HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority
Strategic Plan 2016 – 2020

CONTENTS

1 ABOUT THE HEALTH PRODUCTS REGULATORY AUTHORITY

1.1 Vision, mission and values

The Health Products Regulatory Authority (HPRA) is the independent regulator of health products in Ireland. Our role is to protect and enhance public and animal health. We do this by assessing the safety, quality and effectiveness of healthcare products on behalf of the public to ensure the benefits they provide outweigh any potential risks. Our core regulatory functions and our aims and objectives as expressed in our mission, vision and values.

Our **vision** is to be a leader in effective and innovative regulation, both nationally and internationally, and recognised as a centre of excellence for both the quality and scientific rigour we bring to the work we do and the efficient manner in which it is completed.

Our **mission** is to protect and enhance public and animal health through the regulation of medicines, medical devices and health products.

Our **values** are:

- Acting always in the best interests of patients and consumers.
- Operating to the highest standards of scientific decision-making and quality.
- Behaving with integrity, impartiality and transparency.
- Promoting research, innovation, continual learning and openness to change.
- Treating stakeholders and each other with dignity and respect at all times.

1.2 What we do

- We are responsible for regulating a wide range of health products available in Ireland:
    - Human and veterinary medicines
    - Medical devices for human use
    - Blood components
    - Human tissues and cells
    - Human organs for transplantation
    - Controlled substances
    - Cosmetics
- Other areas include clinical trials using human medicines, clinical field trials using veterinary medicines and clinical investigations using medical devices for human use.
- We regulate manufacturing, wholesale and distribution companies, medical device notified bodies as well as other health product facilities.
- We license and monitor the use of animals for scientific or educational purposes, ensuring that the 3R principles (replacement, reduction and refinement) are applied.

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

- We inspect companies and facilities which test, make or distribute health products to ensure that they comply with relevant standards and legislation.
- We enforce the legislation (as a shared responsibility with other state agencies in some areas).

The organisation is governed by an Authority of nine members appointed by the Minister for Health. It is advised by three statutory scientific advisory committees: for human medicines, veterinary medicines and medical devices; and subcommittees for clinical trials and herbal medicines. We are part of a European network of regulatory agencies and make a significant contribution to European and international health products regulation.

We work strategically with all stakeholders including government and government agencies, healthcare professionals, the research communities and manufacturing industries, to maximise the availability of products with a positive benefit/risk profile for patients. We are also focused on extending our patient engagement initiatives to ensure that the patient experience is considered in our regulatory decision-making and communications.

The industry sectors regulated by the HPRA make a significant contribution to patients and the national health system from the products they produce and market. They are also part of a very substantial life sciences sector in Ireland supplying exports to over 100 countries worldwide. Annual exports of pharmachemicals are over €50bn, making them the largest net exporter of medicines in the EU and representing over 50% of the value of our country's exports. The medical technology sector in Ireland is one of the largest net exporters of medical products in the EU with annual exports from Ireland of over €8bn.

1.4 Our core regulatory work

This plan sets out specific strategic objectives and actions that we seek to achieve over the next five years building on the core regulatory work that is delivered through advisory activities, authorisation and approval functions, inspections and audits, and market and product monitoring.

Annually, with a staff of over 300, we process approx. 40,000 cases including authorisation and certification applications, surveillance reports, and enforcement activities. Recent statistics on regulated products and companies include:

- 7,784 human medicines authorised nationally
- 1,635 veterinary medicines authorised nationally
- 92 manufacturers of human medicines
- 25 manufacturers of veterinary medicines
- 52 manufacturers of clinical trial medicines
- 271 distributors of human medicines
- 4 blood establishments, 24 tissue establishments and 4 centres of organ transplantation
- 1 designated notified body for medical device assessment
- 500,000 approx. medical devices for human use (in EU)
- 23 establishments and 1160 individuals authorised for scientific animal research

This work continues throughout the lifecycle of our strategic plans and is delivered by highly-experienced staff, working to current regulatory standards, in a timely and efficient manner.

2 OUR ACHIEVEMENTS SINCE 2011

Our last strategic plan covered the years 2011 – 2015 and included five goals as shown below.

1. Enhance healthcare product safety and patient outcomes by effective risk management and market surveillance.
2. Deliver clear, relevant and timely communications to patients, consumers and healthcare professionals.
3. Improve service delivery within a high quality, risk-based regulatory framework.
4. Influence legislation and policy development at European and international levels for the benefit of public and animal health.
5. Build future capabilities to meet evolving regulatory requirements, and scientific and technological advances.

Our key achievements in relation to our last strategic plan include:

- Implemented the Commission's 'joint action' plan to reinforce medical devices regulation, and was subject to a successful joint assessment in our notified body surveillance audit.
- Substantially changed the process for re-classification of medicines to a more proactive approach, following extensive stakeholder engagement.
- Delivered a new HPRA website, incorporating a total redesign to focus on improved communications to stakeholders by better navigation and access to content of interest.
- Developed and implemented the Common European Submission Portal (CESP) for submission of medicinal product applications, used in over 32 EU countries.
- Improved service delivery timelines across a broad range of regulatory procedures.
- Contributed to EU discussions on new legislation for clinical trials, medical devices and veterinary medicines, providing support to our parent department at Council meetings.
- Hosted 22 meetings of European medicines and medical device agencies to drive European policy development during the Irish Presidency in 2014.
- Contributed to the development of the International Coalition of Medicines Regulatory Agencies, being elected vice-chair, and leading a number of priority projects.
- Elected to the Executive Committee of the new medical devices competent authority network and to Management Committee of the International Medical Device Regulatory Forum.
- Delivered supporting strategies in ICT, Communications, and Learning and Development.

During these years, we also:

- Successfully launched the change in name from the Irish Medicines Board to the Health Products Regulatory Authority on 1 July 2014, to better reflect the wider scope of our work, functions and responsibilities across the health products sector.
- Became the competent authority for the quality and safety of human organs for transplantation, for veterinary clinical field trials and for the protection of animals used for scientific purposes, and developed the regulatory system for cosmetics.
- Implemented new legislation for pharmacovigilance, falsified medicines,[1] interchangeable medicines and scientific animal protection.

[1] Falsified medicines are medicines which have a false representation of their identity, source or history.

