IRISH MEDICINES BOARD

STRATEGIC PLAN

2011 - 2015

PROTECTING PUBLIC AND ANIMAL HEALTH

The Irish Medicines Board's role is to **protect and enhance public and animal health** through the regulation of medicines, medical devices and healthcare products

Contents

FOREWORD

Mr. Pat O'Mahony
Chairman

Mr. Pat O'Mahony
Chief Executive

We are pleased to present this strategic plan for 2011 – 2015. The plan sets out 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.

Protecting public and animal health

The Irish Medicines Board (IMB) is the independent regulator of the medicines, medical devices and healthcare product sectors. 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 primary objective is to safeguard public and animal health by regulating the healthcare product sectors across the entire product lifecycle from clinical trials, through manufacturing, to marketing, distribution and use by patients and animal owners. Our regulatory actions are grounded in legislative requirements and the application of scientific and regulatory expertise. Decisions are taken in the interests of public or animal health, based on the best available information, by highly-skilled and experienced scientists and healthcare professionals. We review new information as it becomes available and update our decisions and advice in the light of the new data, to ensure the best outcomes for Irish patients, consumers and animal health.

The IMB is largely self-funded by a fees system which is approved by the Minister for Health and Children and operates to the strictest principles of independence and governance to ensure quality of service combined with value for money. The organisation supports innovation and development through its capacity to contribute at the highest level, both nationally and internationally, to product regulation so that optimal outcomes are achieved for patients. We work strategically with all stakeholders including patient groups, academics, researchers, healthcare and animal health professionals and the research and manufacturing industries, to maximise the availability of products with a positive benefit/risk profile for patients.

The industries regulated by the IMB operate on an EU and a global level. The IMB works actively as a fully integrated part of the networked European regulatory model, and both formally and informally with international regulators, to ensure the maximum outcomes for patients, animal owners and for the welfare of animals.

The health life sciences sector is a significant contributor to the Irish economy and will play a vital role in driving export-led growth in the future. The IMB supports this growth by both indigenous and multinational companies through providing regulatory and technical advice in relation to new or expanded facilities and ensuring compliance with standards of good manufacturing practice. The strength and reputation of the regulatory system provided by the IMB is recognised as a significant competitive advantage for the Irish manufacturing industry.

What has been achieved

The plan builds on the previous strategic plan for 2007 – 2010 which focussed on:

- Effective risk management and improving consumer safety;
- Effective regulation through the ongoing development of our work force and non-staff resources; and
- Effective communication with all stakeholders.

During these past four years we have made significant organisational changes to support our commitment to patient and product safety:

- The pharmacovigilance (human drug safety) and vigilance and compliance (medical device safety) functions were amalgamated into a new department which is now the Human Products Monitoring department. This new department brings together a broad range of skills and expertise and has a dedicated focus on post-marketing safety issues for all human products, including innovative and combination products.
- The licensing of medicines and pre-market regulation of devices were similarly merged into the Human Products Authorisation and Registration department. This department is focussed on all pre-market authorisation activities and post-market variations and renewals assessment, with patient safety as the core remit.
- All inspection and audit activities relating to healthcare products have been brought together in the Compliance department, providing additional expertise and flexibility to meet the requirements of compliance activities.

In addition, our remit and responsibilities were broadened by the addition of the competent authority functions for the regulation of cosmetics and for the licensing of precursor chemicals.

We also implemented a major IT development programme under a strategy which ran in tandem with the strategic plan.

These various organisational changes position us to now take on the challenges of the next five years and beyond.

Looking forward

In looking forward to these next five years, we have maintained our mission and vision statements which continue to guide us in our absolute focus on our primary public and animal health remit. We envisage a deepening of the close co-operation and collaboration we have with other Member State regulators and our contribution to the scientific work of the European Medicines Agency (EMA).

It is thus appropriate that the lifetime of this plan has been chosen to coincide with that of the EMA's 'Roadmap to 2015' and with the 'Strategy for the Heads of Medicines Agencies, 2011-15'.

The future regulatory environment for all competent authorities across the EU will be shaped by new European legislation. We will continue to contribute to the development of legislation, aiming to ensure that it maintains a strong regulatory system for human and veterinary products, enhanced patient safety and outcomes, while simplifying administrative procedures and supporting innovation.

We expect significant advances in patient safety within the Irish healthcare system to arise from the implementation by the Department of Health and Children and other stakeholders of the report of the Commission on Patient Safety and Quality Assurance. The IMB is represented on the Implementation Group and on the Medication Safety Forum subgroup. The Forum has an extensive work programme of specific cross-agency projects designed to address areas for improvement in the way medicines are used in Ireland. We look forward to active engagement in this programme of work.

We will review our current communication channels, including the IMB website and newsletters, and ensure these channels meet the developing needs and expectation of our stakeholders. We will also engage more directly with patient associations, encouraging their participation in the work of the IMB and drawing on their perspectives to improve product information, risk communication and outcome measures.

Building on capabilities and efficiencies gained through use of our workflow technology, we are committed to continuous improvement of service delivery and to moving, over the course of the period covered by the strategic plan, to processing all applications within EU or nationally-set timelines. This will give applicant companies predictability over review times and ensure that products are available to Irish patients in a timely manner. In addition, further extending our structured risk-based and proportionate approach to regulation will allow us to allocate our resources to areas where the risks are highest while maintaining appropriate industry compliance.

