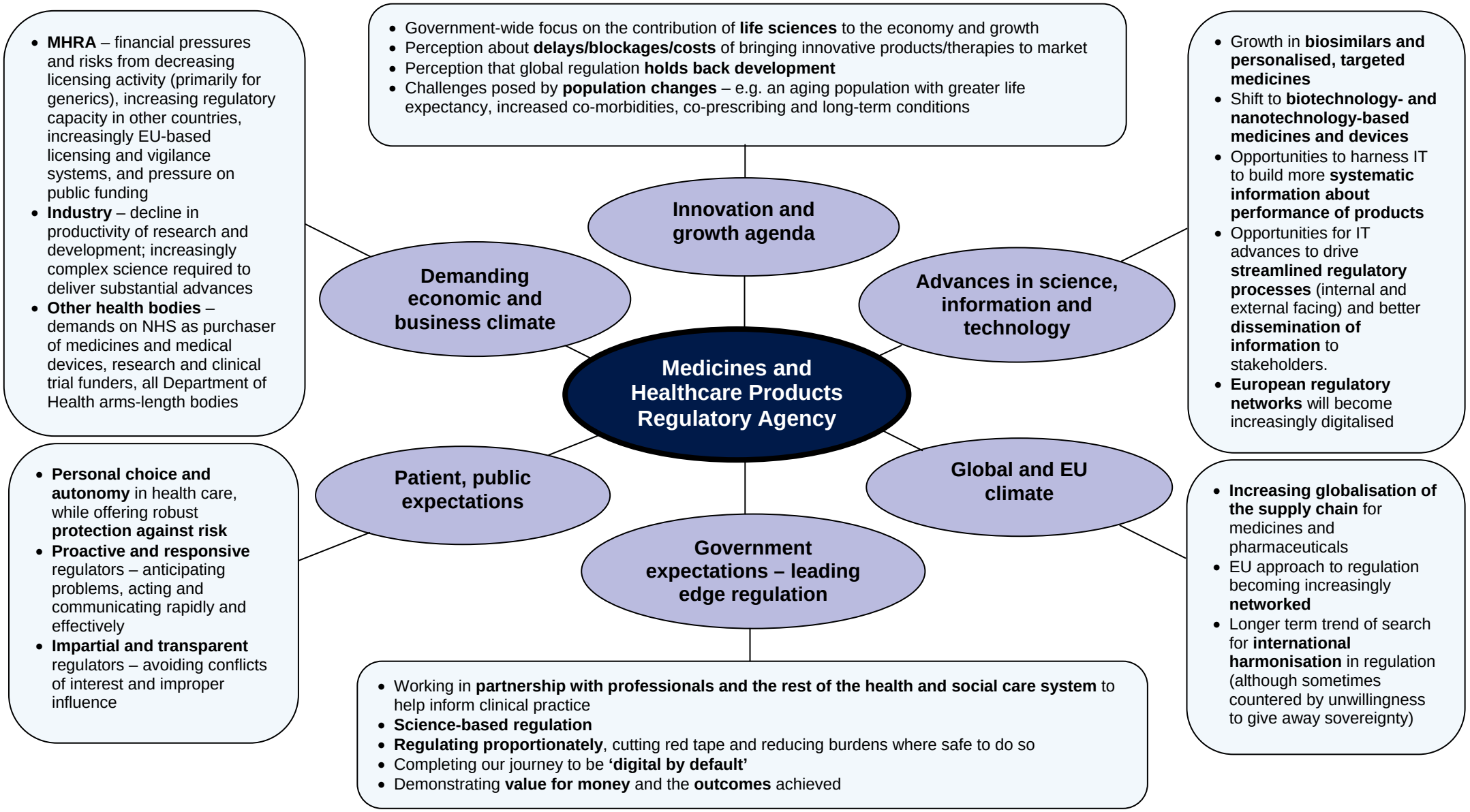
While this plan is predominantly concerned with the strategic change that we are seeking over the next five years, throughout this period we must and will continue to deliver a broad range of core work. Delivered through our three 'centres' and enabled by our various corporate divisions, this work fulfils our statutory obligations and is fundamental to our role as a public health body and Executive Agency of the Department of Health.

We will strive to deliver this work as effectively and efficiently as possible, and to provide an optimal service to our stakeholders. Given its strategic focus, this plan does not list our core work in substantial detail. However, an outline is provided below and more information is contained in our Framework Agreement referred to in chapter 1.



4. Challenges and opportunities facing us over the next five years

A number of factors will influence our strategic direction over the next five years. These will create challenges for us in delivering our public health aims, but also present opportunities to meet these aims more effectively and efficiently. They provide the basis of our objectives in this plan.



5. Our objectives

Our objectives are grouped under five themes. The first four themes cover strategic objectives – the key strategic changes we are seeking to deliver over the next five years. The fifth theme covers operational objectives – *how* we will work in order to deliver our strategic objectives, while delivering our continuing regulatory responsibilities.

The first four themes in this chapter are accompanied by flow diagrams. These show some of the key areas of work that will be undertaken to meet our strategic objectives, and the outcomes and ultimate impact that we expect these to contribute to or achieve. As part of the work to monitor and report on progress on the Corporate Plan objectives, we will establish a set of reporting measures and indicators.

