

# Strategic Plan 2026-2029

Shaping better health outcomes for people and animals in a dynamic regulatory landscape



# Foreword

Trusted regulation is fundamental to protecting public and animal health, enabling timely access to safe and effective products, supporting responsible innovation, and sustaining confidence and competitiveness in Ireland's life sciences sector. This strategy sets out how the HPRA will deliver on this responsibility in a period of rapid scientific, legislative and global change.

Recent years have seen growing complexity in the development, approval and supply of health products, bringing renewed focus to the role of regulators. This trend will intensify over the next four years, which will be shaped by an even more complex and demanding regulatory environment.

Rapid innovation, new EU legislative frameworks and continued pressures on global supply chains will require the HPRA to be agile, science-led and collaborative. Our impact will be measured not only by how effectively we protect public and animal health, but also by how we support timely access to safe and effective products, maintain public trust, enable responsible innovation, and contribute to Ireland's position as a leading life sciences location.

This strategy has been informed by extensive engagement with staff, leadership and key stakeholders across the health sector and the industries we regulate. It reflects a shared understanding of the challenges and opportunities facing both the HPRA and the wider health products regulatory system.

It also supports the strategic priorities of the Department of Health, the Department of Enterprise, Tourism and Employment, and the Department of Agriculture, Food and the Marine. These priorities include a shared focus on protecting public health, supporting innovation, and strengthening competitiveness and resilience. They also include advancing Ireland's life sciences ecosystem and contributing to One Health, food safety and animal health objectives.

**The Strategic Plan is structured around four goals that will guide the organisation's focus over the period ahead:**

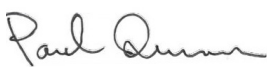
- Regulating for the future: Supporting timely access to safe, effective health products through leadership, excellence and preparedness
- Digital first, data driven: Driving digital transformation to modernise and optimise regulatory activities
- Partnerships, trust and transparency: Driving regulatory impact and efficiency through strategic collaboration and partnerships to serve health system needs and strengthen public trust
- People, capability and culture: Inspiring and leading our people to build future-ready, innovative teams committed to excellence in protecting public and animal health.

Each strategic goal represents a priority area through which we will strengthen and advance our work as an organisation. Taken together, they reflect the HPRA's role not only as a regulator, but as a trusted national body committed to safeguarding public and animal health, enabling safe innovation and timely access to health products, and maintaining confidence in regulatory oversight. They also support and strengthen Ireland's credibility and competitiveness in the European and global life sciences landscape.

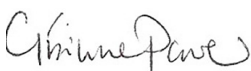
Grounded in our legislative mandate and supportive of Ireland's national priorities - as well as our European and international regulatory obligations - these commitments underline the HPRA's contribution to a modern, robust regulatory environment that supports public health and responds effectively to emerging challenges.

The successful delivery of this strategy will depend on the continued engagement and commitment of HPRA staff, the support of our partners, and a shared commitment to regulatory excellence in the public interest.

As the HPRA marks 30 years since its establishment as an independent body and National Competent Authority, this is an appropriate moment to set a clear direction for the future. This milestone provides an opportunity to reflect on our development and achievements while looking ahead to the organisation's continued evolution within an increasingly dynamic European and international regulatory network. Our new strategy positions the HPRA to meet emerging challenges and opportunities. It ensures that we remain effective and responsive in a changing environment, equipped to contribute at national and global level, with the protection of public and animal health at the heart of everything we do.



**Paul Quinn**  
Chairperson



**Grainne Power**  
Chief Executive



# Our mission, vision and values



## Our mission

We regulate medicines, health products 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.

### Integrity:

We are independent, transparent and accountable.

### Collaboration:

We work with others in partnerships, respect and trust.

### Inclusion:

We believe in the power of diversity, where everyone is valued and supported.

### Excellence:

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

### Innovation:

We continually learn, adapt and improve.

# How we regulate



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 inspect companies and facilities which test, make or distribute health products to ensure that they comply with relevant standards and legislation.



We produce safety and quality information to support the safe use of health products.



We support, through a range of activities, innovation in health products, technologies, and use of regulatory science.