Globalisation of manufacturing and supply has resulted in complex production and supply routes, and concerns about the quality of active pharmaceutical ingredients and excipients sourced from areas outside the EU. We will continue to participate actively in EU and international activities designed to enhance the quality assurance of pharmaceutical products and prevent the introduction of illegal products into the supply chain.

We are committed to managing our operations according to quality management principles and good practice standards for public sector bodies and healthcare product regulators. We will further embed quality and risk management within the organisation's systems and processes and play an active role in the EU's programme for the Benchmarking of European Medicines Agencies.

In developing this plan, we have consulted with stakeholders and staff on the issues and priorities we should consider. Many common areas of priority and focus were apparent in their comments and their input is greatly appreciated. The strategic goals and objectives outlined here will have the support of our staff and, with their assistance, we look forward to delivering on this plan.

Pat O'Mahony
Chairman

Pat A. O'Mahony
Chief Executive

1. PROFILE OF THE IMB

Our **vision** for the IMB is that we are 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.

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

Our **values**:

- Acting always in the best interests of patients and consumers.
- Operating to the highest standards of scientific quality and decision-making.
- Behaving with integrity, impartiality and transparency in our dealings with all stakeholders.
- Treating stakeholders and each other with dignity and respect at all times.

Structure

The IMB is governed by a Board of nine members appointed by the Minister for Health and Children. The Board is advised by three statutory scientific advisory committees for human medicines, veterinary medicines and for medical devices. The Advisory Committee for Human Medicines has subcommittees for clinical trials and herbal medicines. Ad hoc working groups may be established for specific issues.

Day-to-day management of the IMB is devolved to the Chief Executive, who is assisted by the Management Committee, which comprises, in addition to the Chief Executive, the directors of departments and the Senior Scientific Advisor.

Role

The IMB was established in 1995 as a state agency, reporting to the Minister for Health and Children, with responsibility for the regulation of medicines for human or veterinary use. Since its establishment, additional functions have been conferred on the IMB, which is now also responsible for regulating medical devices, blood and blood products, tissues and cells, controlled drugs and, since 1 October 2010, cosmetics. Regulation of healthcare products is carried out in four main service areas.

Approval of:

- medicinal products for human and veterinary use
- clinical trials with medicinal products for human use
- manufacturers of medicinal products for human and veterinary use
- manufacturers of investigational medicinal products for human use
- wholesalers of medicinal products for human use
- export certification of active substances and medicinal products for human and veterinary use
- contract quality testing laboratories
- controlled drugs (narcotics) and precursor chemicals

- blood, tissue and cell establishments
- (certain) medical devices for human use
- Notified Bodies for medical devices
- cosmetics

Inspection/audit of:

- manufacturers of medicinal products for human and veterinary use and of medical devices
- wholesalers of medicinal products for human use
- manufacturers of active substances
- blood, and tissue and cells establishments, and when required, blood banks
- sponsors, clinical research organisations and investigators carrying out clinical trials on medicinal products for human use
- marketing authorisation holders or firms employed by authorisation holders for pharmacovigilance
- contract quality testing laboratories
- controlled drugs licence holders
- medical device manufacturers, including manufacturers of custom-made devices
- Notified Bodies for medical devices
- cosmetic manufacturers (from 2013)

Investigation, follow up and actions taken in relation to:

- adverse reactions to medicinal products for human or veterinary use
- adverse incidents relating to medical devices
- undesirable effects relating to cosmetics
- quality defects and recalls of medicinal products from the market
- recalls of medical devices from the market
- recalls of cosmetics from the market
- sampling and analysis of medicinal products, active pharmaceutical ingredients, and medical devices
- co-ordination of the sampling and analysis of cosmetics
- compliance with legislation falling within the remit of the IMB
- breaches of legislation in relation to medicines, blood products, tissues and cells, medical devices, clinical trials and cosmetics

Provision of advice to:

- the Minister for Health and Children, Minister for Agriculture, Fisheries and Food, Minister for the Marine and others concerned, in relation to any matter connected with the functions of the IMB;
- the Minister for Agriculture, Fisheries and Food in relation to any matter connected with the functions of the IMB relating to medicines for veterinary use.

2. THE OPERATING ENVIRONMENT

2.1 Legislation

Legislative developments, particularly at EU level, have significant consequences for our activities and operations. Over the period of this strategic plan, new legislation is likely to be adopted at an EU level in a number of areas, as discussed below. It is anticipated that some of the proposed changes to EU legislation will be under discussion during the first half of 2013 when Ireland will hold the EU Presidency, providing us with an opportunity to influence the development and advancement of the legislation.

Pharmacovigilance

Significant changes are proposed in relation to the system for pharmacovigilance (drug safety monitoring) for human medicines in the EU. A new Regulation, adopted by the European Parliament in September, clarifies the tasks and responsibilities of Member States, the EMA and marketing authorisation holders and establishes a Pharmacovigilance Risk Assessment Advisory Committee at the EMA. This committee will take a key role in pharmacovigilance assessments and provide support to the scientific and regulatory committees, CHMP and CMD(h). The pharmacovigilance mandate of CMD(h) will be enhanced and the Community procedure for the assessment of serious safety issues for nationally-authorised products will be streamlined. The provisions of the Regulation are expected to apply from mid-2012.

Counterfeit medicines

Counterfeit or 'falsified' medicines pose a significant threat to public health worldwide, being unsafe, ineffective or of poor quality. Measures to ensure the traceability of medicines, to improve controls at EU borders and ensure that active ingredients are of the highest standards are included in draft EU legislation which has completed its first reading with the European Parliamentary Committee. In addition, the Council of Europe is elaborating a convention on tackling counterfeiting of healthcare products, including medical devices, and the topic is also under discussion at WHO.