Medicines and medical devices: different regulatory regimes, common challenges

While the regulatory regimes for medicines and medical devices are significantly different, we see some common challenges facing them and the Agency itself:

- Getting right the balance of regulation before and after entry of medicines and devices to the market, especially risk management in support of innovation.
- Building a controlled space for learning about the performance of medicines and devices, especially those that are innovative and may be higher risk, over the early life cycle.
- Ensuring that quality is maintained as more manufacturers around the world enter the market, especially in the area of biologicals.
- Working across the EU and internationally, especially on licensing, vigilance and inspection.
- Engaging with healthcare professionals to influence clinical practice and improve information on the performance of medicines and devices (i.e. their safety and effectiveness in actual clinical use).
- Ensuring stakeholder understanding of what the regulator can and cannot do, enabling more informed decisions by clinicians, patients and the public.
- Working with other regulators – including making an effective and clearly defined contribution to the work of bodies responsible for health technology assessment.
- Reducing the number of counterfeit medicines and devices in the supply chain.
- Increasing transparency in how we operate.
- Promoting a consistent, proportionate approach to regulation, reducing burdens where it is safe and cost-effective to do so.
- Running an efficient business, ensuring sustainable funding and resourcing of regulatory activity and demonstrating value for money.

This plan and accompanying annual business plans aim to set out a shared and consistent approach to progressing our strategic objectives for medicines and devices regulation, incorporating the contribution from NIBSC and CPRD. Our vision is one of shared, corporate endeavour, recognising that there will always be important work that will be specific to individual parts of the organisation.

Theme 1: The role of regulation and the regulator

We will continue to undertake our core regulatory work, delivering our various legal responsibilities. However, we will also aim to broaden our own – and others' – understanding of our regulatory role, and realise the potential for it to play a more effective and integrated part in the wider public health and healthcare systems.

We will continue to have a vital gatekeeper function in allowing products to come onto and remain on the market, ensuring that they meet required standards. Increasingly, however, we will also have access to real-world data from the Clinical Practice Research Datalink (CPRD) about the performance of medicines and devices – i.e. their safety and effectiveness/performance in actual clinical use. This will extend the opportunities for us to offer authoritative advice to clinicians and patients about the products we regulate. We will work in partnership with others – for example, by working more closely with specialist organisations in medicine and surgery – in order to maximise the value of the information and advice we provide, and the way it is communicated, in order to influence clinical practice for the benefit of patients.

We do not have, and do not envisage having, a role in evaluating the cost-effectiveness of medicines or medical devices. However, the interface between us and health technology assessment (HTA) bodies will increase in scope and importance; data from CPRD has the potential to inform the work of HTA bodies as well as our own regulatory work. We are also looking to improve the way in which our product regulation integrates with the roles of professional regulation and standards.

Effectively informing clinical governance and influencing clinical practice will involve significant work over the period of this plan to strengthen our collaborations with a wide range of health-related bodies within the new health landscape, and with professional bodies. It will also involve a radically strengthened partnership with patients, patient representative groups and the wider public. Greater patient participation in clinical decision-making has to be accompanied by increased understanding of the benefit:risk decisions that are being taken. In particular, we will explore how our regulatory decisions can be more informed by the experiences and perspectives of patients – for example, on issues relating to quality of life and patients' willingness to accept risk.

In summary, over the next five years our objectives will be to:

- **make best use of data available through CPRD and other sources, to provide more information about the performance of medicines and devices (benefit:risk) to influence clinical practice**
- **build partnerships to ensure that information about the performance of medicines and devices influences clinical practice in the interests of patients**
- **enhance understanding of the role our regulation should play as part of wider public health and health care systems.**