- Implemented the Health (Pricing and Supply of Medical Goods) Act 2013 requirements for 'interchangeable lists', allowing cheaper generics[2] for substitute dispensing to patients.
- Underwent a successful external benchmarking assessment.
- Extended our offices with two additional floors.
- Managed the impact on our staff of the public service pay and reform agreements.

3 DEVELOPING THE STRATEGIC PLAN

In this plan, we have set out the strategic direction which will guide the HPRA over the next five years. It describes the environmental conditions and developments expected over the planning period, the strategic goals we have set, and a clear roadmap to our stakeholders and staff showing how we will achieve these goals. The planning process included a substantial stakeholder consultation, internally with staff and managers, and externally with interested parties, including a public consultation through our website. The Department of Health's Strategy 2015 –2017 was also taken into account in drawing up this plan.

The strategic objectives and actions are, of necessity, broadly focussed, and will require planning and delivery over a number of years to achieve. The detailed activities will be developed and delivered through the annual business planning cycle. The outputs of annual business plans will, over time, contribute to the achievement of the strategic outcomes we have defined. Effective management of the planning and reporting process is key to ensuring that the outcomes we have set are met for those patients, users and animals who use the products we regulate.

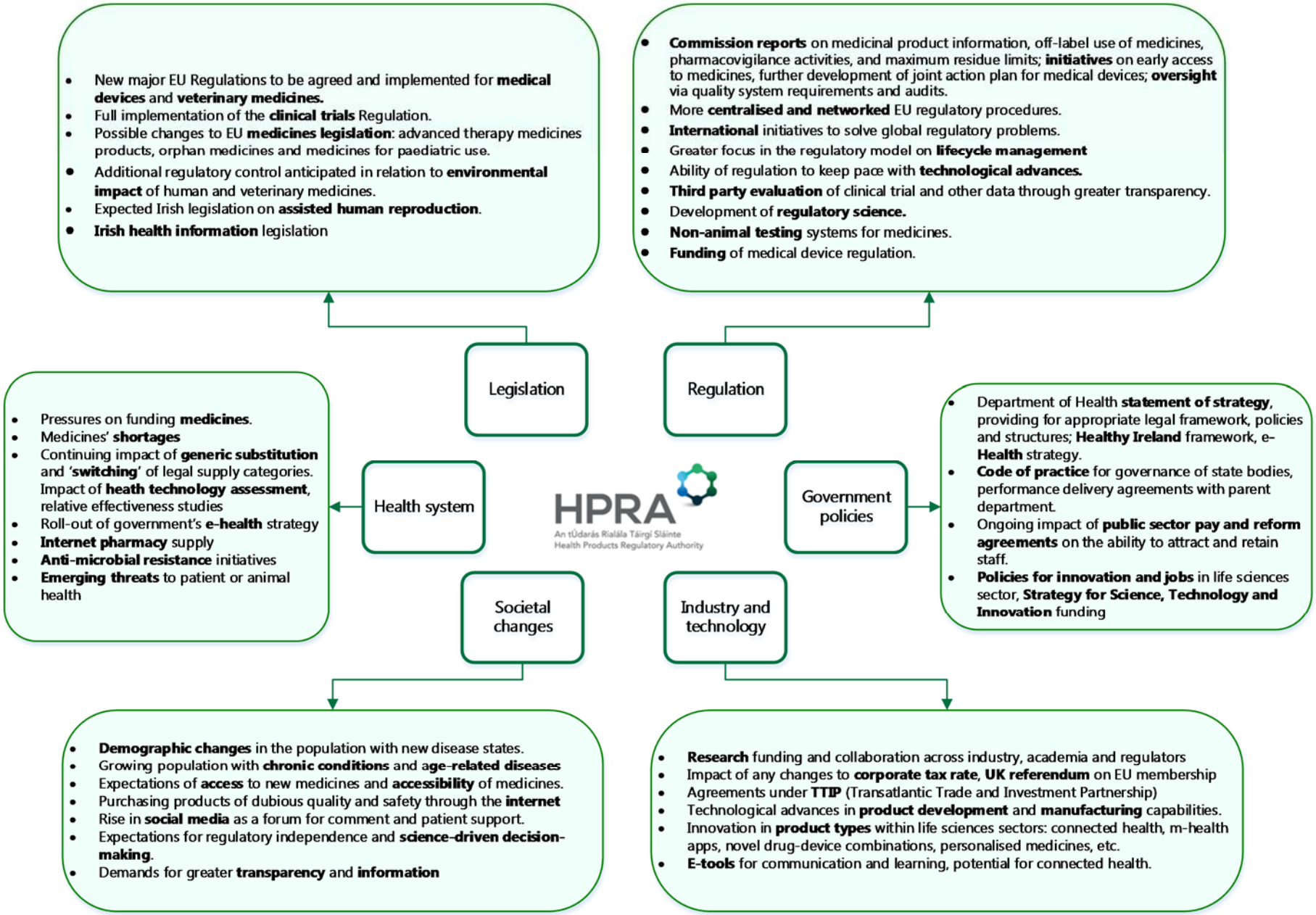
The organisation's Authority has overseen the preparation of this strategic plan by the management team, has reviewed the appropriateness of the goals and objectives in relation to the expected drivers of change over the next five years, and has adopted it following consideration of the plan by the Minister for Health.

4 CHALLENGES AND OPPORTUNITIES

Changes in the environment in which we operate can be major drivers of change in the organisation. The most significant driver is EU and national legislation, and the competencies and functions that government assigns to us as a result. Over the next five years, medical device legislation will be substantially revised, as will the legislation for veterinary medicines, which will have to be reviewed and implemented by the HPRA. Increasingly, efficiencies are being gained within the EU by more single centralised assessments and more effective solutions will be possible through EU co-operation on issues such as medicines shortages which affect many countries as well as Ireland, and early access to new medicines which have important benefits for patients. Continuing financial pressures in the Irish health system will drive a focus on medicines as a significant part of the health spend. Our communication and stakeholder engagement will be shaped by changes in society's expectations of regulators, while technology advances have the potential to transform manufacturing and health products and challenge the system to effectively regulate innovative processes and products.

[2] A generic medicine has the same active ingredient(s) as a brand name medicine and meets the same standards of safety, quality and effectiveness.