Patient information

A proposed EU directive on better dissemination of information on medicines to patients is under development. In the directive, the EU Commission has proposed that, while maintaining the ban on advertising prescription-only medicines to the general public, pharmaceutical companies may disseminate non-promotional information about these medicines to the public. The information content allowed would be standardised, and would be subject to quality standards, approved channels for dissemination and monitoring by national Competent Authorities.

Clinical trials

The EU Commission has begun a public consultation process on the operation of the Clinical Trials Directive (2001/20/EC). The directive has brought about important improvements in safety and ethical soundness of clinical trials on human beings, however there has been criticism that it may have led to a significant decline of the attractiveness of research in the EU, with a negative impact on the development of new and innovative treatments and medicines. The Commission has proposed options to address the key issues, including the possibility of EU clinical trial approval.

Veterinary medicines

While the EU legislation regulating human and veterinary medicines has remained closely similar over the years, practical problems are being encountered in implementing the Directive (2004/28/EC) and Regulation (726/2004/EC) for veterinary medicines. Key questions include the particular characteristics of the veterinary sector; the need for specific incentives (e.g. for medicines for minor use or minor species); the treatment of animals in the absence of authorised medicines; and the potential for simplifying, harmonising or streamlining authorisation procedures. The EU Commission has undertaken an impact assessment in 2010 and will then decide on whether new proposals are needed. It is anticipated that new legislative proposals will emerge in 2012.

Herbal and homeopathic medicines

The 'national rules' schemes which have been developed for the registration of herbal and homeopathic products provide a route to market for those products that do not qualify for either a full marketing authorisation or the simplified scheme for homeopathic medicines. We expect to increase the number of applications for registration over the lifetime of this strategic plan and to ensure that products on the market comply with the relevant legislative requirements.

Medical devices

The Medical Devices Directives were subject to significant revision which came into force in 2010 in addition to changes to the overarching New Approach framework. A more significant recast of the medical devices regulatory framework is currently being considered by the EU Commission. It is expected that an impact assessment of various recast proposals will be concluded before the end of 2010 with subsequent draft legislative proposals by the end of 2011 or early 2012. In addition, the national competent authorities are seeking to improve mechanisms on harmonised decision-making and co-ordination of activities. It is expected that the recast proposed by the EU Commission will further these goals.

2.2 Patient safety, public and animal health

Ensuring the safety, quality and effectiveness of medicines and medical devices is a core function of the IMB. Factors affecting the use of medicines and medical devices within the health system over the coming years are discussed below.

Medication safety

The Department of Health and Children has established an Implementation Steering Group to oversee the implementation of the recommendations in the 2008 report of the Commission on Patient Safety and Quality Assurance, *Building a Culture of Patient Safety*. The IMB is a member of both the Implementation Steering Group and of the Medication Safety Forum subgroup. The report's recommendations on medication safety have been integrated into the work programme of the Medication Safety Forum which includes stakeholder groups with an interest in the medication use process or in medication safety.

Counterfeit products

The IMB has ongoing co-operation with Revenue Customs Service in relation to illegal imports and with the Pharmaceutical Society of Ireland and the Health Service Executive in relation the supply of medicines and medical devices in pharmacies; general sale medicines and medical devices available in non-pharmacy retail outlets are also monitored. At international level, we work closely with the European Heads of Medicines Agencies Working Group of Enforcement Officers and the Permanent Forum on International Pharmaceutical Crime to prevent the infiltration of counterfeits to the legal supply chain. To date no counterfeit medicines have been found in the legal supply chain in Ireland; ongoing vigilance, enforcement and collaboration will be necessary to ensure the Irish public is protected from potentially harmful or ineffective products.

Availability of medicines

The unavailability of medicines leads to a widespread use of unauthorised medicines, with implications for patient safety, product liability, and costs. The IMB has a notification scheme for certain 'exempt' unauthorised products which provides an overview of the supply of unauthorised human products in Ireland and facilitates their recall in the event of safety or quality concerns. Further work by the IMB within the Medication Safety Forum will examine mechanisms to mitigate the risks associated with the use of unlicensed medicines and with medicine shortages.

The relatively small size of the market for veterinary medicinal products in Ireland poses a particular challenge to the animal health industry. Discussions on a suitable regulatory environment to maintain and bring to the market niche medicines for minor indications and for minor species are expected to take some time to achieve a resolution. The IMB is committed to help find solutions to this long-standing problem and is continuing to work with stakeholders to this end.

Antimicrobial resistance

There are increasing concerns about the emergence of antimicrobial resistance in humans and animals. A specific initiative to collect data on the usage of human and veterinary antimicrobials within the EU is underway. It is expected that new risk management measures might result when the data become available. A Scientific Advisory Group on Antimicrobial Resistance at the EMA will address the regulatory challenges ahead in the animal sector and the adequacy of systems in place to ensure the environmental safety of human and veterinary medicines.

Pandemic influenza

Pandemic influenza is an ongoing global health threat for which the EU regulatory system and individual Member States had been drafting preparedness plans for a number of years. These plans were brought into recent operation during the influenza pandemic (H1N1) of 2009 – 2010 and proved effective in accelerating the assessment and authorisation of vaccines by the EMA and management by the IMB of the post-marketing surveillance activities arising from the mass vaccination programme in Ireland. The lessons learnt in Ireland and other Member States will be used to refine the EU's plans for future pandemics.

