Irish Medicines Board Strategic Plan 2007 – 2009

Table of Contents:

1. Introduction

2. IMB Mission Statement

3. Foreword by the Chairman

4. Overview by the Chief Executive Officer

5. The Activities /Functions of the IMB

6. The Business in which we operate
- **6.1 Analysis of Industry**
  - 6.1.1. Human Medicines
  - 6.1.2 Medical Devices
  - 6.1.3 Device/Drug Combination Products
  - 6.1.4 Veterinary Medicines
- **6.2 Constructive Partnership**
- **6.3 Ever Changing External Environment**
  - 6.3.1 National Economy
  - 6.3.2 Legal Environment
  - 6.3.3 Particular Changes in External Environment
- **6.4 Assumptions, Opportunities and Vulnerabilities**

7. Resources

8. Structure

9. Systems and Processes

10. Vision and Values

11. Objectives and Goals

12. Monitoring and Review

Chapter 1 Introduction

The Irish Medicines Board has produced this strategic plan, for the period 2007 to the end of 2009, to provide our stakeholders and customers with relevant information on our positioning, vision and objectives aimed at ensuring that Ireland has one of the most effective regulatory systems in the world, for human and veterinary medicinal products, medical devices and health care products, maximising the protection of public and animal health in accordance with our statutory remit. It is our intention to review activity against targets set in this plan on an annual basis.

Chapter 2 Mission Statement

IMB MISSION STATEMENT

"To protect and enhance public and animal health through the regulation of medicines, medical devices and health care products."

Chapter 3: Foreword by Chairman

The Strategic Plan 2007 – 2009 of the Irish Medicines Board has been developed to help the Board and staff, and all our stakeholders, to understand the priorities, opportunities and challenges that we face over the next three years.

The IMB has responsibility for licensing over 6,000 medicines for human use and over 1,000 medicines for veterinary use as well as regulation of clinical trials, manufacturers and wholesalers of pharmaceutical products, collection and processing of blood, regulation of medical devices and cosmetics and regulation of tissues and cells to ensure they achieve the required standards of quality, safety, efficacy and effectiveness.

The IMB is obliged by statute to be self-financing and funds over 80% of activities from fee income. The additional 20% is derived from the Department of Health and Children for specific funded programmes in the areas of medical devices, cosmetics, human medicines enforcement, controlled drugs and blood and tissues regulation.

The Board works to ensure that the IMB operates efficiently and effectively and that best practice from public and private sector organisations is employed in all areas of activity. We have made significant progress over the past three years by way of a major reorganisation of staffing and a significant investment in enhanced IT. Compliance (incorporating inspection and enforcement) and Pharmacovigilance have been reorganised during 2005 and development of other areas, including medical devices, will follow. While maintaining a clear focus on our public health remit, we will work closely with all stakeholders and strive for continuous improvement across all activities.

I believe that this Strategic Plan will be of great assistance in this regard and I would like to thank all those who have contributed to its development.

Chapter 4: Overview by Chief Executive Officer

The Irish Medicines Board (IMB) is a relatively young organisation having been formed in 1996. The responsibilities and duties assumed at that time were a progression from those carried out by the National Drugs Advisory Board, which had advised the Department of Health and Children on matters relating to the safety, quality and efficacy of medicines for the previous 30 years. Since 1996, there have been very significant changes in the workload of the IMB and in the complexity of the technical assessments our staff undertake. The number of staff, and the base of skills and expertise, has expanded significantly. I expect that the next three years will see a corresponding significant change in both increased workloads and increased complexity in the various activities.

We will maintain an absolute focus on our primary public health remit and we will focus on outputs aimed at serving all of our various stakeholders, including the general public, healthcare professionals, licence holders, the Minister for Health and Children, the Minister for Agriculture and Food and our partners in the European medicines licensing network and worldwide.

