HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Strategic Plan 2021 – 2025

Delivering for patients through collaborative health product regulation

Introduction

This Strategic Plan sets out our ambition for the next five years to deliver better outcomes for people and animals through value-driven regulation and partnerships.

Building on our partnerships with others is a key theme of this five-year strategy. The twin challenges of Brexit and Covid-19 have demonstrated the need for, and value of, working collaboratively across Europe and internationally, with the health system in Ireland, and with patients and the public. Working with national agencies, professional bodies and patient groups can help us regulate more effectively taking into account the needs of the health system, while our input into relevant parts of the system can influence the safe use of health products in clinical practice. The pandemic has also highlighted the importance of the interconnectedness of the health of people, animals, plants and the environment, known as the One Health concept.

Patients are the users of medicines, devices and health products and our most important stakeholder group. Regulators are increasingly mindful that the views of the public and patients must be incorporated into the regulatory process. While we have taken forward specific initiatives over recent years, we are committed through this plan to building greater engagement with patients which we believe will contribute to broader-based and better-informed regulatory decisions.

Major legislative changes will occur over the next five years, with the implementation of EU Regulations on clinical trials, veterinary medicines, medical devices and in-vitro diagnostics, and each Regulation will impact significantly on the operation of the relevant regulatory system. For the HPRA, these constitute major projects which require contribution to national legislation, extensive engagement with all stakeholders, and development of information resources for those affected by the legislation.

We are living in a time in which public demand for information is increasing, and numerous, sometimes unreliable, information sources exist. Conflicting information and multiple channels of communication can undermine the critical importance of the regulatory system. We will maintain a focus on increasing understanding of the work we do, being transparent around decision-making, communicating via suitable channels in a timely manner, and identifying and appropriately managing emerging risks.

Scientific and technological innovation has accelerated dramatically in recent years with advances in personalised medicines, convergence of health products with digital information, and novel manufacturing technologies. Innovative products can greatly improve patient outcomes but may pose challenges to the current regulatory system as well as create the need for appropriate supports. Working together with European and international partners, we will contribute to more timely and consistent approaches to regulating innovative products. We will also need to develop the necessary expertise to regulate effectively in a digitised environment.

The Strategy has been developed in a highly collaborative way, involving all staff and the members of the Authority and the statutory advisory committees. A public consultation provided feedback from many stakeholders to help guide the development of the plan. We would like to thank all those who took the time and effort to make submissions which have been taken into account in the preparation of this plan.

Implementation will require a high level of commitment and effort from everyone, enabled by continuing development of our people, ways of working and a digital transformation programme. Key targets will be included in the Performance Delivery Agreement with the Department of Health. Detailed activities will be planned and delivered through the annual business planning cycle, and implementation monitored through reporting to senior management and the Authority.

We look forward to working with the Authority, the advisory committee members and our staff in delivering on this strategy in a time of some uncertainty but great potential for enhancing the value of health product regulation for people, animals and the healthcare system.

Ann Horan
Chairperson

Lorraine Nolan
Chief executive

What we regulate

- Human medicines
- Veterinary medicines
- Medical devices for human use
- Clinical trials
- Blood and blood components
- Human tissues and cells
- Human organs for transplantation
- Controlled substances
- Cosmetics
- The use of animals for scientific purposes

How we regulate

- We inspect companies and facilities which test, make or distribute health products to ensure that they comply with relevant standards and legislation
- We grant licences to companies to make, distribute and market medicines after a review of their safety, quality and effectiveness
- We continuously monitor medicines, medical devices and other health products, responding quickly to any safety or quality concerns
- We produce safety and quality information to support the safe use of health products

Our mission, vision and values

Our mission

We regulate medicines and devices for the benefit of people and animals

Our vision

Excellence in health product regulation through science, collaboration and innovation

Our values

Patient focused
We put the interests of those who use health products first

Collaboration
We work with others in partnership, respect and trust

Excellence
We work to the highest personal, professional and scientific standards