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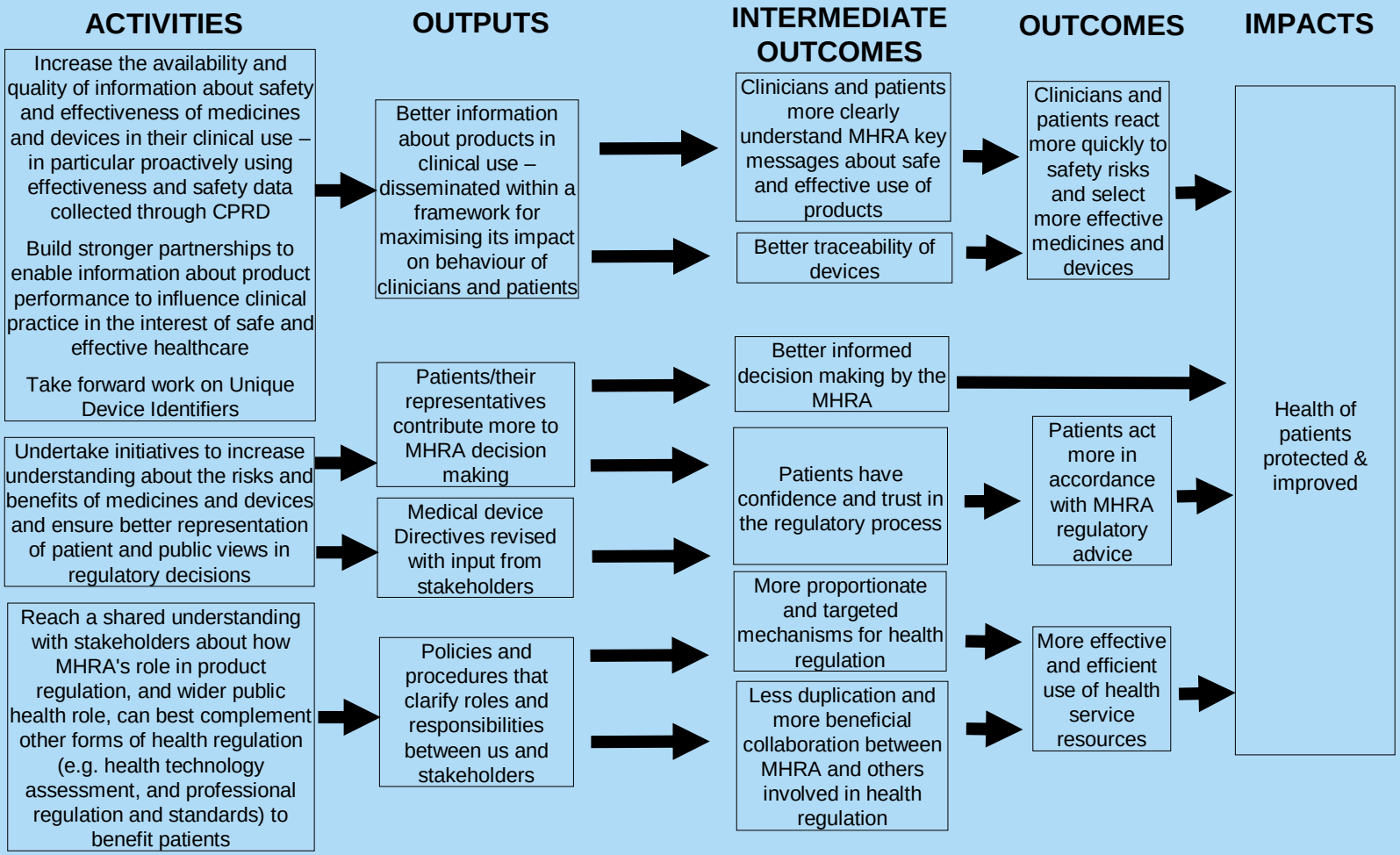

Theme 2: Bringing innovation safely to market

Over the period of the plan, we will aim to capitalise on the wider opportunities created by the enlargement of our organisation. NIBSC is the global leader in standardisation and control of biological medicines and has an international reputation for excellence. We therefore have unique expertise that can support the safe and effective development of biologics, a hugely important and growing class of medicines where opportunities are great but risks need to be managed very carefully. We also believe that the potential of the data and services offered by CPRD will be recognised in the UK and beyond – for example in the prospects it offers for better targeted and more efficient clinical trials, in order to facilitate earlier and more effective development of innovative products. In addition, the excellence of services offered by both NIBSC and CPRD potentially has important economic benefits in highlighting the advantages of the UK as a base for innovation and research.

There are many levels to the role we will seek to play in facilitating innovation beneficial to healthcare. These range from basic good practice as an accessible and efficient regulator, through provision of the crucial standards needed for accurate measurement and consistent manufacture of medicines and devices, to strategic reshaping of the regulatory framework within the UK, the EU, and internationally – based on the best available scientific evidence and a pragmatic approach to risk and benefit.

We will aim to support innovation that promises significant health benefits to reach patients as early as can safely be achieved. We will also aim to introduce a more controlled and structured roll out of innovation in targeted groups – so that efficacy/effectiveness and safety in actual clinical use can be better assessed; and so that outcomes can be fed into clinical governance and practice, and into clinically-led external programmes such as Beyond Compliance. We hope that the Earlier Access and Adaptive Licensing schemes will be significant steps towards these aims. We see these developments as part of a wider strategic move to explore whether targeted adjustments to the boundaries between pre- and post- marketing work may benefit patients, while ensuring that their safety is robustly safeguarded.

In summary, over the next five years our objectives will be to:

- **influence thinking and regulation in the EU and globally to achieve a convergence of standards – ensuring effective EU laws and progressing international thinking about global governance**
- **explore, in the context of Government interest in adaptive licensing, how we might redraw the boundary between pre- and post- market entry regulation to enable earlier patient access to beneficial innovative products, while managing associated risks**
- **realise the full benefits of NIBSC and CPRD to support innovation and contribute to the Government life sciences and growth agendas.**