Health technology assessment

Health technology Assessments (HTA) involve an evaluation of social and ethical issues, quality of life and end-of-life, and cost effectiveness of medicines, medical devices, treatments and procedures. These assessments are relatively new to Ireland where the Health Information and Quality Authority is taking the lead. The clinical data set required to support an economic analysis for HTA is different from that used to support a marketing authorisation application. Collaboration between HTA bodies and medicines and medical devices regulators in the requirements for clinical trials and clinical investigations will ensure that companies can approach the design of their studies in a way which avoids the need for multiple or duplicated studies.

Drugs budget

With the current economic downturn, government has proposed measures to reduce the cost of medicines, including a system of reference pricing and generic substitution by pharmacists. These changes are likely to alter the Irish market for both generic and innovative medicines and impact on our authorisation-related workload.

Cosmetics

The competent authority role for cosmetics was transferred from the Department of Health and Children to the IMB on 1 October, 2010. This new role includes overseeing cosmetic product notifications; generating certificates of free sale; and operating a market surveillance programme. Using the IMB's significant expertise, we will take a proactive and facilitatory approach to regulating cosmetics to ensure consumer safety and high standards in this sector.

2.3 Therapeutic and technology development

New technologies, therapies and medicines are emerging, including regenerative medicine, more personalised treatments, and nanomedicines. A strong regulatory framework has been put in place with the establishment at the EMA of the Committee on Advanced Therapies, however these new therapies constitute a particular challenge to develop suitable regulatory approaches. We will continue to develop our links with experts in academic institutions and to develop the skills base of our staff. Innovations in research, development and manufacturing technologies will also demand extended knowledge and expertise among regulatory staff involved in inspection and assessment activities.

One of the most prominent emerging technologies is in the area of drug-device combination products. There is very significant research and development activity and innovation in this area in Ireland. The IMB is well placed to service this developing area due to our expertise in the regulation of both human medicines and medical devices.

2.4 Communication and information

Access to information

For an effective regulatory system for healthcare products, healthcare professionals and the general public must have access to clear, accessible, and readily available information. The IMB uses a variety of means to provide information to stakeholders and at a European level, is contributing to the unique resources of data on medicines and drug safety in the EudraVigilance and EudraPharm databases. These will be key channels to provide the general public with high-quality information on human and veterinary medicines. In addition, the full implementation of the central medical device database, Eudamed will help to facilitate exchange of information on medical devices between competent authorities.

Risk communication

Communication of the risks associated with healthcare products is a critical element in ensuring that new and emerging information on the benefits and risks of product is brought to the attention of healthcare professionals and to the public in a timely manner. Risk communications relating to particular products need to be targeted to different audiences, effective in changing prescribing habits or patient usage, ensure the safety of foodstuffs from treated animals, and counter the media sensationalism which often hinders appropriate public debate.

Transparency

State bodies in Ireland and elsewhere are subject to a greater level of public scrutiny than before. Standards of transparency have increased over time, with the publication of minutes of state agency boards now commonplace. Ensuring that IMB practices remain consistent with developments in this area will contribute to maintaining the confidence of the public in our role as the independent healthcare products regulator.

2.5 Constructive partnerships

The IMB works with a wide range of national, European and international bodies to maintain a robust regulatory system and co-operate on joint initiatives. The principal networks within which we operate include the EU Commission, EMA, EDQM and their working groups, the competent authorities in the EU and their working groups; the International Summit of Heads of Medicines Regulatory Bodies; and, in Ireland, the Health and Social Care Regulatory Forum. Good liaison is also maintained with individual healthcare professional regulatory bodies. We will continue to build on our strong links with these organisations to ensure ongoing regulation to protect and safeguard public and animal health.

Ensuring the quality of the network of EU medicines agencies is the focus of a number of initiatives, including the Heads of Medicines Agencies' programme for benchmarking European medicines agencies (BEMA), the Joint Audit Programme of the EEA GMP inspectorates and the peer review programme established by the European Notified Body Operations Group.

These programmes provide an opportunity for exchange of ideas with other agencies and ensuring that good practice standards are maintained within the IMB.

2.6 Industry

Ireland is a key global location for the pharmaceutical and medical devices industries which are major exporters in the Irish economy. Longer-term prospects for the innovative pharmaceuticals sector may be less favourable with the potential for more competition, mergers and acquisitions, and a reduced pipeline for bringing new medicines to market. Generic manufacturers of human medicines will be affected by the government decision to allow for generic substitution by pharmacists.

Globally there has been a shift of manufacturing active pharmaceutical ingredients from developed countries to developing countries, in particular the Far East and South America. The IMB has been an active participant in initiatives to avoid duplication of inspections in third-countries and will assist in developing tools to identify high risk sites and triggered inspections to make best use of resources.

The wholesaling sector in Ireland has become more complex in recent years with entry of many new wholesalers, increased use of outsourced operations and increased parallel importation and distribution of medicines. Increased security of the supply chain will be critical as an anti-counterfeit control. The Department of Health and Children is currently developing legislation to regulate the distribution of medical devices. This will introduce new controls in this area including registration, good distribution practice and traceability requirements.