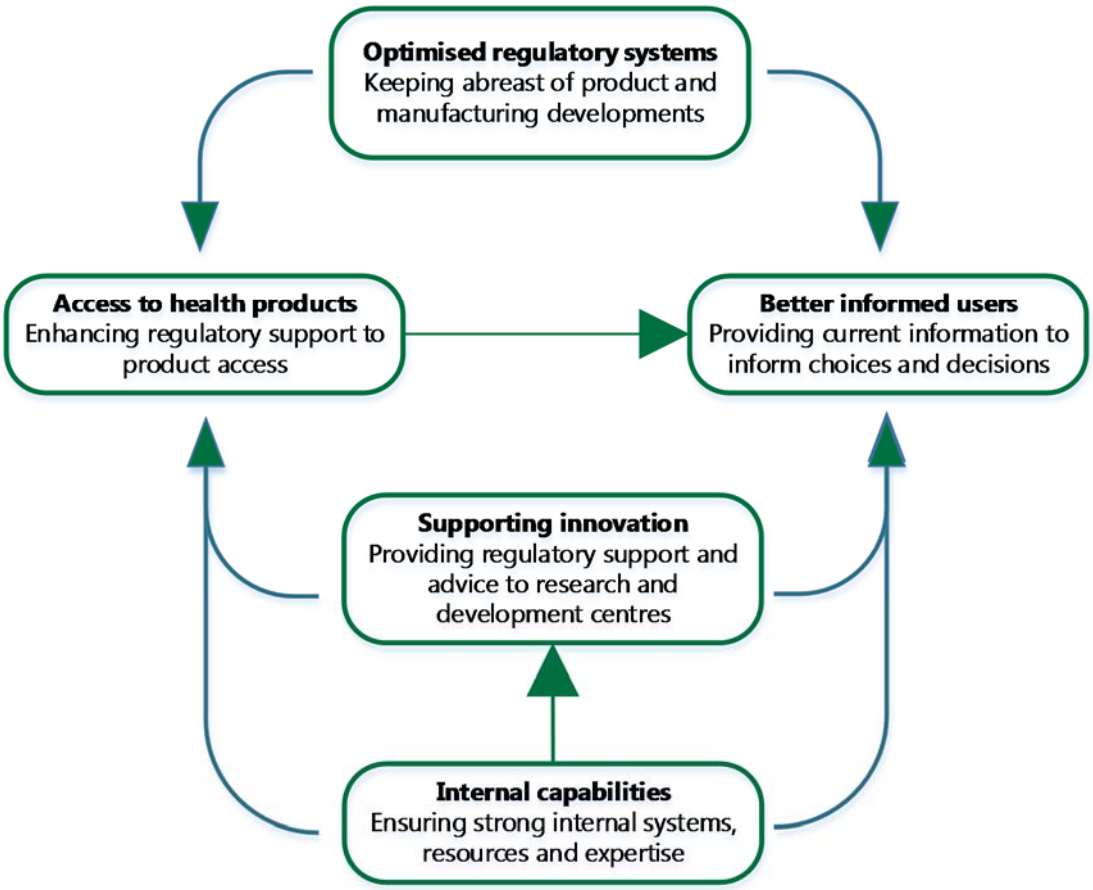
CHALLENGES AND OPPORTUNITIES



5 STRATEGIC GOALS AND OBJECTIVES FOR 2016 – 2020

In response to the challenges and opportunities we see in the environment and building on our achievements over the last strategic plan, we have identified five goals for 2016 – 2020.

The goals and the underlying logic linking them are shown graphically below.



On the following pages, the objectives are set out for each goal and the corresponding high-level actions. These will be cascaded down to annual business plans over the course of the strategy.

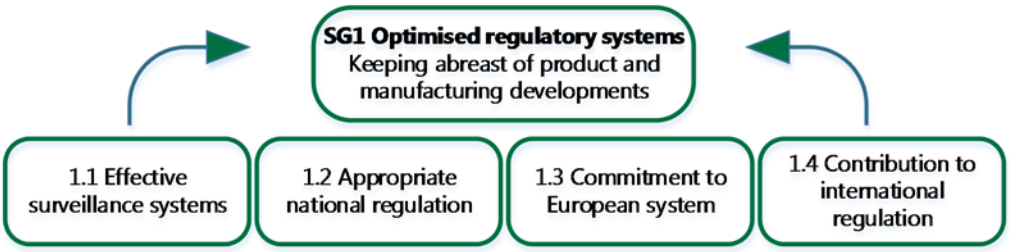
In addition, a number of large projects are in progress now and will continue through some or all of the years of this strategy. They include:

- Clinical trials: implementation of new European Regulation
- Medical devices: development and implementation of new EU legislation
- Veterinary legislation: development and implementation of new EU legislation
- Further development of interchangeable medicines lists
- Redevelopment of IT systems under the current IT strategic plan

We will also remain mindful of the need for contingency capacity, as major issues relating to the areas we regulate that may arise from time to time, may take significant levels of resources to effectively manage.

STRATEGIC GOAL 1 — OPTIMISED REGULATORY SYSTEMS

In our core regulatory work, the HPRA plays a vital role in ensuring that health products taken and used by patients, users and animals deliver their intended benefits while being as safe as possible. The strength of the system derives from the high standards required by Irish and European legislation and from the extensive network of Irish and EU experts who contribute to high quality, scientific decision-making. In recent years, international regulatory initiatives have become increasingly important, reflecting the globalisation of clinical trials, manufacturing and supply chains. These initiatives will play a significant part in ensuring greater convergence of regulatory standards, greater information-sharing between regions, and best use of resources. Nationally, the HPRA will continue to collaborate with State agencies and other stakeholders in the Irish health system, to help achieve continuous development of government policy and our strategic and business objectives. It is a key goal to maintain the high level of regulation which forms part of our core work, and to improve it with the following strategic objectives.



Strategic objective 1.1

To strengthen the effectiveness of surveillance systems for health products

Effective surveillance systems throughout the life-cycle of the healthcare product are critical to public health protection. Recent improvements for human medicines have been introduced through EU pharmacovigilance and falsified medicines directives legislation (Directive 2012/26/EU and 2011/62/EU). Medical device surveillance systems were significantly reinforced by the EU 'joint action plans' and further improvements are likely from EU legislation now being developed. The next iteration of veterinary medicines European legislation may replace the current periodic reporting requirements with central recording of reports of suspected adverse reactions and associated signal detection tools. A key focus of this change will be the need to ensure that adverse reactions are being properly collated and reported.