We are responsible for ensuring the safety, quality, efficacy and effectiveness of human and veterinary medicines, medical devices, and blood and tissue and cell products available to the Irish public and manufactured in Ireland for Irish and export markets. From 2007 we will become competent authority in the area of cosmetics. We will continue to strive for best practice in all our activities, not least in the general management of the organisation.

A major strength in running the IMB is the management and scientific expertise available to us from our Board and Committee structure. We will continue to utilise this to the best advantage of all stakeholders and to develop a knowledge network of specialists available to advise the IMB in their relevant discipline.

Our vision is that the IMB be recognised by all our various customers and stakeholders as a centre of excellence for both the quality and scientific rigour we bring to our work and for the efficient and effective manner in which it is completed. We will strive to maintain and further develop our position as one of the leading medicines and medical devices regulatory authorities worldwide, which is science driven and transparent in the way it operates.

Our objectives are encapsulated as follows:

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

These objectives will be delivered through various goals set out in this plan and made a reality in the annual work plans of each department and individual. A comprehensive Performance Development Programme (PDP) ensures that all our activity is based on the priorities set out in this Strategic Plan, and the continuous review cycle built into PDP will provide for ongoing feed back to the Board, and allow for ongoing revision of annual plans and, indeed, this Strategic Plan.

I would like to thank all my staff colleagues and all Board Members who have contributed to the development of this Strategic Plan and I look forward to delivering on the various objectives and goals set out with the assistance of all staff.

Chapter 5: The Activities/Functions of the IMB

The activities/functions of the IMB are defined in the Irish Medicines Board Acts, 1995 and 2006, and relevant related legislation. In essence these are the regulation of medicinal products (human and veterinary), blood and blood products, tissues and cells and medical devices. From 2007 this will also include cosmetic products. This includes the issuance of manufacturing licences, product authorisations and wholesale licences, the control of clinical trials and investigations, monitoring and advising on the properties and actions of the various products, and disseminating relevant information to health care professionals and users.

Definitions of "medicinal product" and "medical device" are found in the Irish Medicines Board Act, 1995, and relevant EU Directives

These activities may be summarised as:

- To authorise the manufacture, preparation, importation and sale of human and veterinary medicinal products, and the distribution of human medicinal products. including herbal medicinal products.
- To operate a service for the regulation of Controlled Drugs under the Misuse of Drugs Acts 1977, 1984 and 2006.

- To review and authorise Clinical Trials, and to authorise manufacturers of investigational medicinal products, as per the Clinical Trials Directive and S.I. number 190 of 2004.

- To operate a service for obtaining and assessing information regarding the safety, quality and efficacy of medicinal products.

- To operate a service for obtaining and assessing reports on adverse effects of medicinal products in use in the State and to carry out a review of pharmacovigilance systems by way of inspections when considered necessary.

- To regulate the post marketing surveillance of medical devices, grant approval for clinical investigations, manage a register of low risk medical devices and monitor Notified Bodies for Conformity Assessment in Ireland.

- To operate a service for inspection and licensing of blood establishments and to monitor the implementation of appropriate standards in blood banks in accordance with Directive 2002/98/EC

- To operate a service for inspection and licensing of tissue establishments in accordance with Directive 2004/23/EC

- To advise the Minister for Health and Children and the Minister for Agriculture and Food as required.

- To provide information on medicinal products and medical devices to health care professionals and users.

- To enforce the Regulations made pursuant to the IMB Act and other relevant European and National legislation. (Note: enforcement of legislation relating to veterinary medicinal products is carried out by the Department of Agriculture and Food)

- To determine the classification of border line products as medicines, medical devices or otherwise.

Chapter 6: The Business in which we operate

6.1 Analysis of Industry

Human Medicines

Ireland is a key global location for the pharmaceutical/biopharmaceutical industry And most the top companies in the world have substantial manufacturing operations in Ireland. Over eighty foreign companies operate more than 125 plants employing in excess of 17,000 people with total exports that makes Ireland the largest exporter of pharmaceuticals in the world.

