HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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Strategic Plan 2021 to 2025 – Final Report

Introduction and Strategic Context

The HPRA's Strategic Plan 2021-2025, *Delivering for patients through collaborative health product regulation*, set out a clear five-year framework for the organisation's regulatory, organisational and system-level priorities. It was designed to support the HPRA in delivering better outcomes for people and animals through science-based, value-driven regulation, underpinned by strong national, European and international partnerships.

The strategy was delivered during a period of exceptional complexity and change in the regulatory environment. Brexit, the COVID-19 pandemic, major EU legislative reform and rapid scientific and technological development created significant challenges for health product regulation and reinforced the need for a regulatory authority that is adaptive, collaborative, trusted and resilient.

A central premise of the strategy was that effective regulation is not delivered in isolation. It requires strong engagement across the health system, close collaboration with regulatory partners, and sustained investment in organisational capability, digital infrastructure and effective ways of working. These priorities were reflected across five interconnected strategic goals, which together provided a coherent framework for regulatory delivery, organisational development and innovation over the period 2021-2025.

This report is the fifth and final progress update on delivery of the strategy. It summarises the principal achievements, areas of impact and organisational developments delivered over the lifetime of the plan and provides an overall assessment of progress across each of the strategic goals and objectives. A high-level status assessment is set out below.

Strategic Goal 1: Health systems partnerships

Strategic objective	On track/Issue/Delay
Address current and emerging public health challenges and priorities	On track
Enhance the role of the HPRA, as a partner and contributor within the health system	On track
Enhance national systems to better regulate animal health products and scientific animal use	On track

Strategic Goal 2: Progressive regulation

Strategic objective	On track/Issue/Delay
Maximise the opportunity presented by new legislation to enhance regulation of health products	On track
Strengthen use of risk-based approaches to regulation	On track
Respond to the globalised industry and market	On track

Strategic Goal 3: Communication and engagement

Strategic objective	On track/Issue/Delay
Engage with stakeholders to drive improvements on regulatory activities	On track
Strengthen trust in the regulatory system through greater transparency and clarity	On track
Further develop information resources and communication platforms	On track

Strategic Goal 4: Enabling innovation

Strategic objective	On track/Issue/Delay
Promote an agile approach to appropriate regulation of innovations	On track
Contribute to Irish research through outreach and engagement	On track
Prioritise areas of innovation for organisational development	On track

Strategic Goal 5: Great people, great success

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

Strategic Delivery Highlights 2021–2025

Strategic Goal 1: Health system partnerships

The HPRA strengthened its role as a trusted partner across the Irish and European health systems during a period marked by COVID-19, Brexit and wider system pressures. Key achievements included leadership on medicines and device availability and shortages, strengthening national vaccine safety monitoring and data exchange, and enhancing national systems for animal health products and scientific animal protection.

The HPRA is now more deeply embedded in health system decision-making structures, with stronger mechanisms for coordination, information sharing and joint response to public health challenges.

Strategic Goal 2: Progressive regulation

The HPRA played a significant role in shaping and implementing major EU legislative reform across medicines, medical devices, clinical trials and veterinary medicines regulation. Highlights included leadership roles in EMA scientific committees/working parties and EU medical device working groups, completion of Ireland's first coordinated clinical investigation assessment under the Medical Devices Regulation (MDR), and designation as competent authority under the Critical Entities Resilience Directive for relevant regulated sectors.

The HPRA has enhanced its standing as a key contributor within the European regulatory network and demonstrated its capacity to influence and implement complex regulatory change.

Strategic Goal 3: Communication and engagement

The HPRA improved transparency, public communication and stakeholder engagement, particularly in areas of high public interest and during periods of heightened scrutiny. Key achievements included the establishment of the Patient Forum, regular publication of COVID-19 vaccine safety updates, increased proactive communications activity and the launch of a new HPRA website in 2025.

The HPRA has strengthened trust, improved visibility of its role, and established more structured and sustainable mechanisms for stakeholder engagement.

Strategic Goal 4: Enabling innovation

The HPRA strengthened its support for innovation from early-stage research through to regulatory approval, while also building readiness for emerging technologies. Highlights

included increased engagement through the HPRA Innovation Office and research-sector outreach, hosting the EU Innovation Network conference in Dublin, and advancement of organisational preparedness for digital health regulation.