Integrity
We are independent, transparent and accountable

Inclusion
We believe in the power of diversity, where everyone is equal

Innovation
We continually learn, adapt and improve

Our strategy

Delivering for patients through collaborative health product regulation

Our goals

Goal 1

Health system partnerships

Strengthening our collaborations across all areas of the health system

Goal 2

Progressive regulation

Increasing our use of proportionate and adaptive approaches for better patient outcomes

Goal 3

Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

Goal 4

Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

Where our focus will be

Goal 1	Goal 2	Goal 3	Goal 4
Address current and emerging public health challenges and priorities	Maximise the opportunity presented by new legislation to enhance regulation of health products	Engage with stakeholders to drive improvements in regulatory activities	Promote an agile approach to appropriate regulation of innovations
Enhance the role of the HPRA as a partner and contributor within the health system, to optimise safe and effective use of health products	Strengthen use of risk based approaches to regulation	Strengthen trust in the regulatory system through greater transparency and clarity	Contribute to Irish research through outreach and engagement
Enhance national systems to better regulate animal health products and scientific animal use	Respond to the globalised industry and markets	Further develop information resources and communication platforms	Prioritise areas of innovation for organisational development

What we need to do to succeed

Goal 5

Great people, great processes

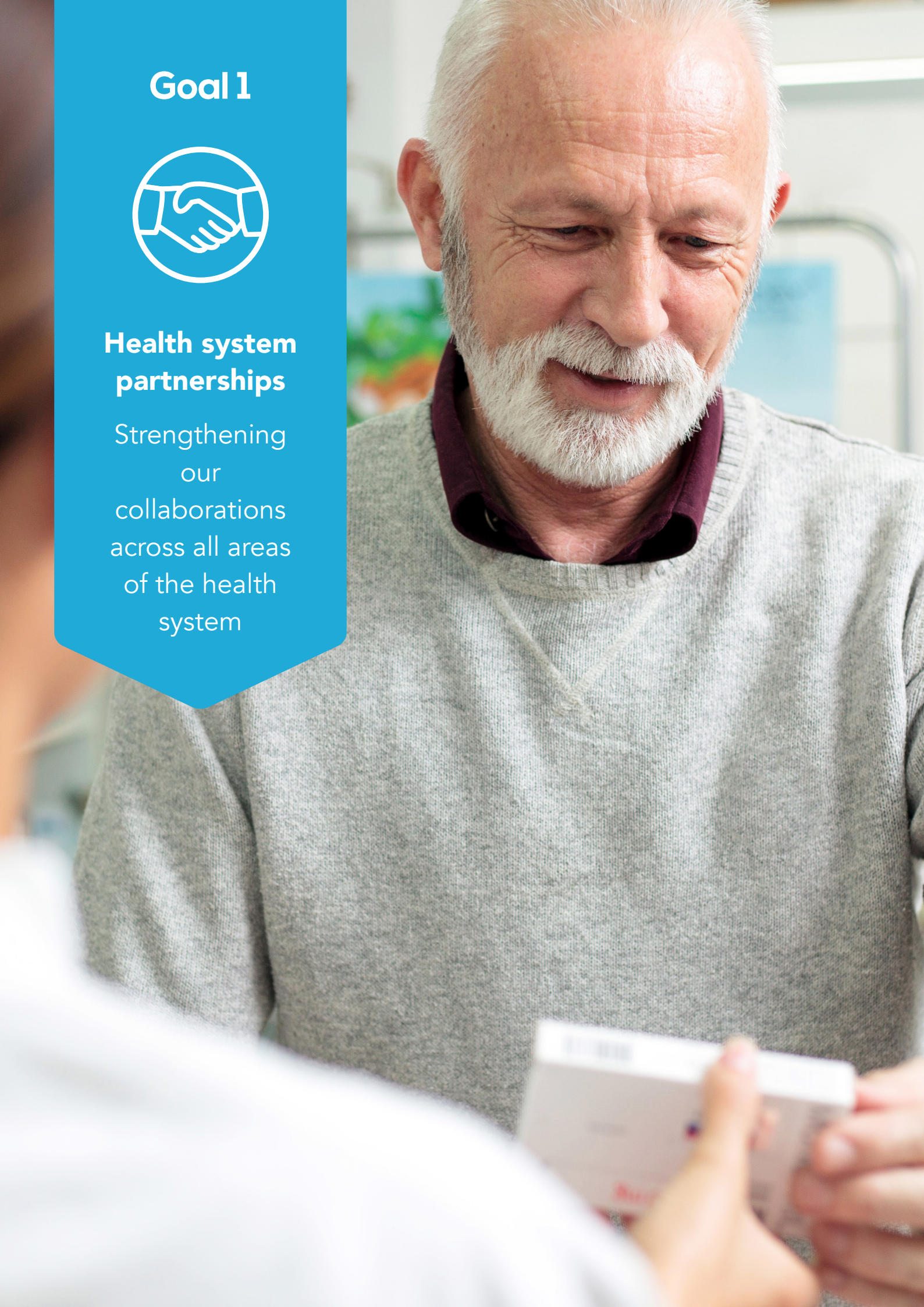
Developing our organisation and people to successfully achieve our goals