Pharmaceutical plants in Ireland compete equally with their counterparts worldwide on quality and reliability. The industry in Ireland is a highly sophisticated one, incorporating advanced manufacturing technology, state-of-the-art equipment and stringent quality control.

The sector is a diversified one. Investment in fine chemical plants producing bulk active materials has been followed by new investments in finished product pharmaceuticals operations. Approximately sixty finished pharmaceutical plants are now in operation. There is considerable investment in research and development facilities.

With regard to the market for pharmaceuticals in Ireland, over 6000 medicinal products are presently authorised by the IMB and there is very substantial state expenditure on medicinal products anually.
The IMB is committed to providing a high quality, timely review of medicinal products to ensure that high quality, safe and effective medicinal products are available to the Irish public.

Under the IMB Act the organisation has specific responsibilities for inspection of services for the collection, processing and quality control of blood and blood components.

Regulation by the IMB of the marketing, manufacture and distribution of medicinal products plays a very significant role in ensuring that appropriate standards are maintained in this sector. This includes post marketing surveillance, which encompasses pharmacovigilance, investigation of reports of quality defects, and a programme of sampling and analysis. This role will develop further in line with the provisions of the revised Directive and Regulations which should be fully in force by early 2007.

6.1.2 Medical Devices

Ireland is home to 13 of the World's top 25 medical devices companies, and this sector is also rapidly increasing its R&D activities. Leading medical device companies have chosen Ireland as a base for developing, manufacturing and marketing a diverse range of products from disposable plastic and wound care products, to precision metal implants, including pacemakers, to microelectronic devices, orthopaedic implants, diagnostics, contact lenses and stents.

The Irish based Medical Devices sector employs over 22,000 people in 110 companies with substantial sales and annual growth approaching 10%. As a result, this sector in Ireland has similar scale to the largest clusters situated globally in Minnesota and Massachusetts, USA.

Apart from further high technology manufacturing projects establishing in Ireland, an increasing number of existing facilities are integrating into R&D, and many are adding further global support functions such as shared financial and IT support services and global supply chain management.

The medical device and diagnostic industry continues to be a vibrant growth sector and a cornerstone of the Irish economy. Regulation by the IMB plays a very significant role in supporting this sector.

6.1.3 Device/Drug Combination products.

One of the most prominent emerging technologies is in the area of combining devices with drugs to enhance patient care. There is very significant R&D 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.

6.1.4 Veterinary Medicines.

There is a substantial animal health market in Ireland. Due to the fact that our main farming enterprises are milk and beef production and are grass based, the industry here is dominated by products used to control internal parasites. The vaccine market is also considerable. Other market segments account for no more than 10% of the market although the companion animal market is growing by 20% per annum. The manufacturing sector, while smaller than its human medicines counterpart, generates significant exports of veterinary medicinal products.

Maintaining Ireland's high status in relation to animal health and welfare is of critical importance given the economic and social importance of agriculture to the country. The Department of Agriculture and Food is charged with promoting best practice in relation to animal health and welfare, preventing, wherever possible, animal disease outbreaks and welfare problems and, where such difficulties do arise, dealing with them in the most effective and efficient manner having regard to all relevant national and international legal requirements and the interests of the animals themselves.

Central to all these challenges is the attainment of the highest standards of food safety within production systems that are economically, environmentally, ethically and socially sustainable. Safety is a non-negotiable element in the whole food production chain. It is underpinned by a raft of EU and national Regulations, which are enforced by inspectors of the Department both inside and outside the farm gate. These controls ensure that the national farm output meets the highest standards of safety. The food industry is a very important industry in Ireland with exports of over 5 billion euro. The domestic market is small compared to the total output.

The regulation of veterinary medicines plays a very significant part in supporting this sector: in assisting in the prevention and treatment of disease; in enhancing animal welfare and in ensuring the safety of foods of animal origin. Over 1,000 veterinary medicinal products are presently licensed by the IMB. Distribution of veterinary medicinal products in Ireland is regulated by the Department of Agriculture and Food (DAF) with which the IMB has a close working relationship.