2.7 Internal resources

Staff

In order to contain the cost of the public sector pay bill, government has imposed a general moratorium on recruitment of staff in the broader public service The IMB will work to minimise any effects of this on its operations through cross-training, transfer of staff to areas of need and prioritisation of work. The application of a moratorium over a number of years has the potential to significantly impact the delivery of services as well as the achievement of strategic objectives. As a largely fee-funded agency, the IMB will dialogue with government to achieve an appropriate tailored solution.

Finances

The work of the IMB is financed by fee income levied on the various regulated industries and sectors (85 %) and government funding for medical devices, controlled drugs and blood and tissue regulation (15 %). Over the next 5 years, it is the intention of the Department of Health and Children that the IMB be fully funded from fee income if an appropriate fee system and legal basis can be established. This poses particular challenges as competent authority regulation of medical devices is typically not funded by fees in other European Member States.

The introduction of a fee model to finance these activities will be a major undertaking over the next few years.

Technology

IMB operations and management depend heavily on information and telecommunications technology systems. Over the past seven years, significant investment has been made in new workflow technologies to manage the licensing functions, medicines and medical device safety cases and, more recently, inspections. A new ICT strategy will be elaborated in line with this strategic plan for the coming years.

3. STRATEGIC GOALS AND OBJECTIVES

The strategic direction for the IMB over the next five years is informed by our core remit of protecting public and animal health, the challenges we identify in the operating environment, and the strategies of our regulatory partners. It also builds on the substantial improvements in service delivery brought about by our change management programme and commitment to continuous improvement.

Our high-level strategic goals

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

The first two goals are focussed directly on our stakeholders. Goal one addresses the ongoing need to ensure that healthcare professionals and the public have access to the human and veterinary healthcare products they need to diagnose and treat medical conditions. Goal two addresses the increasing requirements for access to good quality and timely information on healthcare products and on specific benefit/risk issues associated with them.

Goal three relates to improving internal processes and working practices to allow us to meet timelines for all applications, contribute more to the European licensing processes and allocate resources in a manner proportionate to risk while maintaining an absolute focus on safety.

The legislative changes which will occur over the lifetime of this strategic plan are addressed in goal four where we will seek to ensure that forthcoming legislation will achieve enhanced protection for patients and consumers based on practical and efficient regulatory procedures.

The last goal ensures that we will invest in the resources and the future skills and technologies needed to achieve our goals and objectives.

These high-level goals provide a framework to guide the organisation over the next five years. In the sections below, we outline the strategic objectives for each of the goals to address the identified issues. Performance indicators which we have set for 2015 are focussed not only on outputs but, more importantly, on the specific outcomes we wish to achieve.

Goal One

Enhance healthcare product safety and patient outcomes by effective risk management and market surveillance

This goal is supported by the core activities of the IMB which ensure that healthcare products on the market in Ireland have a positive benefit-risk ratio and that products where risks outweigh the benefit are removed from the market. Significant additional activities to address the issues identified in relation to this goal are indicated by the specific strategic objectives and related indicators of performance described below.

Objective 1.1

Support and enhance systems for monitoring the safety and quality of healthcare products on the market place

Human products

Actions:

- Contribute to initiatives to strengthen the science that supports effective pharmacovigilance and therapeutic risk management.
- Develop programme to support increase in patient reporting of adverse reactions.
- Work with other state agencies involved in patient safety to ensure clear delineation of responsibilities, methods of communication and areas of joint interest.
- Actively contribute to the work programme of the Medication Safety Forum, to improve healthcare systems and patient safety.
- Work with healthcare professional bodies and academic institutions to ensure all education training programmes contain suitable content on quality, safety and risk issues in the prescribing, supply and use of medicines and medical devices so that the professions better understand their role.

Performance indicators:

- Increased levels of adverse reaction reports are received from patients.
- Real-time signal detection methodologies are coupled with robust signal evaluation to support evidence-driven risk evaluation.
- Registry and other epidemiological data are used in benefit-risk assessments and ongoing therapeutic risk management.
- New medicines are intensively monitored to evaluate the effectiveness of implemented national risk minimisation measures.
- IMB has developed strong links with other state agencies involved in patient safety and works closely with them to maximise patient safety.

- The proportion of adverse reaction reports received from healthcare professionals is increased, and report quality is improved.

Veterinary medicines

Actions:

- Work with healthcare professional bodies and universities to enhance knowledge on the quality, safety and risk issues in the prescribing, supply and use of veterinary medicines so that the professions, suppliers and users understand the IMB role.
- Contribute to initiatives to underpin the monitoring of antimicrobial usage.
- Develop linkages and work-sharing arrangements with EU Member States to support the achievement of harmonisation of labelling of medicines.
- Submit applications to European Medicines Agency for maximum residue limits (MRLs) for needed national medicines.

Performance indicators:

- The proportion of adverse reaction reports received from veterinary practitioners is increased, and report quality is improved.
- A stable system for recording antimicrobial sales of veterinary medicinal products used nationally is in place and the data can be appropriately mined.
- IMB has maintained and developed its work-sharing arrangements to cater for new capability requirements.
- IMB has helped to resolve national issues where availability of maximum residue limits is a potential barrier to trade.

Market surveillance

Actions:

- Work with patient groups and representative bodies for wholesalers and retailers to explain the risks posed by counterfeits, highlight the dangers of purchasing from unapproved sources and emphasise the importance of protecting the legal supply chain.
- Put in place agreements and develop strategies with environmental health officers and public analysts' laboratories for monitoring of cosmetics.
- Continue to develop monitoring of sales of non-compliant products in non-pharmacy retail outlets.
- Develop a strategy for monitoring distribution of devices in line with legislative requirements.
- Continue to actively participate in OMCL network to promote work-sharing principles and maximise surveillance data.