- Develop and empower our people to achieve and succeed
- Improve organisation effectiveness through extended and enhanced use of digital technologies
- Create better ways of working for the organisation, its stakeholders and the environment
- Ensure financial stability and capacity to meet the future needs of the organisation

Goal 1

Health system partnerships

Strengthening our collaborations across all areas of the health system



Goal 1: Health system partnerships

Strengthening our collaborations across all areas of the health system

Objectives	Specific actions	Outcomes
1.1 Address current and emerging public health challenges and priorities	Improve preparedness for significant change, threats and crises impacting in health product regulation and availability.	Formalised mechanisms and systems with regulatory and health system partners provide greater responsiveness, continuity and resilience.
	Collaborate with government, the health system and other stakeholders to manage the regulation and availability of health products post Brexit.	The impact of Brexit on availability of health products is minimised and measures are in place that strengthen integration with other European markets.
	Collaborate nationally and internationally on the regulation and surveillance of medicines, medical devices, diagnostics and vaccines for Covid-19.	Covid-19 diagnostics, therapeutics and vaccines used in Ireland are robustly regulated and monitored, with up-to-date information provided to all stakeholders.
	Contribute to One Health initiatives including antimicrobial resistance and impacts of health products on the environment.	Improved understanding of wider impacts of health products, and actions taken to reduce adverse effects.
1.2 Enhance the role of the HPRA as a partner and contributor within the health system, to optimise safe and effective use of health products	Strengthen systems for exchange of information and reporting on health products between health system partners, healthcare professionals, members of the public and the HPRA.	Better quality and diversity of data enhance monitoring and surveillance over the lifecycle of a health product.
	Leverage collaborative efforts to promote and support system-wide responses to important health product issues.	Engagement across stakeholders enables cohesive and coordinated responses to important health product issues.
	Enhance understanding of how important regulatory action is best embedded and implemented into clinical practice nationally.	Approaches developed to evaluate the impact and effectiveness of significant regulatory action at national level.
	Contribute to the implementation of the Sláintecare programme for healthcare delivery.	Health system developments informed and enhanced by regulatory requirements for health products.
	Support the continued development of the clinical research infrastructure in Ireland.	Clinical researchers have access to integrated supports and a streamlined system for clinical study approvals.
1.3 Enhance national systems to better regulate animal health products and scientific animal use	Embed the application of 3R principles in animal-based research in Ireland.	Projects and clinical trials conducted in Ireland meet international best practice in 3Rs.
	Strengthen the pharmacovigilance system through new methods and tools for promotion and analysis of reports and dissemination of safety information to healthcare professionals and animal owners.	The pharmacovigilance system is more responsive and effective, with increased reporting by healthcare professionals and animal owners.

