Stakeholder views on HPRA Strategy 2021-2025

Who we are and what we do

The HPRA is the regulator of health products in Ireland. Our **mission** is to protect and enhance public and animal health through the regulation of medicines, medical devices and other health products. We regulate a range of sectors including

* Human medicines
* Medical devices for human use
* Blood and blood products; tissues and cells; organs for human transplantation
* Veterinary medicines
* Scientific animal protection
* Controlled substances
* Cosmetics

In carrying out our regulatory functions, the HPRA puts the health of people and animals at the core of everything we do. We use our scientific and clinical expertise to review and monitor health products available in Ireland or exported abroad. Our aim is to make sure that the health products we regulate are as safe as possible and do what they are intended to do.

Our current strategic goals

The current Strategic Plan covers the years 2016 to 2020 and is based on the following five high-level goals, each of which has a number of objectives and activities which guide our annual business planning and reporting.

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| 1 | Optimised regulatory systems: keeping abreast of product and manufacturing development  |
| 2 | Better informed users: providing up-to-date information to inform choices and decisions  |
| 3 | Access to health products: enhancing regulatory support for access to health products  |
| 4 | Supporting innovation: providing regulatory support and advice to research and development centres  |
| 5 | Internal capabilities: ensuring strong internal systems, resources and expertise  |

As we begin the development of the next strategic plan to cover the years 2021 – 2025, we invite all stakeholders to give their views on areas that are relevant to them, using the format below, firstly in relation to product areas and secondly in relation to key high-level areas.

Looking forward to the next five years

The 2021 – 2025 period to be covered by the next strategic plan is likely to be a time of uncertainty and change in the regulatory environment. Key drivers include:

Brexit

Whatever the outcome of the current negotiations with the UK, the outlook for the Irish market over the next five years is difficult to predict given the size of the market in Ireland and the supply chain model. Changes to the supply of some human or veterinary medicines and medical devices, particularly where UK companies cease manufacture or supply to EU markets, cannot be ruled out. There is also the potential for opportunities to arise as the work previously undertaken by the UK will be available to other member states, including leading or shaping network initiatives to improve regulatory systems.



Legislation

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. Each Regulation will impact significantly on the operation of the relevant regulatory system. For the HPRA, these constitute major projects including interactions with government departments, contribution to national legislation, engagement with stakeholders, and creation of guidance documents.

Innovation

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. Increasingly complex products have the ability to greatly improve patient outcomes but may pose challenges to the current regulatory system as well as create demands for appropriate supports. Regulatory requirements may need to be adapted for effective regulation, new tools and approaches developed, and regulators themselves will need upskilling and access to additional expertise.

Partnerships

The regulation of health product takes place with a national health system where other activities are also critical to outcomes, upstream through innovation and clinical studies, and downstream through the role of healthcare professionals and, where relevant, health technology assessment and reimbursement decisions. Working with national agencies, professional bodies and patient groups should be a two-way process where information and intelligence coming into the HPRA can help us regulate more effectively taking into account the needs of the health system, and our input into relevant parts of the system can influence the safe use of health products in clinical practice.

Public trust and confidence

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. Therefore regulators, as other actors in the system, must maintain a focus on their own trustworthiness and on demonstrating that to the outside world. This means being transparent around decision-making, communicating via appropriate channels in a timely manner, having robust internal processes, and identifying and appropriately managing emerging risks.

Views of our stakeholder

The HPRA is interested in the particular views you have, as a stakeholder, in what our priorities should be over the next five years.

Views may be expressed on any or all of the questions below in the form of potential challenges and opportunities, needs and expectations, comments or proposals. All will be considered and will help inform the final strategy document.

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| Question 1 |
| What do you see as important strategic considerations in relation to the following key **high-level areas of focus?*** How the sector(s) we regulate will develop over the next 5 to 10 years.

Enter text here * How we protect the health of Irish patients and animals by licensing products and companies, monitoring the safety and quality of medicines used in Ireland, and enforcing the legislation.

Enter text here* Our contribution to the national health system.

Enter text here* Our contribution to the network of competent authorities in the EU and internationally.

Enter text here* Our role in legislation and policy development.

Enter text here* Our support for innovation.

Enter text here* Our vision, mission and values.

Enter text here |
| **Question 2** |
| In addition, we are also seeking views on **how we interact with our stakeholders**. Thinking about your own interactions and those of colleagues:* How well do we currently communicate with you on issues relevant to your work?

Enter text here* Are there additional topics, areas or issues you think we should communicate more about?

Enter text here* In general, what communication methods suit best, e.g., newsletters, email, website alerts, text messages, videos, podcasts, webinars?

Enter text here* How can we increase public awareness and understanding of our work?

Enter text here* Are there ways in which we can better engage and involve patients and the public in our work?

Enter text here |

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| Any other comments |
| Enter text here |

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| Your detailsName: Enter text hereOrganisation: Enter text hereAddress: Enter text hereContact e-mail or telephone number: Enter text hereholder engagement |

Please e-mail the completed form to strategy@hpra.ie by 13 December 2019.

Please note that submissions may be made available under the Freedom of Information Act 2014. Any personal data, within the meaning of the Data Protection Act 2018, submitted as part of the consultation process will be treated in line with the requirement with this Act. Personal identifying information contained in submissions will not be published in accordance with the Data Protection Act 2018 and the Freedom of Information Act 2014.

Thank you for your contributions which are greatly appreciated.