2. Bringing innovation safely to market

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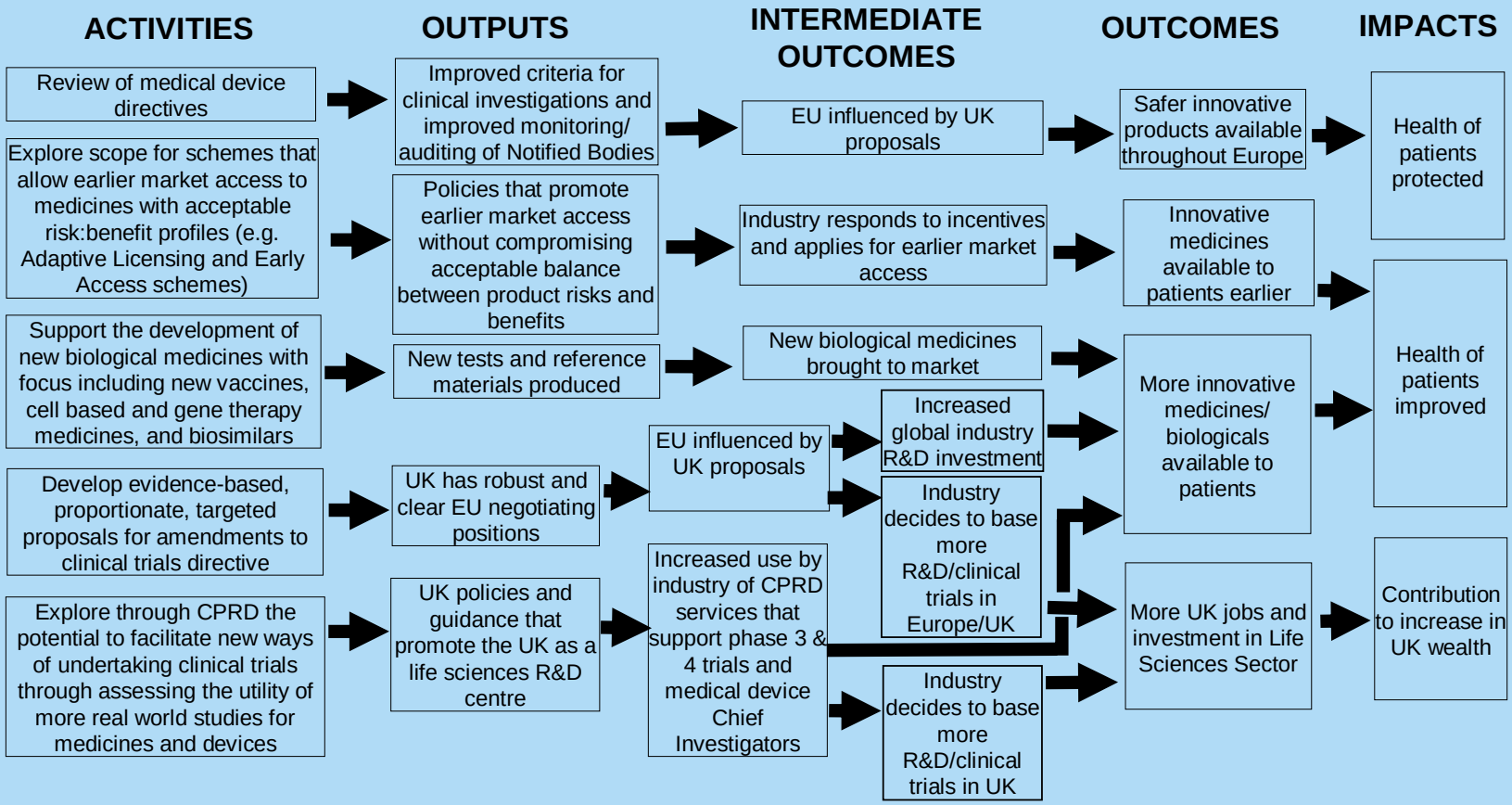
- To explore, in the context of Government interest in adaptive licensing, how we might redraw the boundary between pre- and post- market entry regulation to enable earlier patient access to beneficial innovative medicines, while managing associated risks
- To realise the full benefits of NIBSC and CPRD to support innovation and contribute to the Government life sciences and growth agendas.



Theme 3: Strengthening surveillance

Overall, we will seek to achieve a step-change improvement in the effectiveness of surveillance of medicines and devices on the market and the use to which this is put for the benefit of public health. This will include increased use of real-time benefit:risk data, more prospective identification of areas for monitoring and improved tools, in particular utilising the benefits of CPRD data. We recognise that real-world improvements resulting from changes in devices regulation will generally take time to become visible, and that sustained monitoring of outcomes will be key. This demands greater specificity of outcome audit through an imbued culture of detailed follow up of outcomes by clinicians, an accepted responsibility by the professions and an accepted need by management, including both time and funding.

We will also seek to influence stakeholder behaviour to contribute more effectively to improved surveillance. The results of this work will feed back into our broadening public health role in influencing clinical practice and patient behaviour, and facilitating innovation.

We will work with EU and international partners to improve collaboration. We will play a leading role in Europe in reshaping the medical devices regime to strengthen surveillance of higher-risk products. For both medicines and devices, the norm will be that assessment of emerging safety issues takes place at the European level using expertise drawn from Member States. We will play an active role within these networks. We will also aim to establish a clearer understanding at a UK level of how we can best target our involvement in the assessment of safety issues, without unnecessarily duplicating work that is being led effectively elsewhere within the European network.