The HPRA is better positioned to support innovation while ensuring appropriate regulatory oversight, with early foundations established for future regulation of complex and emerging technologies.

Strategic Goal 5: Great people, great processes

The HPRA invested significantly in organisational capability, digital systems and operational resilience to support delivery of its wider strategic objectives. Key achievements included implementation of the HPRA's first People Strategy and development of a Career and Capability Framework, major progress in digital transformation and systems integration, and a very strong outcome in the 2025 Benchmarking of European Medicines Agencies (BEMA) assessment.

The organisation is more capable, more digitally enabled and better positioned to respond to future regulatory demands.

Detailed Outputs of Strategic Goals and Objectives

Strategic goal 1: Health system partnerships

Strengthening our collaborations across all areas of the health system

Overview

Throughout the 2021-2025 strategy, the HPRA reinforced its position as a trusted and essential partner in safeguarding public and animal health.

The HPRA's work under this goal focused on three core objectives:

1. Addressing current and emerging public health challenges
2. Enhancing the HPRA's role within the national health system
3. Strengthening national systems for regulating animal health products and scientific animal use

Objective 1.1 Address current and emerging public health challenges and priorities

Across the strategy period, the HPRA strengthened preparedness and system coordination in response to major external challenges and sustained supply vulnerabilities, particularly in the context of Brexit and the COVID-19 pandemic. Medicines availability and shortage management became a central strategic focus, with continued development of national approaches and contribution to EU-level initiatives, including work under the Joint Action CHESSMEN (Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network).

In parallel, the HPRA supported system readiness for medical device supply disruption requirements introduced through Regulation (EU) 2024/1860, contributing to EU guidance development and progressing national processes with relevant partners. This work strengthened Ireland's readiness to respond to emerging device availability risks and supported clearer expectations for stakeholder notification and regulatory coordination. The HPRA also progressed significant work associated with the expiry of Brexit exemptions and the implementation of the Windsor Framework, with preparedness actions implemented by the end of 2025 and continuity of supply maintained for human medicines. A preparatory

plan for veterinary medicines was also progressed and resulted in the successful management and mitigation of potential impacts on continuity of supply of veterinary medicinal products.

Finally, the HPRA advanced work in key public health priority areas where long timeframes and external dependencies apply, including implementation of the Critical Entities Resilience Directive.

Objective 1.2 Enhance the role of the HPRA, as a partner and contributor within the national health system, to optimise safe and effective use of health products

During the strategy period, the HPRA strengthened its contribution to national health system decision-making and enhanced the practical mechanisms through which regulatory information is shared, acted upon and embedded into clinical practice.

Key progress included strengthening reporting and information exchange systems for patients, healthcare professionals and the public, particularly during the COVID-19 response. Digital reporting channels supported better surveillance and information sharing, and the new HPRA website further improved reporting functionality and accessibility.

The HPRA also strengthened data exchange with health system partners (including in the context of vaccine use and vigilance information), and coordination mechanisms for system-wide responses to important product issues. Improvements in dissemination of Direct Healthcare Professional Communications (DHPCs), including the use of a standardised identifier for nationally approved DHPCs, strengthened the clarity and visibility of safety communications.

Organisational developments further supported delivery, including establishment of an enhanced focus on pharmacovigilance risk communications and engagement with the health system and patient community. This included continued collaboration with academia and health system partners to build an evidence base for improved risk communication approaches.

In addition, the HPRA contributed to advances in clinical research infrastructure through developments associated with the National Research Ethics Committee and implementation of the EU Clinical Trials Regulation (CTR), supporting more efficient processing and enabling greater access to innovative treatments. The organisation also contributed to health-system-level work on pharmacist prescribing through the Community Pharmacy Implementation Oversight Group.

Objective 1.3 Enhance national systems to better regulate animal health products and scientific animal use

Under this objective, the HPRA strengthened national systems for the regulation of animal health products and scientific animal use. As part of scientific animal protection activities, a targeted plan was implemented to expand inspection capacity and reinforce application of the principles of replacement, reduction and refinement, known as the 3Rs, resulting in a significant increase in inspection activity in 2024. Ongoing promotion of the 3Rs continues through multiple channels, including the Scientific Animal Protection (SAP) quarterly newsletter.