There are several specific issues which relate to veterinary medicines and need adequate consideration, such as the provision of sufficient veterinary medicines for minor species. While these species may not be significant in terms of animal numbers in comparison to major species, they represent a significant challenge and the issue of animal welfare is a major concern. There is also the issue of the lack of availability of certain medicinal products. It is somewhat paradoxical that although Ireland is a major global exporter of animal derived products, the market for veterinary medicinal products is small by European standards and some companies choose not to market some products for commercial reasons. Examples include local and general anaesthetics, emergency type drugs for poisonings etc and lack of medicines and vaccines for minor indications e.g. louping ill of sheep and external parasites of poultry. There is also an issue regarding lack of medicines for horses and lack of medicines for diagnostic purposes. It is anticipated that the challenge of providing an adequate range of veterinary medicinal products in Ireland will be even greater with

the impact of the changes to the Common Agricultural Policy. The speed of change in farming and husbandry practices is expected to increase in the coming years. These changes are expected to impact negatively on the availability of certain medicines.

Bio terrorism in the livestock animal sector is a real and present danger and has yet to be adequately addressed across the EU. In addition, the threat of newer epizootic diseases such as the Blue Tongue Fever and the West Nile Virus Fever, already prevalent in some Member States, will require urgent provisions for the control of such threats. The IMB will have a role to play in the authorisation of suitable vaccines, in a timely and efficient manner, if deemed appropriate by Government.

Finally, both in the veterinary and the human field, there are increasing concerns about developments such as the growth in antimicrobial resistance in humans and animals and a Scientific Advisory Group on Antimicrobial Resistance has been established under the aegis of the EMEA to address the regulatory challenges ahead in the animal sector. In addition, the adequacy of systems in place to ensure the environmental safety of human and veterinary medicines will come under sharp focus.

6.2 Constructive Partnerships.

The IMB recognises there is a shared responsibility in regulation of medicinal products, medical devices and health care products i.e. that others have an interest in assuring that the products available to the public are safe, effective, of high quality and contribute to an efficient health care system, not least the companies that produce and market such products who's primary responsibility is product safety. We also recognise there are other scientists and agencies around the world with important expertise who share our interests and goals. Therefore, one of our key roles in the health care system will be the support of global partnerships, which facilitate ongoing harmonisation efforts.

In Ireland, other Governmental agencies involved in the Regulatory process for medicinal products, medical devices and health care products include the Department of Health & Children (DoHC) (for Human Medicinal Products, Medical Devices, Blood Tissues and Cells, Controlled Drugs and Cosmetics), the Department of Agriculture and Food (DAF) (for Veterinary Medicinal Products), Enterprise Ireland (EI)– the National Standards Authority of Ireland (NSAI) (Medical Devices), the Radiological Protection Institute of Ireland (RPII), the Food Safety Authority of Ireland (FSAI) (Borderline Products), the Irish Blood Transfusion Service (IBTS) (Blood, blood components and derivatives), the National Haemovigilance Office of the IBTS (NHO), the Irish Sports Council, the Irish National Accreditation Board (INAB) and the Environmental Protection Agency (EPA). In the area of enforcement, strong links have been established with the Gardai, Customs, the Environmental Health services of the Health Services Executive and with the Department of Agriculture and Food.

In Ireland, other non-Governmental bodies with interests in the regulatory process of medicinal products and medical devices include industry trade associations such as Irish Pharmaceutical Healthcare Association (IPHA), Association of Pharmaceutical Manufacturers of Ireland (APMI), Pharmachemical Ireland, Irish Health Trade Association

(IHTA), Animal and Plant Health Association (APHA), the Irish Medical Devices Association (IMDA), the Irish Pharmaceutical Union (IPU), the Irish Association of Health Stores (IAHS), the Pharmaceutical Distributors' Federation (PDF), the Irish Association of Distributive Trades (IADT) and the Stonehouse Group. The IMB is committed to ensuring that positive communications are maintained with these organisations.