In summary, over the next five years our objectives will be to:

- **strengthen systems that collect and use information about the performance of medicines and medical devices.**

3. Strengthening surveillance

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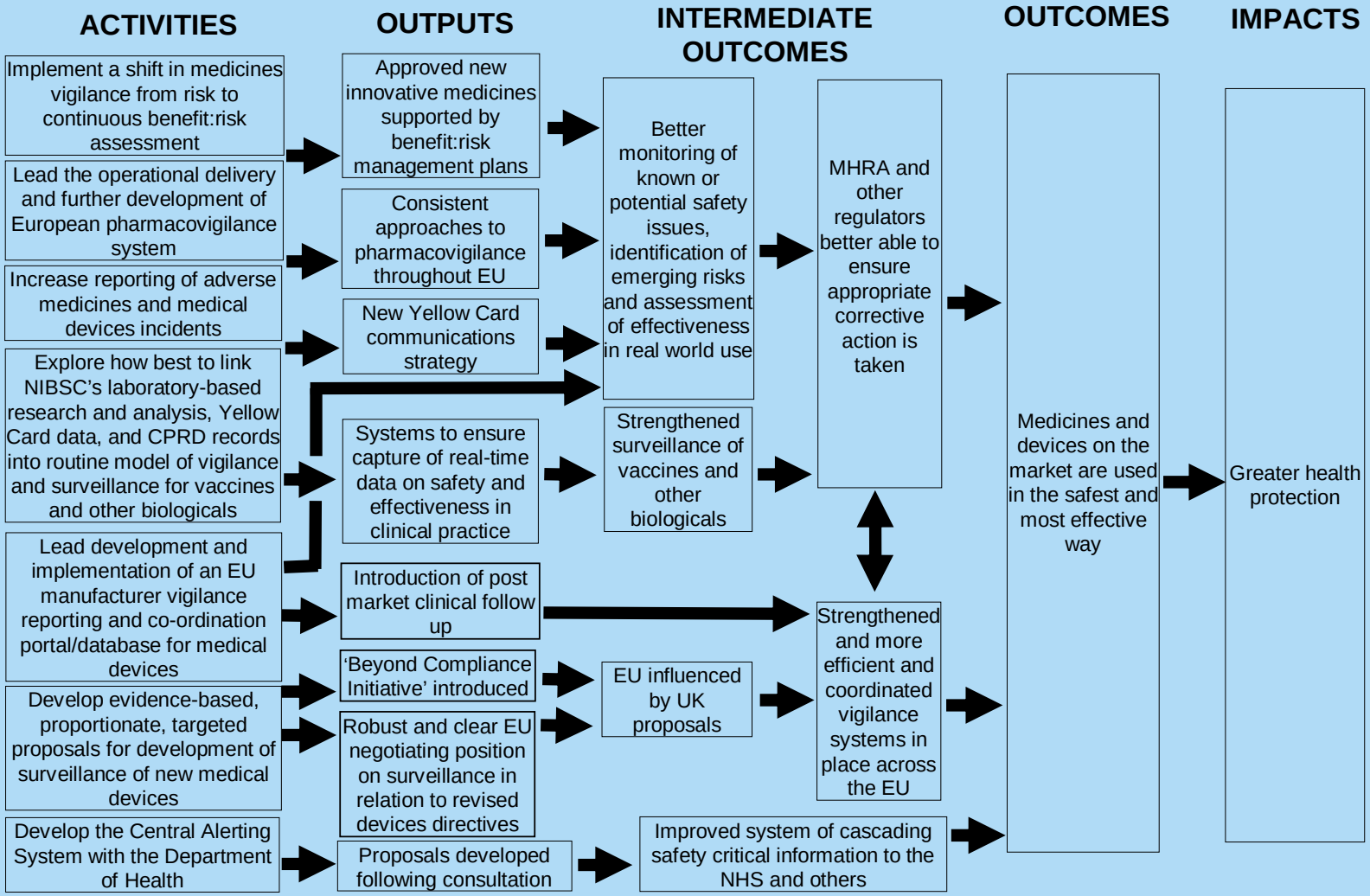


Theme 4: Safe medicines and devices and secure supply in globalised industries

We will aim to protect the UK population in the face of the growing complexity of risk management in globalised supply chains for medicines and devices. To do this we will work in partnership with other regulators to support uniform global quality standards, especially in the biologics arena, and to prevent counterfeit and substandard products entering the legitimate supply chain.

We will also aim to communicate effectively with patients and the public, so that they are better informed about the dangers of sourcing products from outside the assured supply chains – for example by purchasing unlicensed products online.

In addition, we will aim to increase compliance of companies with medicines and devices regulation through better targeting of our compliance and enforcement work. In particular, we will take action to deal with vulnerabilities in the supply of important medicines arising from manufacturing quality issues. We will also play a leading role in discussions at an EU level about strengthening the framework for medical devices regulation, including strengthening oversight of Notified Bodies.[4] Given the integrated arrangements for EU regulation of Notified Bodies, with the Agency only responsible for those designated in the UK, our work to improve the EU legislative framework will be key in ensuring that the standards against which they operate are strengthened.