# What we regulate

Medicines for human use



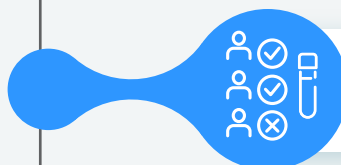
Medicines for animal use



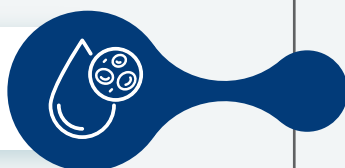
Medical devices for human use



Clinical trials



Blood and blood components



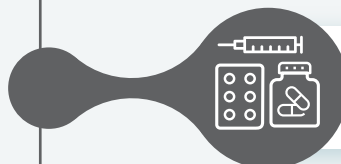
Human tissues and cells



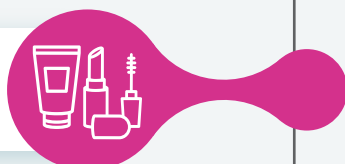
Human organs for transplantation



Controlled substances



Cosmetics



The use of animals for scientific purposes



# Our goals and objectives



## Goal 1

### Regulating for the future

- Support the development of innovative health products and foster agile, adaptive approaches that respond to scientific and technical progress
- Shape emerging legislation and policy across our regulatory remit, including through reinforced network leadership, to maximise system effectiveness and safeguard public health
- Play a key role in the authorisation of medicines and lifecycle management of health products in Europe
- Strengthen systems to proactively manage and reinforce health product availability and to ensure preparedness for public health threats, using a One Health approach



## Goal 2

### Digital first, data driven

- Drive digital transformation to optimise regulatory business processes and activities, and enhance digital interaction with external stakeholders
- Leverage data as a catalyst for regulatory excellence and innovation
- Harness the potential of artificial intelligence in the context of business and regulatory processes
- Advance a digitally skilled workforce equipped to regulate innovative health products and technologies



## Goal 3

### Partnerships, trust and transparency

- Reinforce the HPRA as the trusted authority and definitive source of health product information
- Enhance public trust and understanding through a culture of patient-centred regulation
- Strengthen integration with the health system, optimising regulatory impact to support patient care
- Foster strategic partnerships with national, EU, and international regulatory bodies and networks to support an effective and efficient regulatory environment



## Goal 4

### People, capability and culture

- Build a future-ready workforce, equipping our people with the skills and capabilities needed
- Align our organisational structure and workforce planning to optimise safe, reliable, high-quality, and efficient delivery of our remit and strategic priorities
- Secure long-term financial, environmental, and infrastructure sustainability in compliance with government codes
- Continue to foster and embed a culture of diversity, inclusion, equality, and excellence across how we work, innovate, and lead



## Goal 1

# Regulating for the future

Enabling timely access to safe, effective health products is central to the HPRA's mission. In response to rapidly shifting health and geopolitical landscapes, we will lead with agility and adaptability, strengthening regulatory science and embracing innovation wherever possible. By anticipating challenges and responding quickly, we will maintain public confidence in the safety and quality of health products. We will also pursue opportunities to replace, reduce and refine use of animals for scientific purposes.

With major EU and national legislative reforms on the horizon, we will use our position within the European network and with local partners to help shape these frameworks, so they deliver strong public health outcomes while enhancing EU and national competitiveness. By championing proportionate, forward-looking regulation, we will help reduce unnecessary burden, drive harmonisation, and create space for innovation to thrive.

We will strengthen systems that safeguard the availability of health products, support national preparedness for health crises, and tackle antimicrobial resistance using a One Health approach that recognises the interconnectedness of human, animal, plant, and environmental health. At the same time, we will support innovators through clear, efficient regulatory pathways, helping new technologies reach those that need them. Together, these efforts will build a more resilient, responsive regulatory system ready for the future.

# Regulating for the future

Supporting timely access to safe, effective health products through leadership, excellence, and preparedness.

| Objective                                                                                                                                                                                    | Action                                                                                                                                                                                                                                                                                                                                                  | Outcome                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Support the development of innovative health products and foster agile, adaptive approaches that respond to scientific and technical progress.                                               | Focused contribution to national and EU initiatives supporting the development of health products and technologies throughout the product lifecycle via adaptive and agile regulation.                                                                                                                                                                  | We have strategically focused and organised our expertise to further enable impactful contributions to policy, innovation, and best practice in regulatory science, both nationally and internationally.                                                                                                                                                                                                                                                                              |
| Shape emerging legislation and policy across our regulatory remit, including through reinforced network leadership, to maximise system effectiveness and safeguard public and animal health. | Apply our robust approaches for identification, analysis and planning for new legislative and policy initiatives arising at national, European, and international level, which have an implication for our work and mission.                                                                                                                            | <p>We have collaborated effectively to ensure that Ireland's public health priorities are reflected in new legislative and policy initiatives.</p> <p>We have actively engaged with stakeholders to enable smooth, sector-wide implementation of new and updated legislation and policy relevant to our remit, thereby strengthening stakeholder confidence in the regulatory system.</p>                                                                                             |
| Play a key role in the authorisation of medicines and lifecycle management of health products in Europe.                                                                                     | Strategically enhance the HPRA's participation in the EU regulatory network and contribute tangibly to sustainable EU network capacity through active HPRA participation in and across the EU regulatory network.                                                                                                                                       | We have optimised our substantial contribution across the European regulatory system for authorisation and health product lifecycle management. We have contributed to a net increase in the portfolio of Irish authorised medicines over the course of this plan.                                                                                                                                                                                                                    |
| Strengthen systems to proactively manage and reinforce health product availability and to ensure preparedness for public health threats, using a One Health approach.                        | <p>Strengthen national systems to ensure human and animal health products remain available and shortages are identified, mitigated, and prevented where possible.</p> <p>Contribute to development of national systems for preparedness and responsiveness to health crises and to the One Health National Action Plan on Antimicrobial Resistance.</p> | <p>We have delivered a coordinated national approach, incorporating robust monitoring and reporting systems, that minimises and prevents the impact of shortages on public health and supports an effective response to public health crises.</p> <p>We have systems in place at organisational level to support crisis response and preparedness and, in collaboration with relevant stakeholders, we have delivered relevant actions under the One Health National Action Plan.</p> |