Liaison is also maintained with professional bodies such as the Irish Medical Council, the Veterinary Council of Ireland and the Pharmaceutical Society of Ireland as well as other stakeholders.

Consumers also have an important role to play in our health care system. In recognition of this and to facilitate decision making by consumers, the IMB will endeavour to increase the general understanding of the regulatory system as applied to medicinal products, medical devices and health care products, and to assist in providing appropriate information to those who need to make informed decisions about the use of medicines and medical devices in the management of their health care.

We recognise that health care professionals in Ireland and abroad, and other stakeholders, have objectives and goals similar to ours. We will continue to develop mutually beneficial partnerships with these colleagues to the benefit of public and animal health.

An effective regulatory programme makes use of expertise both within and outside of the organisation. Independent expert advisory committees have been nominated by the Minister for Health and Children to advise the IMB on scientific and regulatory policy and we have set up an efficient and organised process by which these committees can provide input and advice at appropriate stages in our decision-making. The contribution of committee members, free of charge, is gratefully acknowledged.

The IMB recognises the important contributions made by the International Conference on Harmonisation (ICH) and the Veterinary ICH to harmonisation of standards for medicinal products and will continue to monitor closely, and contribute to, developments in these areas. The work of the Pharmaceutical Inspection Co-Operation Scheme (PIC/S) in the training of GMP inspectors and the harmonisation of inspection standards is acknowledged. The IMB will continue to contribute to these activities within the PIC/S.
Ireland is a signatory country to the European Pharmacopoeia Convention operated under the Council of Europe since the mid-1970's. While the Pharmacopoeial authority of Ireland is vested in the Department of Health and Children, the Irish delegation to the Pharmacopoeia Commission has included a representative from the Irish Medicines Board (JMM) since 1996. In March 2004 Dr. J. M. Morris was elected to be the 14th Chair of the European Pharmacopoeia Commission, the first time that this prestigious post had been held by a representative from Ireland. The term of office extends for three years until mid 2007.

The IMB is committed to supporting Dr. Morris in his role as European Pharmacopoeia Chairman and looks forward to greater participation from the

pharmaceutical and chemical industry in Ireland in the work of the European Pharmacopoeia.

6.3 Ever Changing External Environment

6.3.1 National Economy

The Irish economy has been through a period of economic boom and while this has slowed somewhat it poses a number of strategic challenges for the IMB. The issue of retention of existing staff and recruitment of additional staff will continue to challenge us in the next 3 years. In addition to staffing issues, the economic boom has also fed into inflation in the service sector, which has increased our operating costs. While this appears to have slowed, we expect it to continue to be an issue for us over the next 3 years.

6.3.2 Legal Environment:

National, European and international law is becoming more complex and open to interpretation. This is combined with an operating environment which is increasingly litigious. This has two implications for the IMB. Firstly, it impacts on the way we must carry out our work as we are often forced to examine all the legal implications prior to following a course of action. This has both time and cost implications. Secondly, we must deal with actual and threatened litigation which can be highly labour and cost intensive but is non productive.

6.3.3 Particular Changes in the External Environment

6.3.3.1 A Changing Regulatory Environment.

The EU Regulatory System has been confronted with significant changes of a legislative (outcome of the EU review 2001 of pharmaceutical legislation, effective since November 2005, and proposed changes in medical devices legislation) and institutional (impact of the 2004 and 2007 enlargement of the EU) nature. Our procedures have been significantly amended to take account of these changes in legislation.

In addition to these significant challenges having an immediate impact on the overall system, other developing factors, which are nonetheless important, will have to be taken into account. Amongst them are political factors such as the possible continuation of the EU enlargement.