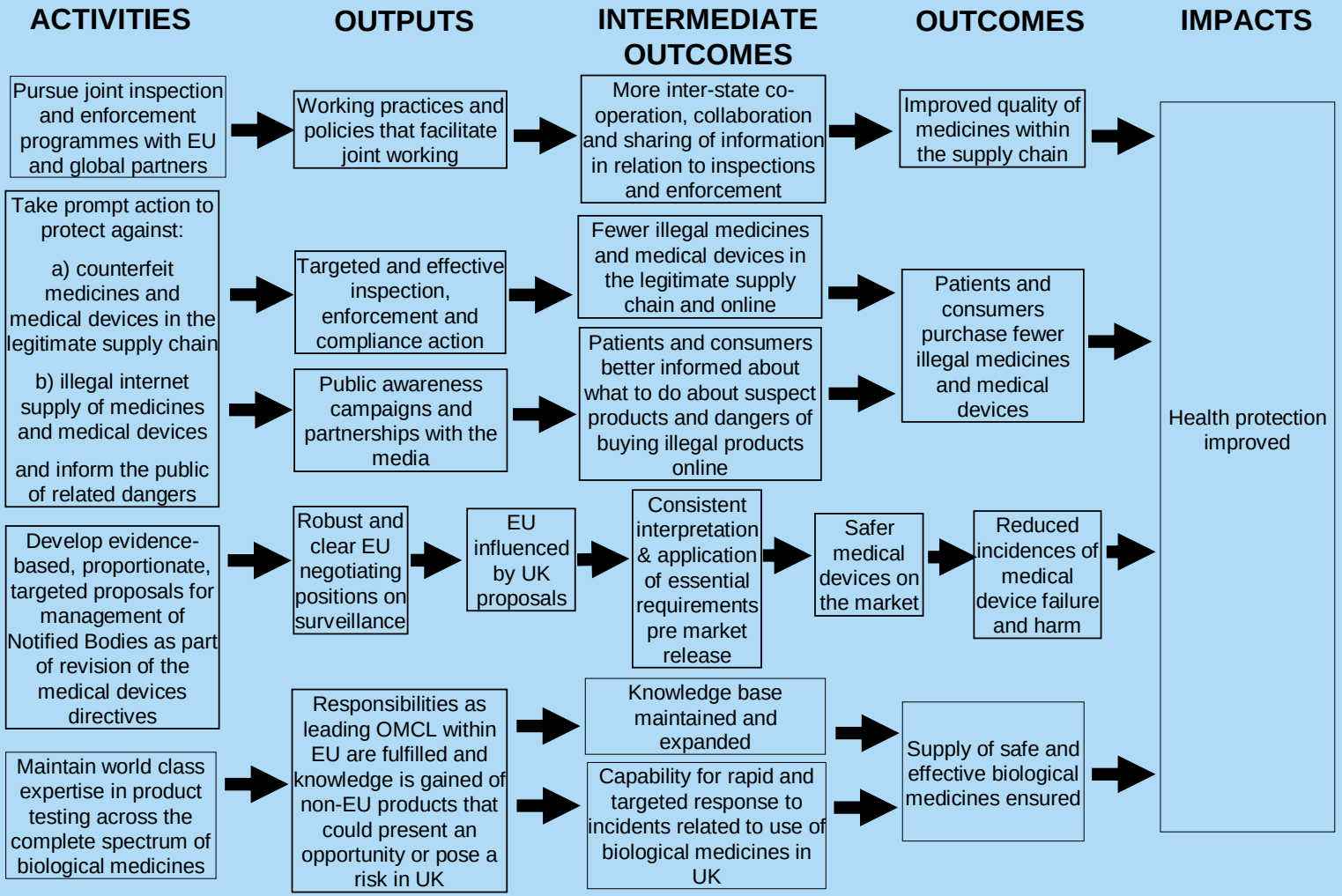
In summary, over the next five years our objective will be to:

- **work with UK, EU and global partners to address the challenges posed by increasingly globalised medicines and devices industries – not least to combat counterfeiting and ensure a more secure supply chain.**

[4] Medium and high risk devices – including active implantables and relevant in vitro diagnostic medical devices, and those Class I medical devices supplied sterile or which have a measuring function – require the use of a Notified Body to carry out a compliance assessment in accordance with the chosen route to compliance before manufacturers can place their products on the market. Notified Bodies are designated by the Competent Body for an EU member state – which for the UK is the MHRA.

4. Safe medicines and devices and secure supply in globalised industries

- To work with UK, EU and global partners to address the challenges posed by increasingly globalised medicines and devices industries – not least to combat counterfeiting and ensure a more secure supply chain.



Theme 5: Achieving excellence – a well-run, efficient and effective organisation

To achieve the strategic objectives set out above, and to deliver our core work, we must continue to be a well-run and cost-effective organisation – especially given our enlargement to incorporate CPRD and NIBSC. We will use effective project and programme management techniques to deliver the demanding agenda of change. We will also ensure that our workforce is skilled and motivated, and that we have modern, fit for purpose facilities that support our scientific and administrative work.

We will deliver our wide range of day-to-day functions and services efficiently, and offer value for money to our licence fee payers and to tax payers. Central to this will be our Operational Excellence Programme, which aims to support and promote a focus on continuous process improvement within the organisation. Many of our stakeholders – ranging from those in the herbal medicine sector to bio-technology start-ups – are small and medium-sized enterprises, and we will ensure that our services are tailored to their needs.

We will continue to manage the UK Government's policy responsibility for medicines and devices regulation, including managing UK Government EU and international policy in these areas. We will take forward work on the Government's Life Sciences and Growth agenda, notably as this relates to regulatory innovation (such as adaptive licensing) and improving the UK's attractiveness as a base for clinical trial activity.