## Goal 2

### Digital first, data driven

Digital transformation drives a more effective HPRA. We will modernise our systems, enhance the quality and flow of our data, and prepare our organisation to confidently adopt artificial intelligence. By doing so, we will create more efficient, better connected, future-focused regulatory processes.

We will optimise the integration of real-world evidence to inform our decision-making and strengthen our contribution to national and European digital health initiatives. As Ireland's e-health landscape expands, we will play an active role in shaping and leveraging new opportunities that enhance regulatory insight and public health impact.

Our digital progress is enabled by the capability of our people. We will build a digitally skilled workforce equipped to use emerging technologies and modern tools. Together, these efforts will position the HPRA to regulate innovative health products with clarity and confidence.

## Digital first, data driven

Driving digital transformation to modernise and optimise regulatory activities.

| Objective                                                                                                                                          | Action                                                                                                                                                                                                                                                                                             | Outcome                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Drive digital transformation to optimise regulatory business processes and activities, and enhance digital interaction with external stakeholders. | Strengthen and modernise our digital systems and processes by enhancing automation, improving connectivity and data exchange, and aligning with EU digital initiatives to deliver efficient, integrated and future-ready regulatory operations.                                                    | Our digital systems and processes are further modernised and integrated with enhanced automation, strong internal and external connectivity, and effective data exchange for external stakeholders aligned with EU digital standards, supporting efficient, consistent and future-ready regulatory operations.                                                                                           |
| Leverage data as a catalyst for regulatory excellence and innovation.                                                                              | Strengthen our data governance and enhance secure data sharing infrastructure in the context of EU initiatives on standards and interoperability.<br><br>Advance the integration of real-world and novel data sources as part of regulatory processes, working together with the EU network.       | Our regulatory processes are more streamlined and data driven, supported by improved interoperability and diverse, high-quality data sources.<br><br>Digital interactions with stakeholders are more efficient and consistent, with reduced manual effort.<br><br>The HPRA operates in the European regulatory network through stronger technical integration and the use of shared EU data and systems. |
| Harness the potential of artificial intelligence in the context of business and regulatory processes.                                              | Explore how advanced data analytics and artificial intelligence can be deployed across business areas to enhance internal analytical and decision support capabilities.<br><br>Contribute to development of standards and guidance on application of AI technologies to health product regulation. | We have expanded our use of digital tools, AI and data analytics to streamline our regulatory and business processes, supported by insights gained through EU regulatory initiatives.                                                                                                                                                                                                                    |
| Advance a digitally skilled workforce equipped to regulate innovative health products and technologies.                                            | Build digital, data, and predictive technology capability across the organisation through targeted upskilling and development programmes that strengthen innovation, collaboration, and effective use of emerging technologies.                                                                    | We have a digitally confident, well-equipped workforce with the skills to assess and regulate emerging technologies, supported by improved tools, stronger collaboration, and modern ways of working that enhance the quality and responsiveness of our public service.                                                                                                                                  |



## Goal 3

### Partnerships, trust and transparency

Strengthening partnerships and building trust are crucial aspects of the HPRA's role in protecting public and animal health. We will reinforce our position as a trusted, authoritative source of information on health products, ensuring that the information we communicate is accessible, understandable, and evidence based. Through transparent actions and accountable practices, we will safeguard public confidence in regulatory decisions and the wider health system.

By engaging openly and empathetically with the public and healthcare partners, we will foster greater understanding of our remit and how evidence shapes our decisions and actions. At the same time, we will deepen collaboration across the Irish health system and strengthen our contribution within EU and international regulatory networks, including supporting delivery of the Irish Presidency of the Council of the European Union. These partnerships will continue to support coordinated regulation, timely responses to emerging issues, and better outcomes for patients and the public.