Actions

1.1a Contribute to strengthening of pharmacovigilance of medicines and vaccines across the EU network and explore new methods for monitoring products and rapidly evaluating safety issues, through involvement in:
- Pharmacovigilance Risk Assessment Committee
- Strengthening Collaborations for Operating Pharmacovigilance in Europe
- European Risk Management Strategy Facilitation Group

- Innovative Medicines Initiative accelerated development of vaccine benefit-risk collaboration in Europe.

1.1b Ensure early involvement through European procedures in risk management planning with particular focus on innovative products and areas of unmet medical need.

1.1c Develop the role of lifecycle market surveillance in ensuring the safety and performance of medical devices available to patients. Use the lifecycle approach across all areas of the supply chain, to improve safety and performance by using data from the post-market phase to inform and update pre-market technical file.

Outcomes
- National and EU surveillance systems provide improved monitoring of the safety of health products.
- Lifecycle management uses standard methodologies and practices linking pre and post-market patient and user experience.

Performance indicators
- Number of European initiatives to which the HPRA provides a leading role
- Number of new or improved surveillance and monitoring methods or tools used.

Strategic objective 1.2

To ensure appropriate national regulation of health products and contribute to national health policy

A key deliverable of the Department of Health's Statement of Strategy 2015 – 2017 is to protect the health and safety of the public through an appropriate legal framework, policies and structures for health products. The importance of this is underlined by recent product development and marketing which has demonstrated the increasing diversity of new products, some of which do not fit easily within the current regulatory framework. A regulatory system which keeps pace with product development will ensure adequate safeguards for patients and consumers. In relation to the veterinary medicines sector, it will be necessary to ensure that products not covered by EU legislation are regulated nationally in an appropriate manner.

Actions

1.2a Examine the broader framework for regulating health products. Determine whether any potential new areas of competence, applying a 'best-fit' principle and options-based assessment, are appropriate for the HPRA to assume.

1.2b Keep a close watching brief on developments in health products, especially in areas where no clear regulatory framework applies, e.g. direct-to-consumer tests, connected health;[3] medical devices for animal use. Explore the potential impacts and

[3]Connected health is a model for healthcare delivery that uses technology to provide healthcare remotely.

possible regulatory model for new areas with the Department of Health and/or Department of Agriculture as appropriate.

1.2c Promote a 'better regulation' approach to effective legislation in areas such as: wider access to emergency medication; mechanisms to facilitate reclassification of medicines such as the introduction of a pharmacist only supply status; utilisation of the Regulatory Science Ireland (RSI) initiative to identify potential areas where improvements and awareness can be considered; and codification of medicines legislation in association with Department of Health.

1.2d Further collaborate with other state agencies, in developing areas of shared interests:
- Health strategies, including Department of Health's Statement of Strategy,[4] Healthy Ireland[5] and eHealth[6] Strategy.
- National systems for dissemination of safety communications
- Product database to support the development of national formulary under the eHealth Strategy
- Changes in healthcare professionals' roles and responsibilities
- Clinical trial regulation
- Antimicrobial resistance
- Borderline product[7] regulation
- Relative effectiveness studies
- Development of legislation on medical devices and veterinary medicinal products
- Autologous veterinary vaccines
- Registration of online pharmacies
- Organ procurement and transplantation

Outcomes
- Products not fitting into the current regulatory frameworks are identified and recommendations are made for their appropriate regulation.
- Health agencies' collaboration enhances the effectiveness of the services and health products provided to Irish patients.

Performance indicators
- Number and range of collaborative initiatives with other state agencies.
- Identification of product classes which require further EU or national legislation.

[4]The Department of Health Statement of Strategy outlines high-level aims and objectives of the overall health system, and the Department's role in leading health service improvements and reforms.

[5]Healthy Ireland is a Department of Health framework to improve public health in Ireland, with an emphasis on prevention and co-operation between the health sector and other public services.

[6]eHealth (electronic health) integrates all information sources involved in the delivery of healthcare via IT-based systems, including patients and their records, caregivers and their systems, monitoring devices and sensors, management and administrative functions.

[7]A borderline product is a product which may be medicine or may be a food, cosmetic or medical device depending on either the ingredients or the claims made for the product or both.

Strategic objectives 1.3

To enhance the HPRA's commitment to the European regulatory system

The regulatory system in Europe is composed of the individual national competent authorities, the European Medicines Agency, the European Commission and other European institutions. Collaboration, work-sharing and surveillance activities are co-ordinated across the Member States in different fora. This ensures an efficient system, avoiding duplication and unnecessary work, while bringing together the knowledge and experience of many hundreds of experts for assessment, inspection and surveillance work. Patients and consumers across the 500M population of the EU benefit greatly from this unique model of regulation, one the HPRA is deeply committed to supporting.

Actions

1.3a Contribute to the implementation of the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) work programmes, arising from the Joint HMA-EMA High-level Strategy,[8] for the period 2016 – 2020.

1.3b Build on our current strategies for lead Member State roles in pre and post-authorisation licensing and surveillance procedures to enhance existing rankings as lead in both centralised and decentralised procedures.

1.3c Focus specific input and support to:

- STAMP: 'Safe and timely access to medicinal products' initiative
- Adaptive pathways pilot project for medicines
- EU Horizon 2020[9] projects
- Joint assessment programme for medical devices and European market surveillance and vigilance projects
- EU Telematics programme[10]
- Common European submission portal developed and maintained by the HPRA
- EU Network Training Centre

Outcomes

- Lead role in European licensing, inspection and surveillance procedures maintained and improved.
- Support to European initiatives advances the appropriate regulation of health products for Irish and European patients and animals.

[8]The Joint HMA-EMA High-level Strategy is a strategy for strengthening collaboration within the European network, to address the challenges and make the most of the opportunities to benefit human and animal health.

[9]EU Horizon 2020 is an EU research and innovation programme, aiming to remove barriers to innovation and make it easier for the public and private sectors to work together to deliver innovation.

[10]EU Telematics is a joint endeavour between the European Commission, the European Medicines Agency and national medicines regulatory authorities to put in place and maintain common information-technology services to implement European pharmaceutical policy and legislation.

Performance indicators
- Ranking in European procedures
- Number and range of European initiatives to which the HPRA provides a leading role.