Over the period of this plan we will play a key role in substantial developments in EU legislation – notably the re-casting of EU rules for devices and clinical trials regulation – and work on transparency and the strategic resilience of the EU regulatory networks for medicines and devices. We will also explore, jointly with the core Department of Health, whether some public health objectives could be better progressed through professional regulation rather than by our efforts to regulate products. Lastly, we will continue work to ensure that we regulate proportionately, reduce regulatory burdens where it is safe to do so and respond actively to the wider Government's objectives to eliminate unnecessary regulation. For example, we will build on the recent successful consolidation of medicines legislation with a comprehensive review of all our guidance.

We will continue to meet our obligations as a Trading Fund over the next five years. In the increasingly networked system of medicines regulation, where the lead on work at the European level is shared out between national regulators, there is considerable uncertainty over the likely size of the overall financial resource, and of the Agency's share of it. In particular, there are considerable uncertainties about the funding arrangements for the new systems for co-ordinating pharmacovigilance at an EU level, and what their practical impact will be. We will need to be flexible in identifying and responding swiftly to changes in workload in an unpredictable financial climate. We aim to be the national regulator of choice in the European systems for a wide range of work that will contribute to achievement of our public health mandate, and to our financial viability; but we will also prioritise on public health grounds our involvement in areas of work which do not attract commensurate funding.

The business development aspect of our work – with safeguards to ensure that our independence and public health aims are not compromised by conflicts of interest – will become increasingly important in the face of financial constraints, and we will need to pursue actively new revenue streams. This is particularly relevant to the work of CPRD and (in relation to biological standards) NIBSC, but also to elements of our regulatory work – for example the production of the British Pharmacopoeia[5], which is a globally used reference source.

[5] The British Pharmacopoeia (BP), which is published annually, is the only comprehensive collection of standards for UK medicinal substances. It contributes to the overall control of the quality of medicinal products by providing an authoritative statement of the standard that a product is expected to meet at any time during its period of use.

We have a wide and diverse range of stakeholders – from the NHS to professional bodies, from academia and research to other regulators, and from the devolved administrations to industry. We will work to build stakeholder engagement and multilateral dialogue over the period of this plan.

In summary, over the next five years our objectives will be to:

- **deliver organisational efficiency and value for money**
- **effectively organise, prioritise and monitor our work**
- **regulate effectively and in a proportionate way**
- **manage our external relationships effectively**
- **ensure a skilled and motivated workforce.**

In an increasingly networked system in Europe, we will maintain and build even stronger **partnerships with EU regulators and institutions, and with key international partners.**

Within a changing healthcare landscape, we will pursue effective **working relationships with other UK health bodies** – to ensure a clear understanding of roles and responsibilities, and efficient delivery of services.

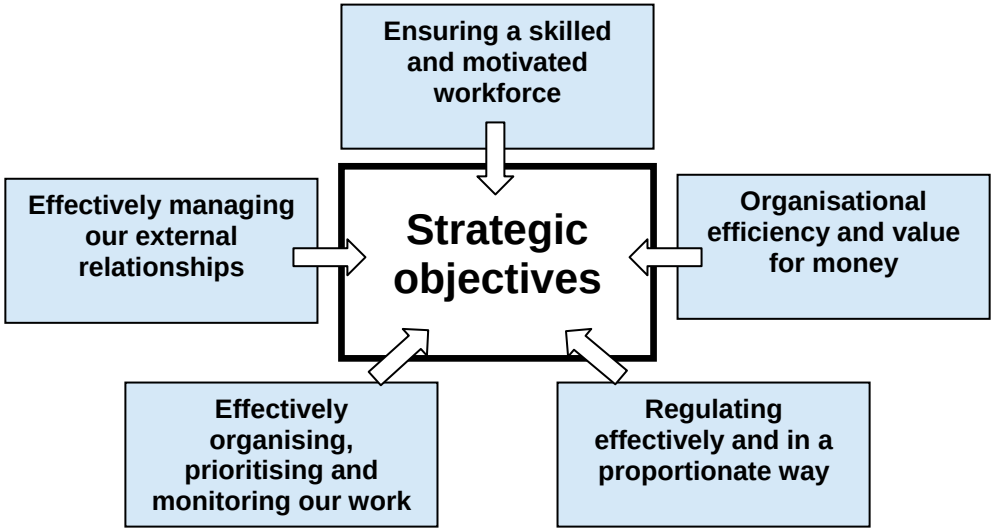
We will work collaboratively **with those we regulate**, providing clear guidance and advice and facilitating compliance with regulatory requirements where possible.

We will aim to increase **patients' and the public's** confidence in the regulation of medicines and devices, and listen to any concerns that regulation is not effective.

We will attract the best talent, and develop and support our staff – a **culture of continuous improvement** so that staff can maximise their contribution and we can react effectively to changing demands on us as an organisation.

We will continue to focus on performance management and training to achieve the right **balance of technical, scientific and managerial skills**; and will also prioritise the health and safety of our staff (e.g. in NIBSC laboratory work).

We will strengthen **succession planning** and facilitate clear **career development opportunities and pathways.**



We will ensure a continuous focus on **improving our processes** through various improvement initiatives and our Operational Excellence Programme. Through challenging and improving *how* we do our work, we will deliver services more efficiently to our stakeholders and customers.