In parallel, the HPRA continued to contribute to national priorities in animal health and antimicrobial resistance, reflecting commitment to the broader One Health approach set out in the strategy and reinforcing the integration of animal, human and environmental health considerations in regulatory work. While progress was made, One Health remains an area requiring continued focus into the next strategic plan period.

Strategic goal 2: Progressive regulation

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

Overview

This goal focused on the implementation of major EU legislative reforms, including new Regulations for clinical trials, veterinary medicines, medical devices, and in-vitro diagnostic medical devices. This required national legislative input, stakeholder engagement, regulatory guidance, and changes to internal processes and systems.

Across the period of the plan, the HPRA increased its use of risk-based, proportionate and adaptive regulatory approaches, while continuing to play a prominent role in EU level scientific assessment and safety monitoring for human and veterinary medicines.

Progress under this goal is structured around three objectives:

1. Maximising opportunities presented by new legislation
2. Strengthening risk-based regulatory approaches
3. Responding to the globalised industry and market

Objective 2.1 Maximise the opportunity presented by new legislation to enhance regulation of health products

The HPRA strengthened its role in the European network in the implementation of the MDR and In-Vitro Diagnostics Regulation (IVDR), helping to addressing barriers and promoting more consistent application of new regulatory requirements. This included a leading role in EU work on to coordinated approaches to market surveillance, vigilance and high-profile safety issues.

Also In medical devices area, the HPRA contributed to EU work to mitigate access risks for specific product categories and supported delivery of guidance on clinical evaluation for orphan devices helping to safeguarding access to essential devices for small patient populations.

In the veterinary sector, the HPRA delivered a significant multi-year programme of readiness for implementation of Regulation 2019/6, including internal process alignment and contribution to national legislative development. This strengthened national capability to implement the new framework with a focus on supporting new product development,

improving product availability and reducing administrative burden while maintaining effective oversight for veterinary medicines.

During the strategy period, the HPRA's remit also expanded to include designation as national competent authority under the Critical Entities Resilience Directive for relevant regulated sectors. The HPRA engaged in coordinated national preparations and progressed toward delivery of the first statutory output.

The HPRA also supported the State's position in negotiations on reform of the EU pharmaceutical legislation and progressed preparations for execution of the HPRA's responsibilities under Ireland's 2026 Presidency of the Council of the European Union.

Objective 2.2 Strengthen use of risk-based approaches to regulation

The HPRA advanced the use of proportionate, risk-based approaches to regulatory activity through strengthened coordination, improved consistency, and contribution to EU-level and international harmonisation initiatives. Key examples include completion of Ireland's first coordinated clinical investigation assessment under MDR in the second half of 2025 and leadership of EU work to improve coordination of extraordinary safety issues with EU-level impact.

These developments strengthened the organisation's ability to support timely decision-making, improve regulatory efficiency, and contribute to consistent approaches across the EU network.

Objective 2.3 Respond to the globalised industry and markets

The HPRA maintained and strengthened contribution to international regulatory cooperation, including active engagement through the International Coalition of Medicines Regulatory Authorities (ICMRA) and participation in strategic discussions on shared global priorities and challenges, including communication, reliance pathways, and the impact of artificial intelligence (AI) on regulatory practices.

A major example of contribution to global convergence was the HPRA's joint leadership of the ICMRA Pharmaceutical Quality Knowledge Management Strategy project, aimed at strengthening harmonisation of submissions, assessments and inspections through international collaboration. Pilot programmes ran from 2022 to 2025, with work undertaken in tandem to explore possible longer-term operating arrangements for collaborative regulatory evaluation.

Strategic goal 3: Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

Overview

The 2021-2025 strategy placed strong emphasis on communication and engagement, recognising that public trust in regulation is essential to effective regulation and the safe use of health products. This priority became even more critical during the COVID-19 pandemic, when the public required clear, timely and evidence-based information on vaccines, treatments and emerging safety signals.

Over the period, the HPRA strengthened its communication channels, stakeholder engagement, and transparency around regulatory decisions, supporting informed decision-making and reinforcing confidence in the regulatory system.

Progress under this goal is structured around three objectives:

1. Engaging with stakeholders to drive improvements
2. Strengthening trust through transparency and clarity
3. Developing information resources and communication platforms

Objective 3.1 Engage with stakeholders to drive improvements

A key development was the formal establishment of the Patient Forum in 2022, creating a structured platform for dialogue on issues and topics relevant to patients in the regulation of medicines and medical devices. Through co-created workplans and related initiatives, the forum strengthened patient-centred approaches across the organisation.

