

HPRA Strategy Public Consultation Review

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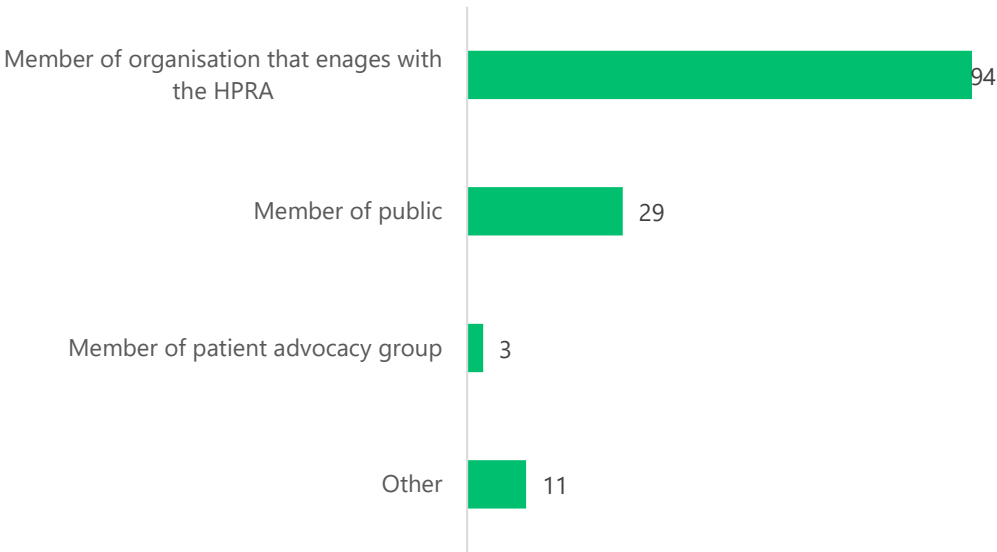
1 EXECUTIVE SUMMARY

The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland for medicines, medical devices, and other health products. To inform the development of our corporate strategy for the period 2026 to 2029, we sought the views of our broad range of stakeholders on issues and priorities to be considered as part of the strategy’s development.

The public consultation was conducted through a survey that was live from 20 December 2024 to 17 January 2025. The consultation elicited good levels of engagement, with a total of 137 responses received, 34 of which provided comprehensive and thorough answers to the majority of questions posed.

The majority of respondents were members of organisations that engage with the HPRA (94), with responses also received from members of the public (29), members of patient advocacy groups (3), and other cohorts (11). The breakdown of respondents is depicted in Figure 1 below.

Figure 1: Respondent affiliation



The purpose of this document is to provide a summary overview of the key themes that emerged in response to each of the questions within the survey, and to outline how these themes are to be addressed in the HPRA’s new strategic plan, where appropriate. Due to the number and nature of responses received, the views of respondents who provided detailed feedback may feature more prominently in the summary information presented within this document.

2 SUMMARY OF FEEDBACK RECEIVED

Question 1: What do you believe to be the strengths of the HPRA as a regulatory agency?

Communication and approachability

The HPRA was commended for its effective communication, approachability to stakeholders, and timely response rate, which facilitates productive interactions.

Regulatory expertise and technical excellence

The HPRA's regulatory strength was characterised by its skilled and experienced staff, technical excellence, and trusted scientific expertise.

European cooperation

The agency's successful cooperation with European partners and its active role in the European medicines regulatory network were highlighted as key strengths.

Confidentiality and independence

The HPRA was recognised for its independence, secure handling of confidential data, and adherence to excellent operational principles and procedures, which contribute to its respected status among stakeholders.

Enforcement

The HPRA's enforcement powers ensure high standards across regulated entities and facilitate the supply of safe medicines to patients.

Pragmatism

The agency is noted for its pragmatic and practical approach to regulatory matters, working collaboratively with companies and stakeholders to find solutions and facilitate progress.

Education and information sharing

The HPRA engages in educational, and information sharing activities with researchers, industry representatives, and other stakeholders including healthcare professionals, reflecting its commitment to knowledge sharing and stakeholder development.

Regulation and safety

The HPRA is responsible for the stringent regulation of medicinal products, medical devices and other health products, ensuring their safety and reliability for the Irish market and supporting public health.