Strategic objectives 1.4
To contribute to strengthening the international regulatory network

National regulatory systems are increasingly vulnerable to the effects of the globalisation of manufacturing and to supply chains which are becoming more complex across many countries and companies. No single regulator can protect the supply of product to its own market without relying on many international partners. The need for global oversight is being addressed by regulatory agencies collaborating across different regions to identify and implement opportunities where international co-operation and communication will benefit patients and consumers. Building trust among fellow regulators facilitates the promotion of mutual reliance on each other's work and allows better use of scarce resources in the network. It also provides a means of building regulatory capacity in less developed areas of the world which supports the regulation of medicines and medical devices both for and from those markets.

Actions

1.4a Contribute at management level to international fora for medicines (International Coalition of Medicines Regulatory Authorities) and medical device (International Medical Device Regulators Forum) to address global challenges, promote convergence of regulatory standards, and sharing of information across international regulatory areas. Participate in specific working groups to support sharing of information and sharing of inspection resources.

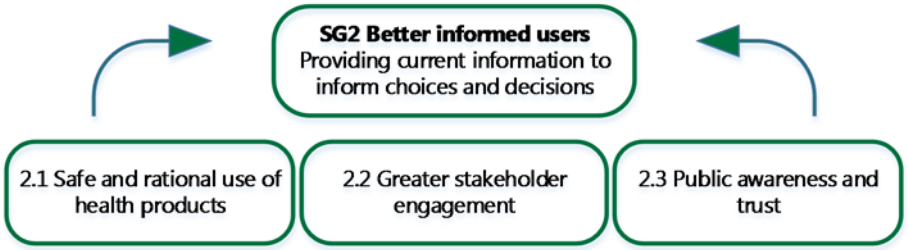
1.4b Contribute to specific capacity building projects and initiatives aimed at improving regulatory standards within the European network and in developing countries, including those that are large suppliers of ingredients and health products to the EU.

Outcomes
- More robust international network with better co-ordinated regulatory activities and reduced duplication of effort.

Performance indicators
- Level of participation in International Coalition of Medicines Regulatory Agencies and International Medical Device Regulatory Forum meetings in which the HPRA takes a leading role.
- Hosting International Conference of Drug Regulatory Authorities in Ireland in 2018
- Number and range of international initiatives and projects.
- Successful delivery of capacity-building projects in developing countries

STRATEGIC GOAL 2 — BETTER INFORMED USERS

Health products are often very complex, used in specialised settings, with detailed instructions and precautions to be taken in use. The role of the regulator is to help ensure that patients and users, and their healthcare providers have adequate information on the products they use to inform their decisions on treatment, and sufficient knowledge of the regulatory system to understand the benefit:risk concept and the lifecycle approach. Keeping users up-to-date with product changes is a key output of regulatory processes, however ensuring translation of new information into expected changes in use of the product in practice is a challenge. Working in partnership with stakeholder groups who use health products and exploring ways to improve the value and impact of the information we provide and the way it is communicated, will assist in this. As always, we will ensure that public trust and confidence in the system is maintained throughout all we do.



Strategic objective 2.1
To promote rational and safe use of health products

For an effective regulatory system for health products, healthcare professionals and the public must have access to clear, readily available, high-quality information on which to base their decisions. As knowledge about a product changes during its use, updated information on benefit/risk needs to be integrated into the user's decision-making. However communicating information on its own is not sufficient; an increasingly important part of ongoing product lifecycle regulation is ensuring that communications are understood and lead to changes in behaviours.

Actions

2.1a Ensure prompt communication to target audiences on new and emerging issues through different channels including social media where appropriate, recognising the importance of tailoring content to specific audiences, and in particular, developing more consumer friendly content.

2.1b Optimise methods for dissemination of benefit/risk information to patients and healthcare providers, animal owners and veterinary surgeons, to best influence clinical/veterinary practice. Encourage and participate in research on the effectiveness and impact of risk communication.

2.1c Provide information on issues relating to unregulated products, to inform debate. Ensure that consumers can clearly differentiate between legal and illegal internet sellers of medicines and that the risks associated with falsified medicines and illegal supply routes are understood.

Outcomes
- Clear understanding among healthcare professionals and patients about safe and effective use of health products and appropriate responses by them to identified safety risks.
- Availability of additional options and means to support and facilitate risk communications.

Performance indicators
- Development of contact lists for targeted communications.
- Publication of risk minimisation information and tools directly through HPRA website on national approval.
- Use of best practice risk communication practices and toolkit.
- Survey of consumer attitudes and practices concerning internet health product purchasing.

Strategic objective 2.2
To promote greater stakeholder engagement in the role of the HPRA

As the role of the HPRA has evolved significantly over time, the range of stakeholders with whom we interact, as regulated entities or as beneficiaries, is now quite extensive. Reaching all interested parties and integrating their views and concerns into the regulatory process helps ensure the greatest positive impact of health product regulation. Where regulated entities understand the legislation, they are more likely to be in a position to meet the requirements. When patients' and consumers' views are incorporated into the regulatory process, they contribute to broader-based and informed decisions. The role of the healthcare professional is also improved when they better understand the process of product lifecycle regulation.

Actions

2.2a Expand our educational programmes at undergraduate and postgraduate levels, using efficient and engaging methods linked to the relevant curricula.

2.2b Increase our engagement with interested parties across all of the stakeholder groups, and develop a regular integrated feedback system. Further a programme of patient engagement to explore better ways of communicating with patients and incorporating their perspectives into the regulation of health products.

2.2c Engage proactively with stakeholders in Ireland to elicit early feedback and input on new legislation, and following adoption, to ensure a smooth and timely implementation.

Outcomes
- Educational activities are linked to relevant curricula and make effective use of HPRA resources.

- Patients and healthcare professionals understand the role and functions of the HPRA and their contribution to the regulatory system.
- Clearer understanding among the regulated sectors of new legislative requirements.

Performance indicators
- Broadened programme of educational activities and modalities; number and range of lectures given.
- Programme of patient engagement activities.
- Number of public consultations.
- Number of stakeholder information days concerning new legislation.

Strategic objective 2.3
To ensure public awareness and knowledge of the HPRA

Maintaining the trust of stakeholders is based on awareness and understanding of the role of the HPRA, on the quality of the regulatory decisions we make and the transparency and accountability we demonstrate. While the Irish Medicines Board was a well-understood regulatory 'brand' developed over many years, re-building awareness is now necessary with the name change to the Health Products Regulatory Authority. This provides an opportunity to communicate the nature of the independent, science-based, regulatory work we do, and so support our communications on the quality and safety of health products.