Goal 2

Progressive regulation

Increasing our use of proportionate and adaptive approaches for better patient outcomes

Goal 2: Progressive regulation

Increasing our use of proportionate and adaptive approaches for better patient outcomes

Objectives	Specific actions	Outcomes
2.1 Maximise the opportunity presented by new legislation to enhance regulation of health products	Develop stakeholder partnerships to support implementation of new legislation for medical devices, clinical trials and veterinary medicines.	Implementation delivers value to all stakeholders, reduces regulatory burden where appropriate, while ensuring protection for the users of health products.
	Promote European network approaches, expertise development and mutual reliance among regulators in line with new requirements.	Strengthened cooperation across the EU regulatory network with measurable impacts.
	Influence the development of national legislation to enhance standards and regulation.	Gaps in regulatory approaches and areas not covered by regulation identified and actioned.
2.2 Strengthen use of risk based approaches to regulation	Further develop internal capabilities to identify areas of risk through greater use of intelligence sources.	Increased organisational competency in risk and risk management principles. Intelligence sources identified for proactive management of emerging risks.
	Adapt assessment, compliance monitoring and enforcement approaches in line with identified risks.	Risk-based strategies increase use of proactive approaches, and reduce the level of non-compliance.
	Enhance focus on lifecycle management in our regulatory approach.	Demonstrated use of data-driven, risk-adaptive approaches to support regulatory decisions pre and post approval.
2.3 Respond to the globalised industry and markets	Promote greater use of mutual reliance among global regulators.	Demonstrated influence on the European and international networks' strategic objectives on mutual reliance.
	Drive the development of greater international convergence and harmonisation on regulatory standards.	Active participation and contribution in relevant international committees and projects.
	Promote greater communication of risk and intelligence sharing among global regulators.	Demonstrated influence on the establishment of infrastructure to support intelligence sharing among global regulators.

Goal 3

Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

Goal 3: Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

Objectives	Specific actions	Outcomes
3.1 Engage with stakeholders to drive improvements in regulatory activities	Develop new engagement and communications strategies in consultation with stakeholders.	Stakeholder analysis is regularly conducted, their views are valued and taken into account across corporate and regulatory activities.
	Use the voices of patients and the public to inform our regulatory and safety monitoring programmes.	Demonstrable proactive partnership model based on listening, understanding and communicating with the public.
	Establish a greater level of ongoing engagement with healthcare professionals and their representative bodies.	Engagement with healthcare professionals contributes to greater patient safety and optimal use of health products.
3.2 Strengthen trust in the regulatory system through greater transparency and clarity	Promote awareness and understanding of the HPRA's role in protecting the health of people and animals.	Greater public profile of the agency and perception of trust in health product regulation.
	Increase proactive publishing of clear, relevant and understandable information.	Additional information and data sets published, with greater transparency around the evaluation process.
	Incorporate current best practices in communicating science and risk.	Improved ability to communicate in clear terms with the recipient in mind.
3.3 Further develop information resources and communication platforms	Develop our website as a key communication tool for interacting with stakeholders and an authoritative source of reliable regulatory information.	Communications with stakeholders integrated into organisational processes. Timely website content in plain language, accessible in formats appropriate to the different stakeholder groups.
	Increase use of social media and other communication methods including traditional and non-media where appropriate.	Increased reach and diversity of content across different audiences and channels, supporting key safety messaging.
	Contribute to educational programmes for key target groups.	A range of resources is available for patients, and for healthcare professionals and researchers at relevant points in their careers.