HPRA response

Stakeholders highlighted strong communication, scientific expertise, European cooperation, independence, pragmatism, and commitment to safety as being some of the HPRA's core strengths. These will be embedded throughout the HPRA's strategy covering the period 2026 to 2029, reinforcing the HPRA's role as a trusted, science-led regulator.

The HPRA is committed to sustaining excellence in regulatory science, enhancing clarity and accessibility of information, and deepening patient-centred engagement. We will build on existing foundations for collaborative, solution-focused regulation by prioritising agile approaches to emerging technologies, strengthening preparedness systems, and supporting innovation while maintaining high safety and quality standards.

The strategy will also directly advance themes such as partnership, transparency, and international leadership. We plan to optimise our cooperation across the European regulatory network, strengthen integration with the national health system, and modernise digital and data capabilities to improve responsiveness and stakeholder interaction. Our continued focus on organisational culture, emphasising integrity, inclusion, and continuous learning, reinforces the independence and professionalism valued by our stakeholders. Overall, our new strategy will serve to further develop the strengths identified during the consultation, positioning the HPRA to continue delivering trusted, high-quality regulation in a rapidly evolving environment.

Question 2: What areas do you believe the HPRA could improve as a regulatory agency?

EU collaboration

The HPRA could put further focus on influencing EU legislation, and updating guidance documents regularly to support compliance, consistency, and effectiveness in regulatory practices.

Public trust

In terms of public engagement the HPRA should focus on strengthening the assurance of its independence from the industry it regulates, taking a leading role in topical health issues, and enhancing engagement with academic research and stakeholders.

Digital transformation

The HPRA should focus on digital transformation including EU initiatives for patient leaflets and licensing documentation to keep pace with advancements in this area.

Communication efficiency

The HPRA should improve the communication channels used to engage with the public and healthcare professionals to ensure a wider audience is reached. Engaging with healthcare professionals, promoting regulatory science, and providing accessible resources for the public would enhance the HPRA's collaborative efforts and educational impact.

Medicines shortages

Increasing oversight of drug shortages and ensuring continuity of supply to the market would improve the public's trust in the HPRA. Additionally, continuing enforcement activities against illegal and falsified medicines will continue to serve public health.

HPRA response

European engagement, enhanced public trust, digital transformation, effective communication, and medicines availability will continue to be key strategic focus areas for the HPRA in the years ahead. The new strategy will address these collectively by reinforcing the HPRA's leadership across the European regulatory network, maximising opportunities presented by emerging legislation, and strengthening partnerships both nationally and internationally. We will place clear emphasis on patient-centred transparency, improved communication channels, and collaboration with healthcare partners, all of which will help strengthen public confidence and broader stakeholder engagement.

In parallel, dedicated workstreams focusing on digital transformation will outline the HPRA's comprehensive commitments to modernising our digital infrastructure, enhancing the quality and flow of our data, and preparing the organisation to confidently adopt AI. Meanwhile, our continued focus on supply chain resilience and crisis preparedness demonstrates a proactive approach to managing availability of medicines. Overall, our new strategy will provide a coherent and future-focused response to the themes identified in survey responses.

Question 3: What do you see as important trends or developments in the sector in the next 5 to 10 years that the HPRA should take into consideration when developing its strategy?

Technological innovation and digital transformation

The HPRA should prioritise advancements in AI, machine learning, cybersecurity, and the growing significance of Software as a Medical Device (SaMD) for the upcoming strategy. Embracing digitalisation, including the adoption of new clinical trial modalities and other digital interfaces, is essential to meet the demands of a technologically evolving sector.

Sustainability

Integrating sustainability and environmental considerations into the development and lifecycle of health products is increasingly important for the industry and should be considered as part of the HPRA's new strategy.

Personalised medicines and new therapies

The emergence of personalised medicine, cell and gene therapies, and the increasing use of digital healthcare solutions will require the HPRA to consider the impact on its regulatory framework and practices to support these innovations while ensuring patient safety.

Changing regulation

Adapting to changing regulatory obligations as a result of new and updated legislation, and responding to global healthcare regulatory changes will have a significant impact on the HPRA's upcoming strategy.

Medicines shortages

The HPRA's continued focus on the Medicines Shortages Framework and its impact on supply chain resilience is critical to ensuring the continuous availability and safety of medicines.

Healthcare professional development

Supporting the evolving roles of healthcare professionals and ensuring their scope of practice is appropriate as they adapt to advancements in healthcare services.