Actions

2.3a Implement a sustained public information campaign to build awareness of the HPRA brand and the role of the organisation.

2.3b Continue to build a planned and proactive media engagement programme with agreed key messages for each product area, focussing on a mix of media and target groups and including contributions from media-trained subject matter experts.

2.3c Define and implement an effective online and digital communications strategy that is focused on the needs and expectations of key stakeholder groups.

2.3d Monitor brand awareness trends and levels of trust among the general public and carry out further bespoke research among key stakeholder groups.

Outcomes
- Increased awareness among patients and the general public of the HPRA and enhanced understanding of its public health role.
- Enhanced understanding across the HPRA of the general public's attitudes and behaviours in respect of health products.
- Easy online access to high quality stakeholder targeted content.

Performance indicators
- Increased percentage awareness of the HPRA brand for each phase/year of the campaign.
- Minimum 3 proactive media engagements per quarter.
- Levels of user satisfaction with hpra.ie.

STRATEGIC GOAL 3 — ACCESS TO HEALTH PRODUCTS

The expected outcome of the regulatory system for development and supply of medicines is that patients have access to authorised medicines, at the right time, and at reasonable cost to themselves or the State. However in practice, access depends on many factors including the particular health economic pressures that apply in Ireland due to our small population size; product shortages which occur from time to time; currency exchange rates; and the reimbursement status of high-cost medicines. Public health risks increase when critical medicines are not available or when falsified or toxic products are used.
On the other hand, early access to promising medicines can improve the health of patients with debilitating diseases. The greater use of generics and biosimilar[11] medicines within the Irish health system lowers the costs of medicines, providing the opportunity to allow access to newer medicines. A wider choice for patients and consumers can result from the reclassification of medicines from prescription to non-prescription status where it is safe and appropriate to do so.

Strategic objective 3.1

To work with national agencies and international regulators to address the challenges of medicines shortages

Medicines shortages in Ireland, Europe, and indeed, internationally, are an increasing problem across many categories of medicines, including critical medicines where alternatives may not exist. The impact on patients is unclear though shortages must, necessarily, increase the risk of inadequate treatment compared to the standard, and vaccine shortages are a public health concern. Regulators and the industry are engaged with this topic, guidance on preventing and responding to shortages has been developed but much work remains to be done in order to ensure, as far as possible, uninterrupted supplies of medicines to patients. Nationally the HPRA is in regular contact with the HSE and industry companies to manage the impact of specific drug shortages and mitigate the risks to patients.

[11] A biosimilar medicine is a biological medicine that is highly similar to another biological medicine (reference medicinal product) which already has a marketing authorisation and has been approved for use in patients.

Actions

3.1a Take the lead in the coordination of efforts by national agencies to manage medicines shortages, including the development of new initiatives and refinement of existing measures.

3.1b Prioritise measures within the remit of the HPRA to manage medicines shortages.

Outcomes

- Potential shortages identified in advance insofar as possible.
- Shortages of health products are managed quickly and effectively.
- Impact of shortages on healthcare professional and patients is reduced.

Performance indicators

- Percentage of cases in which alternative product is sourced from other markets.
- Established protocols with other relevant state bodies.
- Good practice tools and procedures implemented to handle shortages and mitigate risks.
- Extent of information supplied to affected stakeholders via relevant online channels.

Strategic objective 3.2

To optimise the use of the current regulatory system to maintain authorised products on the market in Ireland

As a small market, Ireland has a limited number of authorised medicines of which 25% may not be marketed at any given time. Consequently it is vulnerable to shortages in cases where medicines were never authorised, when authorised medicines are withdrawn for commercial reasons or when there are supply issues. Loss of authorised critical medicines may be compensated by the import of medicines which are either unauthorised or authorised in another country but not in Ireland. Use of the 'exempt medicinal products' scheme, whereby the importation of these medicines is notified to the HPRA, is high. It is essential to manage and support the standard authorisation system to ensure that there are sufficient numbers of authorised products on the market to safeguard access to medicines.

Actions

3.2a Manage use of the exempt product scheme by considering a threshold above which a marketing authorisation must be applied for and, with relevant national stakeholders, encourage new applications for products supplied through the scheme or considered vulnerable to shortages.

3.2b Explore with the Department of Health the possibility of greater clarity in national legislation on the obligations of both marketing authorisation holders and wholesalers to maintain continuity of supply of authorised medicinal products.

3.2c Seek to influence European discussions to ensure legal frameworks promote medicines' availability and do not restrict supply.

Outcomes

- Patients have access to authorised products as much as possible.
- There is greater continuity and dependability in the medicines supply chain.

Performance indicators
- Reduction in exempt medicinal product notifications.
- Proposal to Department of Health on public service obligations of wholesalers.

Strategic objective 3.3
To protect supply chain integrity

Around the world, increasingly well-organised counterfeiters, backed by sophisticated technologies and criminal operations, are profiting from introducing falsified or counterfeit products into the supply chain. Controls within the supply chain from manufacturing to distribution can reduce the risk as can item-level serialisation (implementation for medicines in 2018 and for medical devices when the revised regulatory framework is implemented) and track and trace systems. However risks still remain and enforcement action is needed to protect patients and consumers from substandard, unsafe or ineffective products. Illegal online supply in Ireland may now arise from unregistered suppliers posing as pharmacies that are registered by the Pharmaceutical Society of Ireland for online supply of non-prescription medicines.

Actions

3.3a Build intelligence capability and move increasingly towards risk-based and intelligence-led enforcement that has public health at its centre.

3.3b Continue to develop further relationships with agencies nationally, at EU level and globally to protect the legal supply chain and to disrupt the illegal one. Explore and develop with other agencies and international bodies, mechanisms for a risk based approach to target the supply lines of falsified/unauthorised health products.

3.3c Oversee the effective implementation of repository and verification systems for safety features for human medicines and unique identifiers for medical devices to ensure these operate as intended.

Outcomes
- Public health threats are identified at an earlier stage, and appropriate enforcement actions are taken.
- Patients are not exposed to the risks of falsified health products in the legal supply chain.

Performance indicators
- Intelligence system built and operational in 2016.
- Threat analysis developed in 2016 for the remainder of the plan period.
- Absence of falsified health products in the legal supply chain.