In addition, one of the key issues to be addressed by the international regulatory environment will be its ability to prepare adequately for the introduction of new technologies, from a scientific, legal and regulatory perspective. Appropriate measures will have to be taken in order to ensure that the pharmaceutical industry can

take advantage of new pharmaceutical technologies in the manufacturing and analytical areas, and anticipate the implications of gene and cell therapies, and for the medical devices industry developments in nanotechnology, miniaturisation, diagnostic imaging etc. The speed of medical device innovation is challenging, as more complex devices are coming to market in response to patients' needs. Research and development are essential if the medical device sector is to grow both at a global level and locally in Ireland. The challenge will be to support this progression with a positive regulatory environment, while ensuring public health and safety.

Other factors to be considered are the impact of an ageing human population, increased demands for medicines in areas of unmet medical need, the possible unavailability of medicines both in the human and veterinary field, the ever increasing concerns about the development of antimicrobial resistance, the challenges of home care and remote access to patients, etc.

Such changes effecting the EU Regulatory System should, however, not be regarded as pure challenges, but rather as new opportunities, which, through adequate proactive initiatives should lead to an enhanced protection and promotion of public and animal health in an enlarged EU.

6.3.3.2 The European Medicines Agency (EMEA) in the changing regulatory environment

The impact of the changing environment on the EMEA has been considerable. The Agency with its network of National Competent Authorities (NCAs) in Member States in the European Economic Area (EEA), through which scientific resources are made available to the EMEA, has become one of the world's foremost Regulatory Authorities for medicinal products. The impact of the EMEA's scientific opinions will become increasingly important, both from a public/animal health perspective and an economical viewpoint. In addition, its role and responsibilities will also change. One of the major tasks of the Agency will continue to be the coordination of the scientific resources provided by the Member States and such tasks will be further extended, e.g. in the field of Good Manufacturing Practice (GMP) , where inspections of the manufacturers of active pharmaceutical ingredients may be carried out, as required, and in pharmacovigilance. Another example of increased responsibilities for the Agency is the implementation of Community legislation on herbal medicines and the establishment of a new Scientific Committee. The scientific component of the Agency's activities will also become more important. Provision of scientific opinions to World Health Organisation (WHO) is one such an example of increased scientific input. In addition, the EMEA's tasks will become more public health orientated and its international role will be further developed.
The main challenge for the EMEA over the next few years will be its ability to meet the increasing expectations of its stakeholders. The EMEA will particularly focus on the needs and expectations of patients and users of medicines. The EMEA will have to find the right balance in terms of expectations such as applying high scientific knowledge for the timely delivery of science based opinions, increased involvement in the protection

and promotion of public and animal health, regulatory and scientific consistency, predictability, greater transparency, better information and earlier communication.

The continuation of the Agency's networking model will also require that Member States are able to adequately respond to the changing regulatory environment. In order for the EU Regulatory System to position itself successfully in the international environment as one of the world's foremost regulatory systems, NCAs must continue to provide high-level scientific expertise since this will be key for the overall success.

One of the strengths of the EU system is the ability to source expertise from whatever location in the EU. This system will be confronted with particular challenges, such as in the field of new therapies, due to the scarcity of experts in these areas. Transparent and robust conflict of interest mechanisms will need to be available to reassure the public. In certain areas there may be an overcapacity of scientific expertise, due to a shift in workload. Adequate measures need to be taken by the EMEA to ensure that the existing pool of scientific experts in the Member State Competent Authorities is maintained at the highest level of expertise.

IMB will contribute actively to the work of the EMEA by participation in the Management Board and various Scientific Committees and working groups. We will provide appropriate resources to the scientific advice, product assessment and inspection activities.