Public engagement

Enhancing public engagement strategies to address scepticism in the sector, leveraging digital platforms for information dissemination, and involving patients or patient representatives in the regulatory process are key to maintaining public trust and ensuring transparency.

HPRA response

The HPRA strongly welcomes stakeholders' comments highlighting the importance of considering rapid technological and scientific change, data and digital systems, evolving regulatory requirements, and supply chain resilience. These strategic priorities will underpin the HPRA's future-focused approach to regulating innovative products, strengthening preparedness, modernising digital capabilities, and helping shape national and European regulatory frameworks.

The new strategy will reinforce the HPRA's commitment to transparent, accessible communication and strengthened public engagement, including through initiatives of the HPRA's Patient Forum, particularly in the context of remaining a trusted source of product information in the face of scepticism. The HPRA will also work collaboratively with healthcare professionals and the wider health system to support delivery of shared goals. In relation to comments received regarding healthcare professional development and scope of practice, while certain aspects may fall outside the remit of the HPRA, we will continue to assess the impact of legislative change on our market surveillance and enforcement remit for all health products.

The HPRA will take meaningful steps to integrate sustainability and environmental considerations into how health products are regulated. This will be achieved through future-oriented approaches that support innovation while promoting proportionate, forward-looking regulation that takes account of emerging scientific, environmental, and societal expectations. By adopting a One Health approach to our regulatory practices, we will recognise the interconnectedness of human, animal, and environmental health.

Question 4: What do you see as important strategic considerations in relation to how the HPRA protects the health of the Irish population?

Public engagement

The HPRA should prioritise visibility, transparency, and clear communications, ensuring its presence in spaces where the population is receiving information, including social media platforms, with a tone that is accurate yet approachable.

Proactive engagement

Being proactive in educating the public about the regulation of health products, the risks of buying unregulated products, and ensuring that key quality and safety information effectively reaches healthcare professionals amidst informational noise are important strategic considerations.

Cybersecurity

Addressing cybersecurity threats and risks is an important consideration for the HPRA's strategy to protect public health.

Market access

Working with Marketing Authorisation Holders (MAHs) to bring supply to the Irish market, reducing fees, and seeking government support to make products more viable are strategies to improve market access and affordability of medicines that the HPRA should consider.

Clinical research and data

The HPRA should provide input on electronic health records and registries in Ireland, facilitating access to anonymised patient data for clinical researchers, and positioning Ireland as an attractive location for clinical trials with rapid assessments and approvals.

Access to medicines

Ensuring the continuity of supply of essential medicines, faster access to new medicines in line with international standards, and easier public access to high-tech medicines are important strategic considerations.

Market surveillance

Focusing on robust safety and efficacy evaluations, including through post-market surveillance, are core to the HPRA's public health mandate.

Collaboration

Encouraging collaboration among medical professionals and recognising the vital roles they play in protecting health is essential for a comprehensive strategy to protect public and animal health.

Health Technology Assessment (HTA) and regulatory support

Providing support for HTA and clinical trials and ensuring a quick derogation process for In Vitro Diagnostics (IVDs) as regulatory timelines approach, are strategic areas the HPRA should consider.

HPRA response

Through our new strategy, the HPRA will place an emphasis on accessible, evidence-based communication, thereby deepening engagement with the public, patients, and healthcare professionals. We will support innovation so that together we can address emerging challenges, leverage new opportunities, and maintain the robust systems in place to ensure the availability, quality, and safety of health products.

The HPRA shares stakeholders' views on the importance of areas such as digital transformation, advanced data use, cybersecurity, and support for clinical research. Under the new strategy, these will be addressed through commitments to modernise our internal systems, enhance digital integration, and build the organisational capability required for a rapidly evolving regulatory environment. Our strategy will reflect expectations around collaboration, both across the health system and internationally, while also recognising the need for a resilient, skilled, and adaptive workforce.

With respect to comments regarding access and affordability of medicines, the HPRA will continue to place a focus on supporting and enabling the development and authorisation of medicines. However, other matters relevant to medicines access, such as pricing and reimbursement, are not within the HPRA's remit and therefore will not be covered in the new strategy. The HPRA will engage with health system partners and the Department of Health on matters of national supply resilience and policy.

Question 5: How should the HPRA support innovation and prepare for the regulation of emerging technologies?

Stakeholder engagement

The HPRA should engage with bodies that support the introduction of medical devices, and learn from universities, startups, and other innovators by inviting them to present emerging technologies and innovations. This includes consulting with clinicians, researchers, patient groups, and practicing healthcare professionals to avoid information silos and identify problems immediately.