This has reinforced the HPRA's commitment to patient-centred regulation and will remain a focus of the next strategic plan.

Objective 3.2 Strengthen trust in the regulatory system through greater transparency and clarity

The HPRA delivered a sustained and proactive communications response during the COVID-19 pandemic, including publication of regular safety information, extensive media engagement, and development of supporting communications resources. This included

initiation of regular COVID-19 vaccine safety reporting, which transitioned into enhanced transparency through a dedicated webpage on the HPRA website.

Following the acute pandemic period, the HPRA continued proactive communications in areas of ongoing public risk and high public interest, including medicines safety and enforcement-related public awareness activity.

Objective 3.3 Further develop information resources and communication platforms

The launch of the new HPRA website in January 2025 was a major milestone in the strategy, strengthening the organisation's digital presence and improving public access to regulatory information and services. The redevelopment improved navigation and accessibility expanded digital self-service, and enhanced key information journeys, including improvements to the 'Find a Medicine' functionality.

The strategy also drove improvements to internal data flows and systems integration supporting website content, including improved capture of shortage and safety notice indicators. In parallel, the HPRA increased strategic use of social media and participated in multi-organisation public awareness campaigns, reinforcing safety messaging and encouraging reporting of suspected adverse effects to health products.

Strategic goal 4: Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

Overview

The 2021-2025 strategy recognised the accelerating pace of innovation in medicines, medical devices, digital health and scientific research. To remain effective, the HPRA must anticipate emerging technologies, adapt regulatory frameworks and support innovators throughout the product lifecycle.

Over the strategy period, the HPRA strengthened its role as an enabler of responsible innovation through support for clinical research infrastructure, contribution to EU-level initiatives, enhancing national engagement with researchers and developers, and prioritising innovation within organisational development.

Progress under this goal is structured around three objectives:

1. Promote an agile approach to appropriate regulation of innovations
2. Contribute to Irish research through outreach and engagement
3. Prioritise areas of innovation for organisational development

Objective 4.1 Promote an agile approach to appropriate regulation of innovations

The strategy period reinforced the importance of regulatory agility, particularly during the pandemic when academic sponsors required regulatory support to conduct clinical research in an emergency context. HPRA resources supported improvements in national clinical research support and helped advance more coherent approaches to prioritisation and coordination.

The HPRA also contributed to horizon-scanning and regulatory science initiatives, including EU-level work on emerging methodologies and technologies, and progressed work through EU borderline classification collaboration. In addition, the HPRA contributed significantly to the COMBINE programme, which aims to streamline the regulatory pathway for combination products, which are products composed of a medical device and a medicine.

Objective 4.2 Contribute to Irish research through outreach and engagement

A key achievement was hosting the EU Innovation Network conference in Dublin in 2024, supporting engagement with researchers, innovators, technology transfer offices and other stakeholders, and strengthening awareness of national and EU regulatory supports.

Ongoing outreach through the HPRA's Innovation Office included engagement at national events and sustained relationships with research centres and clinical trial stakeholders. The Innovation Office remained an important access point for support throughout the strategy period.

Objective 4.3 Prioritise areas of HPRA innovation specialisation

To strengthen readiness for regulation in a digitised environment, the HPRA initiated a Digital Health Project to better understand the digital health ecosystem, the extent of activity within its remit, and the implications of emerging legislative frameworks including the MDR, IVDR, AI Act and European Health Data Space. The project progressed a structured programme of assessment and proposed outputs to inform future strategy and capability development.

Strategic goal 5: Great people, great processes

Developing our organisation and people to successfully achieve our goals

Overview

Organisational development was a core enabler of the 2021-2025 strategy. Over the period, the HPRA strengthened people capability, digital infrastructure, ways of working, operational resilience and governance, supporting sustained delivery while building longer-term capacity for an evolving remit.