Performance indicators:

- There is a high level of understanding by the public of the risks posed by counterfeit / falsified medical products.
- Monitoring of new areas of responsibility for cosmetics and device distributors is fully integrated with existing programmes and operating effectively.

Objective 1.2

Work with key stakeholders to reduce the supply of unauthorised medicinal products

Action:

- Review the extent of importation of medicinal products under the legislative exemption provided for practitioners who prescribe unauthorised medicines for patients under their direct responsibility, and work with key stakeholders to provide authorised alternatives for high-volume or high-risk products.

Performance indicators:

- Decrease in supply of high-risk or high-volume exempt medicinal products and products with an authorised alternative.
- Established mechanisms in place for ongoing contact and collaboration on product supply issues with the Department of Health and Children, Health Service Executive, healthcare professionals and suppliers.
- Improved understanding and knowledge among relevant healthcare professional groups about the legislative requirements in relation to the supply of exempt medicinal products and a stated preference for using authorised products where possible

Objective 1.3

Review the method of sale and supply of authorised products

Action:

- Working with stakeholders across the health sector, elaborate a policy for review and amendment of the method of sale and supply categories for human medicines and implement a system for product reviews for key categories of medicines.

Performance indicator:

- Medicinal products have a method of sale and supply classification which is appropriate to their risk classification.

Objective 1.4

Maximise the impact of enforcement activities on illegal and counterfeit product supply

Actions:

- Publish a policy on enforcement activities which will define the approach of the IMB to achieving compliance with and enforcement of the legislation for healthcare products and the approach to communicating issues of concern to the public.
- Work with enforcement and inspection colleagues and external partners on risk-based and proactive projects to detect and remove from the market illegal and falsified healthcare products.

Performance indicators:

- Combined inspection-enforcement system provides high level of protection of legal supply chain.
- Strong co-ordinated action continues to be taken against illegal supply.

Goal Two

Deliver clear, relevant and timely communications to patients, consumers and healthcare professionals

Goal two is supported by the communication activities of the IMB which ensure that patients, carers and users of healthcare products and healthcare professionals have access to information on the products they use and are kept informed of any quality or safety concerns, or recalls of products from the marketplace. Our communications activities are based on use of a wide variety of methods including our website, e-mail alerts, and RSS feeds, newsletters, information days, and stakeholder meetings.

Significant additional activities to address the issues identified in relation to this goal are indicated by the specific strategic objectives and related indicators of performance described below.

Objective 2.1

Provide healthcare professionals, patients and the public with increased access to clear and timely information on the benefits and risks of healthcare products in the context of ongoing risk management

Actions:

- Use feedback from our stakeholders to improve our methods of communications with healthcare professionals and the public.
- Involve patient associations in developing risk communication tools and content.
- Publish information on risk and safety issues and on current topics on a frequent and timely basis so that stakeholders are kept up-to-date on emerging issues.

Performance indicators:

- Risk communication tools and materials are effective in informing prescribing and patient behaviour in line with regulatory and safety guidance.
- There is a high-level of awareness among the public of the risks posed by counterfeit products.

Objective 2.2

Encourage engagement of patients and the public in the activities of the IMB

Action:

- Review patient and user engagement models used by other regulatory and state agencies and implement a strategy for the greater involvement of patients and users in the regulatory activities of the organisation.

Performance indicator:

- Public and patient representatives are involved in the activities of the IMB and their knowledge, experience and views are taken into account in decisions and communications.

Objective 2.3

Improve information resources and transparency for healthcare professionals and the public

Actions:

- Review the current provision of information to both healthcare professionals and the public against best practice models, and implement a strategy to improve the accessibility and relevance of information provided and public awareness of best practice for using healthcare products.
- Publish Board minutes, biographies and declarations of interest for Board members and members of the management committee.
- Ensure that all communication channels reflect the expectations of patients and healthcare professionals and the changing healthcare environment.
- Further develop our website as a source of information on products and a key tool for risk communication to all our stakeholders.

Performance indicator:

- The IMB is viewed as a valuable resource of information to healthcare professionals and the authoritative source for patient information on healthcare products; and as the most important resource of information to vets, suppliers and users in respect of authorised veterinary medicinal products.

Objective 2.4

Position the IMB as an effective, strong and robust regulator across all stakeholders to underpin its authority and independence in safeguarding public health

Actions:

- Conduct proactive outreach programmes to include national, health, regional, online, and specialist media.
- Ensure key influential health commentators are briefed on the remit and activities of the IMB.
- Plan and deliver an annual IMB lecture.

Performance indicator:

- The IMB is viewed as the regulatory authority responsible for ensuring public and animal health and wellbeing, with enforcement powers to protect individuals and communities in relation to healthcare products.

Goal Three

Improve service delivery within a high quality, risk-based regulatory framework

Goal three is supported by the core licensing, inspection and surveillance activities which ensure processing in a timely manner using standardised, efficient procedures based on workflow technology and electronic document management. Significant additional activities to address the issues identified in relation to this goal are indicated by the specific strategic objectives and related indicators of performance described below.

Objective 3.1

Meet agreed timelines for all licensing, inspection and monitoring procedures

Actions:

- Put in place timelines for all national procedures, and monitor results against the timelines to progressively meet the performance indicator by 2015.
- Review our key processes and workflows on an ongoing basis to streamline them and eliminate any unnecessary steps and variability.
- Develop our staff's ability to continuously improve their own work areas and support them in doing so.