## Partnerships, trust and transparency

Driving regulatory impact and efficiency through strategic collaboration and partnerships to serve health system needs and strengthen public trust.

| Objective                                                                                                                                                       | Action                                                                                                                                                                                                                                        | Outcome                                                                                                                                                                                                                                                           |
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| Reinforce the HPRA as the trusted authority and definitive source of health product information.                                                                | Continue to build on the functionality of the HPRA website and other channels to provide information and service to regulated entities, healthcare professionals, and the public which reliably meet evolving information and service needs.  | Our website and communication channels provide clear, timely, and reliable information and services that meet the evolving needs of our stakeholders.                                                                                                             |
| Enhance public trust and understanding through a culture of patient-centred regulation.                                                                         | Deepen our understanding of patient needs through the HPRA Patient Forum and broaden the types of regulatory activities on which we engage, to support patients.                                                                              | We have strengthened public trust and understanding by deepening engagement with patients and ensuring accessible, inclusive, and meaningful ways for them to share their experiences with health products, with their insights reflected in our regulatory work. |
| Strengthen integration with the health system, optimising regulatory impact to support patient care.                                                            | Promote collaboration and development of partnerships to enhance the role of the HPRA as part of inter-health system cooperation on important health product issues.                                                                          | We have delivered strategic frameworks that set out how we engage with the health system on significant regulatory issues to optimise safe and rational use.                                                                                                      |
| Foster strategic partnerships with national, EU, and international regulatory bodies and networks to support an effective and efficient regulatory environment. | Provide leadership in contribution to and collaboration within regulatory networks and development of best practices and standards to support risk-based, proportionate regulation, engaging with industry to support optimal implementation. | The HPRA is an enabler of continuous development in regulation and opportunities for joint working, focusing on efficiency and effectiveness whilst safeguarding public health.                                                                                   |



## Goal 4

### People, capability and culture

People are the power behind the HPRA's success. Their expertise and commitment drive excellence to protect public and animal health. We will continue to invest in our teams, building skills, fostering adaptability, and creating opportunities to thrive in an evolving landscape. Guided by our People Strategy and through strategic optimisation of our organisational structure and workforce planning, we will embed learning, succession planning, and workforce agility to stay future-ready. This, coupled with a focus on long-term sustainability, will serve to secure a stable foundation for our work.

Our culture champions diversity, inclusion, and equality. Every voice matters, every difference is valued, fuelling innovation and high performance. We uphold human rights and equality in all we do, in line with the requirements of the Irish Human Rights and Equality Commission Act 2014. By continuing to do so, we ensure a resilient, inclusive organisation that serves both our people and the communities we protect.

## People, capability and culture

Inspiring and leading our people to build future-ready, innovative teams committed to excellence in protecting public and animal health.

| Objective                                                                                                                                                   | Action                                                                                                                                                                                                                                                                       | Outcome                                                                                                                                                                                                                                                                                                                                          |
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| Build a future-ready workforce, equipping our people with the skills and capabilities needed.                                                               | Create a continuous learning environment, embedding learning into culture. Invest in targeted upskilling and development programmes. Develop critical skills for the future and strengthen succession and leadership pipelines.                                              | We have a future-ready workforce with increased agility, a strong leadership bench and a culture of multifaceted continuous learning.                                                                                                                                                                                                            |
| Align our organisational structure and workforce planning to optimise reliable, high-quality, and efficient delivery of our remit and strategic priorities. | Optimise our organisational structure to align with growth, evolving remit, and regulatory developments, maximising internal collaboration and continuously improving forecasting, business, and workforce planning to ensure agility and effectiveness.                     | We are organised for success. The right people, skills, culture, and sustainable structures are in place to support the delivery of our remit and strategic goals now and into the future.                                                                                                                                                       |
| Secure long-term financial, environmental, and infrastructure sustainability in compliance with government codes.                                           | <p>Deliver long-term sustainability through robust financial, environmental and infrastructure planning.</p> <p>Work collaboratively with the HPRA's government partners and parent departments to support optimal performance and delivery of our regulatory functions.</p> | We have maintained a strong and stable financial foundation that ensures the delivery of our regulatory responsibilities. This stability enables us to support sustainable practices, reduce our environmental impact, contribute to Ireland's climate goals and demonstrate success through full engagement with government reviews and audits. |
| Continue to foster and embed a culture of diversity, inclusion, equality, and excellence across how we work, innovate, and lead.                            | Create an environment that celebrates differences, drives high performance, and strengthens our shared culture, ensuring meaningful impact for our workforce and stakeholders.                                                                                               | We continue to build on the foundations we have established, further strengthening and embedding equality, inclusion, and human rights considerations into the way we work.                                                                                                                                                                      |