Regulatory flexibility

Providing more guidance and control, especially for medical devices and technologies involving AI, and maintaining a flexible regulatory framework that can adapt to rapid technological changes are crucial. The HPRA should offer priority reviews and direction to innovators, ensuring that regulatory frameworks are adaptable to emerging technologies.

Best practices

Collaborating with stakeholders and looking to other countries and regulatory bodies for technology trends will help the HPRA stay informed and align its processes with best practices. This includes aligning regulatory pathways centrally with EU processes.

Innovation Office

The HPRA's Innovation Office should be staffed with experts in fields such as cell and gene therapies, medical devices, and AI, with a focus on hiring people with relevant experience and implementing robust retention policies to keep them. Continuous upskilling of employees is essential to remain abreast of technology developments.

Role expansion

Encouraging the expansion of roles and capabilities, particularly in nursing, to support innovation and adapt to emerging technologies. This includes lobbying for equal access to new technologies and ensuring inclusivity in the regulatory process.

HPRA response

Within the responses received, stakeholders emphasised the importance of strengthened engagement with innovators, regulatory flexibility, alignment with best practice, and the need for specialist capability to anticipate fast-moving scientific and technological developments. These considerations are key to the HPRA's forward-looking regulatory approach centred on adaptive, science-led decision-making. Our new strategy will place a clear emphasis on collaboration with national and international partners, deeper engagement with innovators and healthcare professionals, and enhanced use of digital technologies to support timely, consistent, and future-ready regulatory processes. Collectively, these actions will respond directly to calls for an agile and supportive environment for emerging technologies.

The HPRA's new strategy will also provide a strong framework for building the organisational capabilities required to regulate innovative products with confidence. This includes commitments to expanding digital and data expertise, strengthening workforce skills, and embedding continuous learning so that the organisation remains equipped to assess novel technologies. Simultaneously, enhanced communication channels, deepened patient and stakeholder involvement, and reinforced contributions within the European regulatory network will ensure inclusive engagement across the health system and alignment with international best practice.

While the HPRA will continue to engage collaboratively with other health system regulators to ensure coordinated and effective approaches to market surveillance and supervision, regarding feedback received in relation to roles and capabilities of healthcare professionals, such matters are outside of the scope of the HPRA's regulatory remit.

Question 6: How can the HPRA increase public awareness and understanding of its work?

Integrated communication campaigns

Utilise an integrated approach to media campaigns that combines social media engagement and traditional media to reach diverse audiences. This includes leveraging the potential of social media and ensuring regular updates and interactive content.

Educational initiatives and collaboration

Engage in educational outreach by collaborating with universities and healthcare associations, including input into relevant courses and guest lectures. Broaden communication efforts to include school children and work with healthcare professional groups to amplify the HPRA's message.

Accessible information

Enhance the accessibility of information through clear language, webinars, and public campaigns. Implement publicity initiatives such as including the HPRA information on prescription labels and releasing press updates to maintain public visibility.

Dedicated communication role

Establish dedicated communication roles within the HPRA to focus on strategic public outreach and to promote compliance with treatment regimens. Collaborate with related bodies on campaigns that emphasise the benefits of following prescribed treatments.

HPRA response

In response to the consultation, stakeholders emphasised the importance of clear communication, accessible information, and public engagement to help deepen understanding of the HPRA's role. These priorities will inform the HPRA's strategic actions to improve how information is shared, strengthen evidence-based communication, and ensure that the public, patients, and healthcare professionals can engage meaningfully with our work. The HPRA is committed to modernising our digital channels, continuing to enhance clarity of information, and improving stakeholder engagement over the course of this plan to ensure that regulatory decisions are communicated in ways that are transparent, understandable, and responsive to public needs.

The new strategy will address calls for a more visible, outward-facing HPRA by strengthening partnerships across the health system and the wider regulatory network. Through expanded collaboration, active engagement with patients and healthcare partners, and investment in digital capability, we aim to build greater trust, broaden public awareness, and support informed understanding of our remit. These combined efforts will reinforce the HPRA's position as a trusted, authoritative source of health product information and ensure that our communication and engagement activities reflect the expectations identified through the consultation.

Question 7: How can the HPRA improve its communications and engagement?