6.3.3.3 Pharmacovigilance & Continuous Monitoring of Medicinal Products

This is probably the most challenging area with the greatest potential of vulnerability for all national Competent Authorities. A proactive approach in pharmacovigilance and the introduction of additional risk management strategies will be further developed. In addition, a further strengthening of the close collaboration between Member States, the EMEA and other agencies, i.e. WHO, FDA etc. is of paramount importance.
Although new legislative tools will be made available in order to support the conduct of pharmacovigilance, regulators will need to ensure that national systems are equipped to deal in an efficient and timely way with crisis situations in terms of robust scientific assessment, sound regulatory action, adequate transparency, appropriate communication and monitoring of impact.
The IMB will evaluate any new data affecting benefit: risk assessment of medicinal products authorised and marketed in Ireland in a balanced and timely manner. In conducting its evaluation, the IMB will maintain as its priority the protection of the public and the animal populations, while taking into consideration the use of the medicinal product, availability of alternative therapies and all available scientific information. The IMB will adapt its pharmacovigilance systems to meet the changing requirements of EU legislation. This will include, where necessary, inspection of the pharmacovigilance systems of marketing authorisation holders.

The IMB will also adapt its controls on the monitoring of the labels and package information leaflets in respect of nationally authorised medicines, including veterinary medicinal products, in order to ensure compliance of these products with changing national requirements.

6.3.3.4 New therapies.

New therapies will constitute a particular challenge due to the scarcity of experts in these areas. We will continue to develop our links with experts in academic institutions and to develop the skills base of the full time staff of the IMB.

6.3.3.5 Access to Information and Transparency

Adequate electronic systems will have to be available in order to allow the EMEA link with the National Competent Authorities to build up a unique resource of data regarding pharmaceuticals and manufacturers. EuroPharm and EudraVigilance will be key channels in order to provide the general public with high-quality information on medicines. The IMB has invested in new technology to support improved communication with its stakeholders. Improved methods of submitting data electronically will be made available to applicants together with a mechanism to follow the progress of applications at the IMB. The IMB website will be further developed to support the needs of its users.

The new EU Directive 2004/27/EC also has a significant impact on transparency and the accessibility of documents. Articles 21.3 and 21.4 require that SPC s and Assessment reports are made publicly available / accessible respectively. Article126b requires that rules of procedures, agendas and records of meetings also are publicly accessible.

6.3.3.8 Enforcement in the event of Breaches of Legislation

In the area of enforcement, the IMB will face emerging challenges over the next three years. These challenges will move the agency from dealing primarily with illegal activities in Ireland to also dealing with illegal activities which transcend national borders. In this context, the counterfeiting and diversion of medicinal products pose significant risks to human health. Such products are offered for sale over the Internet, and via other routes. Certain sectors are particularly vulnerable to such unauthorised products, notably the sports, recreational and lifestyle sectors. Effective co-operation with our counterparts in other countries will be a key component in ensuring an effective response to such illegal activities.
It is anticipated that enforcement in the area of medical devices, where counterfeiting has also been detected, will also develop significantly over the next three years.

6.4 Assumptions, Opportunities and Vulnerabilities

As with any business, the IMB's ability to operate at the highest level and in line with the goals identified in this strategic plan is subject to a number of assumptions, opportunities and vulnerabilities.

If we look back at the role, workload and resourcing of the IMB just five years ago we can see how rapidly the organisation has evolved in a relatively short timeframe. Legislative, market and efficiency driven initiatives have changed the operation of the IMB at every level.

In order to define a strategic direction for the next three years, assumptions are made in respect to a number of key areas, including predictability of workload, financial stability and flexibility, and ability to obtain necessary resources.

While recognising that the mixture of activities may change, we assume that the workload of the IMB will continue to grow over the next three years.

One of the key challenges for the IMB will be its ability to react to change and to develop a flexible business model that enables it to optimise resources in line with public and animal health requirements and market forces.

It is therefore vital that the IMB has the ability to review its fee model in a timely manner and that any new resource needs can be met immediately, and we make the assumption that this will continue to be so.

We expect that the IMB will continue to remain competitive at EU level. The EMEA is pursuing a "costing exercise" to review the remuneration of national agencies for work done on its behalf. We make the assumption that the net revenue from the EMEA for services we provide will not be reduced.