Performance indicator:

- 95 % of procedures are completed within EU or nationally set timelines.

Objective 3.2

Increase IMB contribution to EU licensing, inspection and monitoring procedures

Actions:

- Continue to review our capacity and capability to take on additional EU work and implement specific strategies to ensure we maintain the necessary outputs.
- Increase participation in initiatives on joint inspections with other agencies.

Performance indicators:

- Rapporteurships and RMS procedures for veterinary medicines are within the top five agencies in the EU and within the top eight agencies for human medicines.
- Lead Member State/topic rapporteurships for pharmacovigilance and medical device vigilance activities are within the top eight agencies in the EU.
- A well defined network is in place for information sharing on inspections.
- Extent of multiple inspections of individual sites is considerably reduced.

Objective 3.3

Extend the use of risk-based and proportionate regulation

Action:

- Based on our experience to date and on current developments in this area at an EU level, agree a policy and strategy for further application of risk management tools to a wider set of regulatory processes. Develop a systematic and integrated approach based on principles of quality risk management, best practice methodologies, and close monitoring and control of the outcomes.

Performance indicator:

- Risk-based regulation ensures sound and consistent regulatory actions which protect public and animal health while improving the use of IMB resources.

Objective 3.4

Define regulatory areas of additional special interest, while recognising the requirement for a general service offering

Action:

- We will review the opportunities and potential for developing a broader and deeper level of expertise in a number of areas across all our regulated healthcare products and define a small number of special interest areas in which we can further contribute to EU regulatory activities.

Performance indicator:

- The IMB contributes to EU licensing and inspection procedures on the basis of defined areas of special interest in line with evolving EU regulation.

Goal Four

Influence legislation and policy development at European and international levels for the benefit of public and animal health

Goal four is supported by the extensive knowledge and experience the organisation has in contributing to the development of legislation nationally and in Europe, and in implementing new and amended legislation which affects our regulatory processes as well as impacting on stakeholders. Significant additional activities to address the issues identified in relation to this goal are indicated by the specific strategic objectives and related indicators of performance described below.

Objective 4.1

Influence the strategic direction of new legislation on clinical trials, falsified medicines, information to patients, recast of the medical devices legislation, and veterinary medicines

Actions:

- Actively contribute to EU discussions in relation to legislation being proposed or progressed through the EU Council, working parties and the European Parliament.
- Work constructively with the government departments of Health and Agriculture, providing assistance to them in relation to EU meetings and national transposition legislation.
- Aim to ensure that meetings hosted by the IMB under the EU Presidency are practical and productive, with outcomes which deliver benefits to patients and users of healthcare products.

Performance indicator:

- The IMB fully participates in the development of new legislation and, where feasible, its views and concerns are taken into account.

Objective 4.2

Influence strategic discussions and decisions at European and international levels

Action:

- Continue to maintain a high profile in the European and international committees and working groups responsible for co-ordinating or managing the different networks of healthcare regulatory agencies and in the EMA's Management Board, contributing to policy proposals and initiatives for improving the effectiveness of the regulatory systems.

Performance indicator:

- Strategic decisions taken at EU and relevant international levels reflect IMB proposals and contributions.

Objective 4.3

Work with organisations within the state agency sector to develop the sector, with a particular focus on capability building and shared services

Action:

- Continue to be a leading contributor to the work of the Health and Social Care Regulators Forum and the working group of chief executives of state bodies, proposing areas for future development of both the agencies and the services they provide.

Performance indicator:

- IMB contributes to the development of improved internal management processes, greater collaboration across agencies, and better quality outcomes for the users of state agency services.

Objective 4.4

Influence IT developments within the EU regulation of healthcare products

Action:

- Participate actively in the EMA Management Board Telematics Committee and relevant EU working parties, working to ensure successful implementation of the EU Telematics Master Plan for standards for communication and exchange of information between industry and regulators.

Performance indicator:

- The IMB contribution to cost-effective and, where possible, integrated IT developments across the EU, is recognised.

Goal Five

Build future capabilities to meet evolving regulatory requirements, and scientific and technological advances

Goal five is supported by the effective systems in place to manage quality and risk across all of our processes, to support learning and development of our staff and provide information technology and telecommunications services to staff and stakeholders. Significant additional activities to address the issues identified in relation to this goal are indicated by the specific strategic objectives and related indicators of performance described below.

Objective 5.1

Further embed quality and risk management within the organisation

Actions:

- Further develop our quality and risk management systems to ensure that all key activities continue to meet stakeholder needs and expectations, provide quality assurance of the core scientific work, deliver continuous quality improvement, and manage the potential risks to the business.
- Make a significant contribution to the debate and proposals for the development of the third cycle of the BEMA (benchmarking) programme, ensuring that it focuses on best practice standards for agencies' management systems, the particular requirements for regulatory authorities, and the areas of strategic endeavour agreed by the Heads of Medicines Agencies.

Performance indicators:

- Quality and risk management are well integrated into key processes and used to support all major business decisions.
- The organisation achieves a successful EU benchmarking outcome.

Objective 5.2

Develop and implement an organisation-wide scientific expertise matrix for current and future needs

Actions:

- Building on our current HR systems and in particular our learning and development programme, develop an organisation-wide framework for analysing current skills and future needs.
- Identify and provide for future needs through staff development and use of external experts. Put in place systems to access and manage external experts which ensure independent and high quality scientific assessments.