We will be agile in anticipating and **responding effectively to changes in our working environment** (e.g. numbers of applications for marketing authorisations or variations) so that we efficiently match resources to demand.

We will continue to drive the use of digital interfaces to provide more effective and efficient ways for our stakeholders to interact with the Agency.

We will ensure that we have **facilities that are fit for purpose** – safe, modern and equipped for future technological changes.

We will organise, prioritise and monitor our work **with appropriate governance and** through **modern, proportionate programme and project management techniques.**

Our **annual business plans** will set out specific outputs and deliverables that will help us achieve the **outcomes** set out in this Corporate Plan. We will measure these outcomes to help assess the impact that our work has had.

We will **regulate only where it is clear that we need to**, and then we will do so in the most **proportionate** way. We will ensure that the actions we take are **evidence-based**, and we will be clear what outcomes we are seeking.

Our Regulatory Excellence Programme will enable us to **manage and prioritise our key regulatory activities**, to help ensure that we regulate proportionately and reduce burdens where appropriate.

6. Supporting programmes and strategies

We will be taking forward our work over the next five years through a number of strategies and programmes. These will help to ensure that we are well organised and efficient, offering value for money to those who pay for our services; and that we respond coherently to the major strategic and operational challenges facing us, while continuing to deliver our core regulatory work to the highest standards.

Regulatory Excellence Programme

Our Regulatory Excellence Programme helps us prioritise initiatives in collaboration with industry and keep our outputs under continual review; react quickly and appropriately to the environment; and communicate what we plan to do and our expectations. It groups together our major regulatory initiatives under five workstreams: Life Sciences and Growth, EU/International Regulation, Regulatory Policy Development, Burden Reduction/Simplification, Regulatory Strategy.

EU and International Strategy

Our EU and International Strategy helps us prioritise activities in the EU and internationally. It defines objectives and key countries that we need to work with while focusing on public health benefits for the UK. A new strategy will be developed in 2013 to reflect the launch of CPRD and the integration with NIBSC.

Communications Strategy

Our Communications Strategy helps us prioritise and focus our communications efforts on our key audiences, messages and initiatives, as well as co-ordinate our communications and stakeholder engagement work. This coordination and focus is increasingly important with the launch of CPRD and the merger with NIBSC: our stakeholders will become more widespread and diverse, and our name and reputation will become more widely known. Key elements of the strategy include working with partners to improve the dissemination of information to clinicians and healthcare professionals, thereby influencing clinical practice; and engaging more with patients and the public, particularly in terms of patient input into the regulatory decision making process.

Finance and delivering value for money

Our extended functions of CPRD and NIBSC will mean that we become even more diversified and global in our orientation, and that we achieve our influence through a broader range of interactions. This will be supported by new funding streams, with our resources targeted at our regulatory, biological and research activities according to their different needs. The three ‘centres’ will operate within their own financial boundaries and contribute to the overall achievement of the Agency’s statutory financial obligations.

Our regulatory role within Europe is changing, and this will be accompanied by a more constrained level of regulatory income. As a Trading Fund we will ensure that our services are not cross-subsidised, and that our customers can see a transparent connection between our activities and fee income. Our customers will expect a faster, more efficient service based on more collective and coordinated effort across the network, and this in turn will affect how we target our contribution.

As the roles of national agencies change, an increasing proportion of our income will be set by Europe. This will have a more tangible impact on our discretion to fund regulatory activities compared with the past five years. We will continue to be a leading regulator by prioritising where we can best deploy our skills and expertise. As a Trading Fund required to recover all of the costs of its activities from fees, it will be vital that the Agency is managed as flexibly and cost-effectively as possible, and responds at the earliest opportunity to any volume or fee level reductions in income.

In the area of devices regulation, we will seek to influence the development of a more resilient funding model which operates within a wider EU network and shares the cost of safer products more broadly between industry and government.

Operational Excellence

Our Operational Excellence initiative aims to support and promote a continuous focus on process improvement in the Agency. Through challenging and continuously improving *how* we do our work, we will deliver more effective, higher quality internal processes and external services. We have started to develop a competency in this area and will build on it through the lifetime of this plan.

IT Strategy

IT is core to the Agency's ability to deliver its overall business strategy. Our IT strategy sets out the capabilities which will be required in order to deliver our Corporate Plan. A key area of focus for the period of this plan will be to maximise our ability to share high quality information with stakeholders.

In addition to delivering capabilities to support the business, IT is a direct value discipline for the Agency. It is our strategy to continue to collaborate with partners to build or improve innovative systems which benefit public health. We will do this in a way that ensures that the benefits of the investment and leadership that we have shown in IT systems and expertise are leveraged, on behalf of the Agency and the wider EU Medicines Regulatory Network.

People and Organisational Development Strategy

Staff are our key resource, and we need to recruit and maintain a highly skilled and motivated workforce in order to deliver our responsibilities. Our People and Organisational Development Strategy will ensure that we provide excellent HR services, support organisational and people development, and are able to adapt to the changing requirements of the organisation.

Medicines and Healthcare Products Regulatory Agency

Corporate Plan 2013-2018

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