STRATEGIC GOAL 4 — SUPPORTING INNOVATION

New trends and technologies are emerging which are predicted to significantly change how products are designed, made and supplied across a range of sectors in the manufacturing economy. Digitisation will enable advances in production equipment and processes, smart

products (the 'internet of things'), and data tools and analytics. In life sciences manufacturing, current improvement programmes include operational excellence, quality by design, data management and comparative benchmarking.

Strategic objective 4.1

To support research and development in the Irish life-sciences sector

The Irish life sciences sector is a major contributor to the economy, employing over 50,000 directly in manufacturing, research and development, and services. Nine of the top ten pharmaceutical companies and 18 of the top 25 medical devices companies are located in Ireland. For future growth, a greater focus on effective research and development is critical. The Irish State has recognised this in the National Research Prioritisation Exercise[12] and more recently in the development of the new Strategy for Science, Technology and Innovation, both of which include the health sector, and health products, as a key action area. Strong links between academia, industry and regulators will help leverage these developments for the benefit of the sector and the patients who take or use health products.

Actions

4.1a Build on existing links to enhance support to State agencies working in the life sciences sector.

4.1b Develop clear policies and process for providing regulatory and scientific advice to companies at different stages of product, process and facilities development. Consider creating a 'virtual innovation office.'

4.1c Promote effective utilisation of Regulatory Science Ireland to foster research and innovation as well as the development of better approaches to regulation.

Outcomes

- Stakeholders, including SMEs and start-up companies, have access to regulatory information and advice to support product development and lifecycle management.

Performance indicators

- Formal procedures in place for regulatory and scientific advice procedures.
- Increase in the number of clinical trial/investigation applications.

[12]The National Research Prioritisation Exercise is the Department of Jobs, Enterprise and Innovation's template for public investment in research and development for the period 2013-2017.

- Number of early development advices given.
- Number of RSI projects contributed to.

Strategic objective 4.2

To look for opportunities to leverage new technologies for the benefit of health product users

New technologies are constantly in development to help people stay healthy, better diagnose disease, treat illness, and provide a better quality of life. Personalised medicines,[13] nanotechnology and cell- and gene-based products are some of the known and expected developments while others include intelligent medicines delivering targeted doses of active substances, sensors to improve medication adherence, and 3D printing of health products. At the level of information technologies, implementation of the government's e-health strategy proposes to integrate all information sources involved in providing healthcare in Ireland, including information on health products used in the system, for the benefit of Irish patients.

Actions

4.2a Promote the use of new technologies for labelling of products, to enhance traceability and recording of information in order to benefit users and consumers.

4.2b Identify emerging technologies through links with IDA, Enterprise Ireland, industry and academia, examine their potential impacts and make proposals for regulatory system adaptations where necessary.

4.2c While appreciating that animal studies are needed to ensure the safety and quality of certain medicines in order to protect public health, work with stakeholders to encourage the development and use of non-animal tests and studies to replace those involving animals.

Outcomes

- Implementation of the government's eHealth Strategy takes account of product identification and traceability technologies.
- Stakeholders are informed of the availability of replacement non-animal tests and encouraged to use them.

Performance indicators

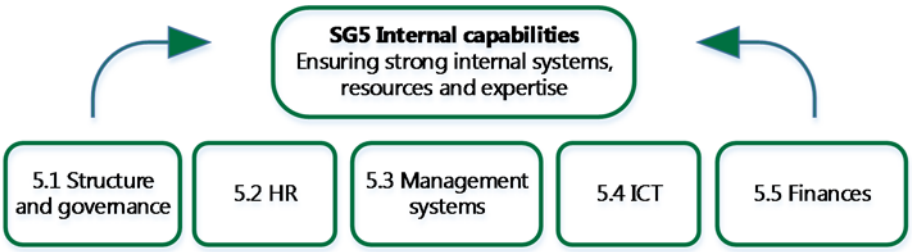
- QR codes[14]guidance in place in 2016
- Number of new technologies identified and regulatory adaptations proposed.
- Communications with stakeholders concerning replacement non-animal tests.

[13] A personalised medicine is a medicine that is targeted to individual patients, based on their genetic characteristics.

[14] Quick response (QR) codes are a type of machine-readable barcodes, used to provide a link to information as approved by the competent authority.

STRATEGIC GOAL 5 — INTERNAL CAPABILITIES

To achieve the strategic goals set out above, and to deliver on our core work, we will continue to manage the business efficiently and effectively, and develop our organisational capabilities to meet the challenges of the ever-changing regulatory environment.
Over the next five years we will ensure that we have the scientific and regulatory expertise needed to enhance our contribution to European procedures and to monitor the quality and safety of products on the Irish market. . We will continue to manage our finances prudently, ensuring sufficient resources are available to run the organisation in a cost-effective manner. Current development of Eolas, our proposed new IT case management system, will ensure an integrated platform for different regulatory activities and a single dataset to allow improved searching and reporting functionalities. We will continue to pay particular attention to operational efficiency, harmonising and simplifying processes where possible, and further develop our ability to manage projects through our Project Management Office.



Strategic objective 5.1

To ensure the optimal organisational structure and governance is in place.

The HPRA must ensure that it continues to meet the highest standards of governance and complies with government policy where it affects the work of the HPRA. Revision of the 'Code of Practice for the Governance of State Bodies' is expected in 2015 with HPRA review and compliance with the new requirements scheduled thereafter. In addition, we must ensure that we continue to have committees and structures which reflect the increasing diversity of products that we regulate and the extensive change in regulatory activities and oversight which is likely to result from the revision of EU medical device legislation in 2016 and the revision of EU veterinary medicines legislation.

Actions

5.1a Ensure that the revised Code of Practice for the Governance of State Bodies[15] is implemented.

5.1b Keep under review the roles, responsibilities and composition of key committees and internal departments, to ensure they adapt to the developing role of the organisation and the changing regulatory environment.

[15] TheCode of Practice for Governance of State Bodies is a framework for the application of best practice in corporate governance by both commercial and non-commercial State bodies.

Outcomes
- Governance arrangements meet good practice requirements.
- Organisational and committee structures facilitate the discharge of responsibilities and attainment of organisational objectives.

Performance indicator
- Compliance with Code of Practice for the Governance of State Bodies.
- Competence and skills mix in Authority and committee members.

Strategic objective 5.2
To develop and roll out a comprehensive HR strategy.