Progress under this goal is structured around four objectives:

1. Develop and empower our people
2. Improve organisational effectiveness through digital technologies
3. Create better ways of working for the organisation and stakeholders
4. Ensure financial stability and future capacity

Objective 5.1 Develop and empower our people to achieve and succeed

A new People Strategy was developed in 2022 and launched in 2023, following a review of the Human Resources and Change 2016-2020 strategy, and consideration of internal and external best practice. A key achievement under goal 5 of this HPRA Strategic plan was the embedding of the People strategy across the organisation. A major focus over the period was the development of a Career and Capability Framework, to support employee development, strengthen organisational agility and align with strategic goals. This framework was finalised and delivered in 2025, with associated processes updates to be a priority for the organisation moving into the next strategic cycle.

Objective 5.2 Improve organisation effectiveness through extended and enhanced use of digital technologies

A digital transformation strategy introduced during the pandemic accelerated improvements to organisational resilience and system standardisation. The HPRA progressed consolidation and cloud transition of core systems and strengthened disaster recovery arrangements.

Consolidation of case management progressed significantly, with multiple functions onboarded the HPRA's cross-organisational case management system. The organisation also progressed integration activity with European systems including the Union Product Database

for veterinary medicines and the Clinical Trials Information System, which was introduced in the context of the new Veterinary Medicines Regulations and the Clinical Trial Regulation.

In parallel, upgrades and redesigns across key systems were delivered that will enable further work to improve the quality of our data and support improved information exchange with regulatory and health system partners.

Objective 5.3 Create better ways of working for the organisation, its stakeholders and the environment

The strategy period required rapid adaptation of working arrangements, including transition to remote working during the COVID-19 pandemic and implementation of remote inspection approaches to maintain regulatory oversight and continuity. This experience supported subsequent evolution of hybrid models as restrictions eased.

Operational Excellence capability was strengthened through dedicated capacity to drive more efficient and effective ways of working through organisation-wide innovation initiatives. Departments also reviewed and refined operational approaches, including workflow management improvements, organisational redesign and capability mapping in relevant areas.

Organisational effectiveness was further validated through European benchmarking exercises, namely BEMA and the Joint Audit Programme, which delivered very positive outcomes and strong recognition of the HPRA's regulatory maturity, network contribution, patient focus, strategic clarity and leadership.

Objective 5.4 Ensure financial stability and capacity to meet the future needs of the organisation

Over the period, the HPRA advanced a multi-year programme of building works and modernisation designed to create a more sustainable, efficient and future-ready working environment. This included targeted upgrades to office facilities and refurbishment works to reduce lease holdings while supporting hybrid working and modern workspace standards. These investments were aligned with national public-sector sustainability targets and contributed directly to the organisation's substantial reduction in energy consumption. They strengthened the HPRA's physical infrastructure and ensured that the HPRA building is capable of supporting its operational needs for the long term.

Throughout the 2021–2025 strategic period, the HPRA maintained a strong and sustainable financial position through disciplined financial-governance framework. Annual integrated budgeting, multi-year activity modelling, detailed forecasting of staff and operational costs, and structured fee-review processes ensured that resources were aligned to organisational priorities and emerging external pressures.

Conclusion

From 2021 to 2025, the HPRA delivered substantial progress across its strategic priorities during a period marked by exceptional disruption, heightened public scrutiny and major regulatory reform. The organisation maintained continuity of core regulatory functions through the COVID-19 pandemic and Brexit-related pressures, while also strengthening the resilience and effectiveness of the regulatory system through targeted delivery across partnerships, regulation, communication, innovation and organisational capability.

Over the lifetime of the plan, the HPRA delivered against all five strategic goals, with all objectives assessed as on track. This translated into meaningful organisational and system-level outcomes, including stronger support for medicines and device availability, improved national and EU-level coordination on risk and safety issues, enhanced transparency and public communication, expanded support for innovation and clinical research, and significant progress in people capability, digital transformation and ways of working. Independent external validation of organisational capability and performance was also achieved through strong outcomes in external assessments and audits.

The HPRA enters the next strategic period from a position of strengthened capability and proven delivery. However, several areas will require continued focus, including medicines availability and supply resilience, implementation of evolving EU legislative frameworks, regulation of emerging and digital health technologies, continued strengthening of data and digital capability, and sustained investment in organisational capacity and capability.
Taken together, the outcomes of this strategy provide a strong foundation for the next phase of development. The HPRA enters the 2026-2029 period as a more integrated, influential and capable regulator, well positioned to respond to an increasingly complex and interconnected regulatory environment.