Audience-specific messaging

Increase the visibility of the communications team and tailor the tone and content of communications to match the audience. This includes providing detailed and industry-specific jargon in newsletters to professionals, while offering accurate, jargon-free information with additional resources for the general public.

Regulatory guidance

Develop educational resources, guidelines, and mandatory trainings or webinars for specific roles such as Responsible Persons and Qualified Persons. Publish clear regulatory guidance on responsibilities, particularly in specialised areas.

Frequency of communications

Issue more press releases to maintain a steady flow of information in order to increase the public's awareness of the HPRA's existence and the role of the organisation in public health.

Healthcare professionals

Acknowledge and engage with healthcare professionals and professional associations. Foster open, transparent dialogue with all stakeholders and establish regular channels of communication.

Consultation forums

Host consultation forums or roundtable discussions to gather diverse sector input, build trust within the community, and ensure the HPRA remains responsive to the needs of its stakeholders.

Platform diversification

Diversify the platforms used for communication to include social media channels, using methods that resonate with varying target audiences. Adopt more direct messaging about the consequences of using illegal products, similar to impactful public safety campaigns, in order to target specific public health concerns.

Website

Enhance the HPRA website to make it more intuitive for first-time visitors and the general public, ensuring ease of use and better access to information.

HPRA response

The themes raised during the consultation emphasised the need for clear, accessible communication, engagement with healthcare professionals and stakeholders, and intuitive digital channels. These priorities will be reflected throughout the HPRA new strategy, with an emphasis on evidence-based communication, strengthened public understanding, and ensuring that information is shared in ways that are transparent, accurate, and easy to navigate. Planned improvements to digital systems and website functionality will support efficient interactions, provide clear guidance, and make it easier for different audiences to find the information they need.

Stakeholders also highlighted the importance of targeted engagement and opportunities for deeper collaboration. The HPRA will strengthen engagement across the health system and support patient and stakeholder involvement in regulatory activity, including through the HPRA's Patient Forum. The new strategy will include a focus on partnership, digital modernisation, and organisational capability to enable responsive, consistent, and outward-facing communication. Cumulatively this will help to build trust, strengthen stakeholder relationships, and support a connected regulatory environment.

Question 8: Do you have any additional comments or suggestions about the HPRA's current or future strategy, priorities, or operations?

Availability of medicines

The HPRA should explore ways to facilitate the import of UK products to the Irish market post-Brexit, potentially by setting up a working group to liaise with the other key stakeholders. Encouraging MAHs to continue supplying the Irish market through reduced fees, improved communication, and electronic communications to healthcare professionals could help reduce shortages.

Maintaining accessibility and engagement

Preserve the accessible and personal approach that the HPRA is known for. Continue to encourage patient and public engagement with the organisation and provide information on regulatory areas that are expected to evolve, such as cell and gene therapies and the challenges presented by AI in healthcare

Public awareness and education

Informing the public about the remit of the HPRA and educating them on the importance of using qualified, regulated healthcare professionals for healthcare are important for public safety and trust

Resource

Increased staffing is necessary for the HPRA to handle its growing responsibilities and to ensure effective execution of its public health role.

Notified Bodies

Inviting more Notified Bodies to set up in Ireland could address the mismatch between the number of manufacturers and available Notified Bodies, as seen in other EU Member States.

HPRA response

Stakeholder feedback in response to the consultation's final question again underscored the importance of meaningful stakeholder engagement, clarity of communication, and availability of safe, effective health products. These priorities will be reflected throughout the new strategy as part of the HPRA's ongoing efforts to strengthen collaboration and support continuous availability of medicines in Ireland.

Across the draft strategy, there will be a consistent focus on addressing expectations around workforce capability and capacity. Commitments to develop a digitally skilled organisation utilising modern systems will support the HPRA's delivery of a responsive, efficient regulatory environment.

As the authority responsible for the designation and oversight of notified bodies based in Ireland, the HPRA does not solicit notified bodies to establish operations here. We are, however, open to engaging prospectively with any notified body considering the Irish market to discuss regulatory requirements and the designation process.

3 CONCLUSION

The HPRA sincerely appreciates the valuable input and engagement from all respondents throughout the consultation process. The feedback provided has played a crucial role in shaping our understanding of stakeholder needs and priorities over the years to come. We are committed to ensuring that the insights received will be thoughtfully integrated into the development of our new strategy, supporting ongoing enhancements to our regulatory practices to the benefit of public and animal health in Ireland.