The HPRA must continue to operate effectively across all functions and contribute to European systems in an ever changing regulatory environment. In addition we must meet needs related to innovative processes and products for the future and having the necessary scientific, regulatory and management expertise is critical in this endeavour. Targeted training supported by an effective infrastructure will be an important enabler of talent development. Ensuring employee engagement, commitment and motivation supported by a culture of performance and accountability will also be a particular focus. With the improvement in the Irish economy, retaining skilled staff is of concern and will be a specific objective of this strategy.

Actions

5.2a Strengthen the approach to talent management and succession planning; measure and drive engagement levels to support commitment and motivation; and refine the Performance Development Programme to support the culture of performance and accountability.

5.2b Develop a learning and development plan to provide for a technology-based learning management system, an internal training centre to maximise transfer of learning, and build on current management and leadership development to support the HR strategy.

Outcomes
- Strengthened approach to talent management and succession planning capable of meeting current, emerging and future challenges and opportunities.
- An enhanced culture of performance and accountability.
- Optimised learning and development capabilities.

Performance indicator
- HR strategy finalised in 2016, specific programmes developed and rolled-out to all areas.
- Internal training centre operational during the lifetime of this plan.

Strategic objective 5.3
To enhance knowledge and quality risk management systems.

Our regulatory actions are grounded in legislative requirements and application of the scientific and regulatory expertise of our highly-trained staff. A key component of this expertise is the knowledge of our staff as well as the information held in databases and documents.

The development of Eolas, a new workflow system, provides the opportunity to improve explicit knowledge sources while development of a new HR strategy allows us to design best practice learning and development systems and methods of collaboration and networking to maximise the sharing of knowledge across the organisation. The quality management system will support these developments and ensure that we keep up-to-date with international standards.

Actions

5.3a Develop knowledge management services and processes which integrate key information sources, expert skills and technology solutions.

5.3b Enhance the quality risk management system in tandem with the development of Eolas, the European benchmarking self-assessment questionnaire and principles from International Conference on Harmonisation quality and risk management guidelines.

Outcomes

- New knowledge resources and processes improve quality and consistency of scientific work, and reduce access effort.
- Continuous improvement culture recognised by European benchmarking assessment.

Performance indicators

- Knowledge management strategy in place, staff survey.
- Average rating in benchmarking visit in 2017, and number of strengths and opportunities for improvement identified.

Strategic objective 5.4
To further develop ICT systems and business services.

The HPRA is currently implementing a significant new technology upgrade for case management, data warehousing, as well as document and record management. The project is well underway using an agile development approach which improves stakeholder engagement, provides early and predicable delivery, focusses on the business value and allows for change. Roll-out of the system will be on a phased basis starting in Q1 2016 and run on until the end of 2017. The Eolas project is part of the current ICT Strategy which covered the period up to 2015. Work on a new ICT Strategy will begin shortly. Key issues to be considered in the next strategy are the alignment with the key objectives of the 'Public Service ICT Strategy': build to share; digital first; data as an enabler; improving governance; and improving capability.

Actions

5.4a Finalise and implement the new 'Eolas' system to support the HPRA in its regulatory activities, with data structures and processes in line with European standards

5.4b Develop a new IT strategy, ensuring alignment with the EU Telematics Roadmap and national eHealth Strategy. Enhance project management and business analysis processes and services.

Outcomes

- Successful implementation and roll out of EOLAS. All users are fully trained and system fully implemented and used by all staff.
- Enhanced IT and business services capabilities.

Performance indicators

- Eolas system roll-out delivered as planned, and legacy systems decommissioned by 2017.
- IT strategy in place by 2016, and implemented over the course of this plan.

Strategic objective 5.5

To appropriately manage financial performance

Delivering on the strategic plan will require funding for the activities which will support its achievement. The HPRA will ensure that value for money principles and guidance are used to ensure that the best possible value is obtained with available funds. We will also manage the impacts on costs and staffing resulting from the recovery in the economy.

Actions

5.5a Implement new financial systems to improve management of the finances, monitoring against budgets and financial reporting.

5.5b Ensure procedures are in place to achieve value for money in all expenditure categories.

5.5c Explore potential for further revenue-generating work with other regulatory authorities.

Outcomes

- Current and capital expenditure continues to comply with relevant government requirements.
- Procurement activities continue to comply with legal requirements and best practice.

Performance indicators

- Compliance with the Public Spending Code.[16]
- Compliance with EU and Irish procurement law.

[16] The Public Spending code is a set of rules and set of rules and procedures to ensure that value-for-money standards are upheld across the Irish public service.

6 IMPLEMENTING THE PLAN

6.1 Assumptions and risks

This plan is based on certain assumptions and risks concerning the future:

External environment

It is assumed that the main external drivers are known. However, while some contingency is provided for, there is a risk that major changes could impact the achievement of certain goals or objectives or could change priorities including:

- New legislation not flagged at this point in time
- Additional competencies or functions assigned by government
- A very serious safety or quality issue affecting a widely-used health product or a class of products
- A pandemic
- Changes in EU membership
- Changes to responsibilities for health products within the European Commission

These type of events require a substantial response which usually cannot be deferred. Should any such major event occur, a review of the goals and objectives in this plan will be conducted.

Staff/experts

The plan is based on the assumption that we will continue to retain suitably qualified staff to deliver on all actions arising from the plan. A risk for the organisation is that the economic recovery and salaries in private industries regulated by the HPRA may lead to a loss of staff. The HPRA will continue to monitor the situation and seek creative solutions to accessing suitable qualified staff while remaining in line with government policy on staffing and remuneration. Access to expertise will also form a major theme in the HR strategy being developed.

Income and expenditure

Industry costs in Ireland rise disproportionately, leading to contraction of the sector.
Impact of EMA costing exercise on income.
Redirection of assessment activities from the HPRA towards the EMA, with associated loss of income streams.

6.2 Monitoring and reporting

Achievement against the plan is monitored through regular monitoring of annual business plans and reported to the Management Committee and Authority on an ongoing basis throughout the year, with a formal strategy status update annually to the Authority and in the Annual Report.

6.3 Review

The timeframe for this plan, as for the last plan, is kept in line with the timelines of the strategic plans of the European Medicines Agency and the Heads of Medicines Agency. It is acknowledged however, that this timeframe is long and significant changes in the environment are likely to occur which may change the priorities, as discussed above. For this reason, the strategic plan and the activities which support it, will be kept under review by the Authority during the annual business planning process and will be subject to formal review of the goals and objectives mid-way through the five years.