Goal 4

Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

Goal 4: Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

Objectives	Specific actions	Outcomes
4.1 Promote an agile approach to appropriate regulation of innovations	Actively contribute to EU and international horizon-scanning initiatives.	The regulatory system is well positioned to respond to the dynamic life sciences environment.
	Support regulatory science tools and approaches that effectively respond to scientific and technological innovation.	Novel therapies and technologies are effectively regulated while facilitating safe and timely access.
	Promote cooperation and integration between regulatory networks and frameworks to facilitate harmonisation and avoid duplication.	Regulatory standards and guidance provide for consistent and integrated evaluation of borderline/combination products.
4.2 Contribute to Irish research through outreach and engagement	Work with national partners to use existing networks to raise awareness of regulatory supports among Irish life sciences researchers.	Established mechanisms in place for systematic outreach to relevant research communities.
	Provide advice and guidance for researchers that can be accessed throughout the development cycle.	Regular use by researchers of regulatory and scientific advice provided by the HPRA or the European regulatory system.
	Engage with Irish researchers and developers to identify mechanisms and support initiatives that facilitate the translation of research into clinical practice.	Input from researchers informs the development of new or improved regulatory supports. Irish researchers participate in initiatives aimed at this sector.
4.3 Prioritise areas of innovation for organisational development	Develop and implement a strategy that identifies key areas of innovation for organisational specialisation.	A programme of activities for competence development in focus areas relevant to patients, the research community and the life sciences sector in Ireland.
	Develop knowledge and skills to regulate in a digitised environment encompassing regulatory processes, products, manufacturing, wholesaling, and healthcare delivery.	Capabilities contribute to and keep pace with the advances in digitisation in the regulatory environment.
	Engage with EU regulatory network to maximise contribution of key expertise.	Increased levels of advice provided within areas of specific expertise.

Goal 5

Great people, great processes

Developing our organisation and people to successfully achieve our goals

Goal 5: Great people, great processes

Developing our organisation and people to successfully achieve our goals

Objectives	Specific actions	Outcomes
5.1 Develop and empower our people to achieve and succeed	Design and implement a new people strategy.	An organisation-wide strategy based on developing the skills and competencies needed to ensure a resilient, evolving workplace. An enhanced employee experience and wellbeing at work. Values based, purposeful working.
	Define key areas of expertise and future skills needs.	Agreed development pathways to access key skills, e.g. training programmes, recruitment, contract workers.
	Enhance leadership capability to manage the organisation through change and growth.	A resilient organisation, flexible, responsive and adaptable to meet emerging challenges.
5.2 Improve organisation effectiveness through extended and enhanced use of digital technologies	Consolidate case management onto a single, optimised platform. Enhance data quality and decision support capabilities.	Streamlined operational processes and analytics. Reduced complexity of technology environment.
	Extend digital integration with stakeholders, providing integration with core applications.	Enhanced engagement with stakeholders and contribution to the national health system. Improved integration with the European regulatory network.
	Improve performance and resilience of the technology infrastructure. Enhance the security of the digital infrastructure.	Improved technology risk profile and enhanced operational flexibility. Reduced risk of cyber intrusion or data loss.
5.3 Create better ways of working for the organisation, its stakeholders and the environment	Define the optimal organisational design to support delivery of our remit now and into the future.	A sustainable organisational structure underpinned by a robust succession plan and people strategy.
	Develop models of working that meet the changing environment and future of work.	Flexible approaches to support performance and productivity conducive to an adaptive model of working.
	Improve cross-organisational methodologies for better management of capacity and organisational performance.	Balanced resource utilisation, consistency of processes, and enhanced use of expertise across different functional areas.
	Continue to take actions that sustain more environmentally friendly practices.	Government targets for public sector energy efficiency are met, staff encouraged to reduce their own energy usage and CO_2 emissions, and goods purchased reflect environmental considerations where possible.
	Ensure ongoing compliance with the public sector equality and human rights duty.	Equality of opportunity and treatment for staff, stakeholders and those we communicate and interact with.

Goal 5

Objectives	Specific actions	Outcomes
5.4 Ensure financial stability and capacity to meet the future needs of the organisation	Update financial and fee modelling to take account of the changing environment for the organisation and for regulated sectors.	Stable financial systems allowing management of the organisation in a steady state and with ongoing changes in the external environment.
	Conduct a structured review of the use of the infrastructure and utilisation plans to reflect the new paradigms of working.	Sustainable and efficient use of resources including the building.

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