Performance indicator:

- The organisation has access to the required high-quality scientific expertise from internal and external sources to support all regulatory activities as well as areas of additional special interest.

Objective 5.3

Improve the management of knowledge across the organisation

Action:

- Acknowledging the central and critical role of knowledge to our technical and scientific work, enhance information storage and accessibility and the sharing of knowledge across the organisation, using new technologies and communication tools.

Performance indicator:

- Staff have improved, timely and ready access to information from a range of technologies and networking solutions.

Objective 5.4

Ensure income remains aligned with costs

Actions:

- Continue to conduct annual reviews of fee structures to maintain a sufficient income level from fees which are proportionate to the costs involved.
- Review fee models for medical devices among EU Member States with a view to proposing fees for services not currently charged for.
- Review the fee options for the regulation of cosmetics in order to provide an income for the competent authority services we now provide.

Performance indicator:

- The fee model provides stable income streams which match costs.

Objective 5.5

Maintain investment in information management systems to support effective work practices

Action:

- Develop a new ICT strategy to reflect the business objectives over the coming years, including requirements for an improved website servicing a broader audience, further development of web-based applications across all activities, and new technology solutions for the regulation of cosmetics.

Performance indicator:

- Information management systems support the efficient operation of the IMB, provide improved 'online' services to patients, industry and other stakeholders, and support EU requirements for data exchange.

4. IMPLEMENTATION AND MONITORING

Our strategic plan articulates the direction for the IMB over the next five years from 2011 to 2105, incorporating both service delivery and supporting functions. Achievement of our objectives is contingent on the adequacy of resources available to the organisation, on the ability of the organisation to respond to any proposals of government under the public sector reform programme, and on the requirements of new legislation being no greater than currently envisaged.

The plan provides the framework within which annual business plans will be developed based on key actions identified in the strategic plan and the performance standards to be achieved by 2015. The annual business plans identify the specific tasks to be carried out for each strategic objective, the timeframes involved and the responsible director and department. Annual plans are developed down to individual level within departments, allowing each employee to see how their work contributes to the achievement of the organisation's goals and objectives.

We will monitor achievement against the strategic plan through our business planning and reporting system and through our performance management and development programme. We will report progress against the plan to the Board of the IMB and to stakeholders in our annual report.

GLOSSARY

CHMP

(Committee on Medicinal Products for Human Use)

A scientific committee at the European Medicines Agency which gives opinions on the authorisation (or approval) of medicines for human use to the European Commission and develops guidelines on authorisation applications for pharmaceutical companies and medicines agencies.

CMDh

(Coordination Group for Mutual Recognition and Decentralised procedures - human)

A committee of representatives of the medicines agencies in the EU and EEA which addresses procedural, regulatory and scientific issues relating to specific applications for marketing authorisations for medicines for human use.

EDQM

(European Directorate for the Quality of Medicines)

A European organisation involved in harmonisation and co-ordination of standardisation, regulation and quality control of medicines, blood transfusion, organ transplantation, pharmaceuticals and pharmaceutical care.

EMA

(European Medicines Agency)

An agency of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The IMB is represented on the scientific committees which conduct the main scientific work of the EMA.

Eudamed

A central European database created to capture data relating to medical devices that are registered with competent authorities across the EU, typically class I and in-vitro diagnostic devices. It also includes national competent authority reports associated with vigilance information.

EudraPharm

The central database of information on all medicinal products for human or veterinary use that have been authorised in the EU. It currently holds data on medicines authorised by the European Commission and will be extended over time to all nationally-authorised products.

EudraVigilance

The data management system for reporting and evaluating suspected adverse reactions experienced by patients during clinical trials and from use of medicines once approved.

GMP

(Good Manufacturing practice)

A set of internationally recognised requirements or standards which ensures that products are consistently produced and controlled to the appropriate quality for their intended use.

Healthcare products

Healthcare products include medicines for human or veterinary use, medical devices for human use, blood products, tissues and cells, controlled drugs and cosmetics.

ICT

(Information and Communications Technology)

Notified body

An organisation that has been accredited (or approved) by a Member State to assess the compliance of medical device with EU standards.

National competent authority reports

Method of communication between national competent authorities on medical device vigilance issues.

OMCL

(Official Medicines Control Laboratories)

The Official Medicines Control Laboratories support the regulatory authorities and the national inspection services in controlling the quality of medicinal products on the market by independent retesting based on legal requirements.

Patients and consumers

Patients and consumers include humans and animals who take medicines or use medical devices, their carers, and users of other healthcare products.

Periodic safety update reports

Cumulative reports of all adverse reactions to medicinal products received in defined reporting periods.

Rapporteur(ships)

A person who is responsible for a regulatory activity such as assessing an application for marketing authorisation in the centralised procedure or drafting a guideline or legal instrument. A rapporteurship is the activity which the rapporteur carries out.

RMS

(Reference Member State)

The EU country which takes the lead in assessing applications for marketing authorisation on behalf of other countries.

RSS

(Really simple syndication)

A format for delivering regularly-changing web content.

Telematics

EU Telematics are a set of systems and databases that provide information on medicines to the general public and support post-authorisation monitoring of medicines in the EU.

Notes

Irish Medicines Board
Bord Leigheasra na hÉireann

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Tel: +353 (0) 1 676 4971
Fax: +353 (0) 1 676 7836
Email: customerservice@imb.ie
Web: www.imb.ie