Advances in science, together with more rapid delivery of products to the EU market, also have an impact on the workload of the IMB. Safety and enforcement issues continue to grow and these issues can often place considerable stress on the resources of the IMB. In line with existing arrangements and the provisions of European medicinal products legislation, we make the assumption that central funding will be provided in the future for this activity.

While the profile of the manufacturing sector will continue to evolve, we make the assumption that this sector will continue to thrive.

Investment in technology and the introduction of the Performance Development Programme (PDP) have delivered key benefits to the organisation and also improved the management of work across the IMB. Unplanned work in any area impacts significantly

on the ability of the organisation to deliver on its targets. However it is envisaged that improved management information systems will support improved planning and throughput of work.

Maintaining good industrial relations is an essential part of delivering on the strategic plan. Organisational change can pose difficulty for some. We will work carefully with all staff, and their representative bodies, to manage these issues without business disruption.

Finally, we also assume on-going support from our parent Department, the Department of Health and Children, all other Government Departments and State Agencies, and all our various clients, on whom we rely for continuing cooperation.

A formal risk management process will operate in tandem with our Quality Management System to identify and handle possible risks.

Chapter 7: Resources

The Irish Medicines Board now.

7.1 Assets

7.1.1 Tangible Assets:

The work output of any organisation will ultimately depend on the financial and human resources available to it. Under the Irish Medicines Board Act, 1995, the IMB is charged with ensuring that the full costs of all of its operations are recovered. While the costs associated with bringing a product to market must be borne by the applicant company, given the relatively small size of the human and animal health market in Ireland, it is important that the costs of authorisation for minor use products should not be so uneconomic as to deny the Irish public and their animals access to essential or useful medicines. Moreover, certain tasks e.g. provision of technical advice to Government departments and agencies as well as the evaluation of data on residues of veterinary medicinal products in foodstuffs cannot be charged against particular product related activities but do require funding.

The financial resources of the IMB derive primarily from fees charged by it in respect of the discharge of its functions, primarily licensing activities for human and veterinary medicines, manufacture and wholesale licences and clinical trials.

The IMB also undertakes a number of additional activities such as acting as the national competent authority for medical devices, blood and tissues, enforcement and controlled drugs at the request of the DoHC and on the basis that Government finances these activities by an annual subvention, following the submission of estimates. However, fee income remains the major source of funds for the IMB. There is no competing organisation in Ireland but there is competition with other NCAs for certain functions within the European Community.

The major cost items are salaries, related variable costs and office accommodation.

7.1.2 Revenues:

Revenue from fees is estimated at €17M for 2007. It is anticipated that income levels will rise in the years 2008 –2009 in line with increased activity and that fees will increase generally in line with inflation. IMB engages in a detailed financial planning process each year, commencing in June, to determine predicted activity levels and staffing/cost requirements for the following years. This process involves detailed consultation with stakeholders. Fee paying stakeholders generally welcome this approach as the process is transparent and any proposed fee increases are generally in line with inflation. We will continue to strive for cost savings in all areas and to pass the benefits of any savings achieved to fee paying stakeholders. Additional income is also anticipated by way of

increased income from Government relating to increased levels of activity in Government funded projects. This income is on a cost recovery basis and therefore has no impact on the bottom line of the IMB. The projections for the year 2007 are based on historical figures for national authorisations, renewals and variations, upon existing product authorisation numbers for maintenance charges and upon a combination of historical data and EMEA estimates for European work.

Fees are related as closely as possible to the amount of work involved. Some of these figures have a degree of uncertainty e.g. for the numbers of new applications. Some core fee activities such as maintenance fees are more predictable (about one-third of revenues).

We will also have a particular focus on expanding revenue opportunities and will apply an innovative approach to looking at business development opportunities.

7.1.3 Costs:

Costs for fee funded areas are projected to be in line with the revenue figure of €17M in 2007.

The following is an overview of the anticipated key issues in each of the major cost categories:

7.1.3.1 Salaries:

This is the single most significant cost for the IMB representing 72% of expenditure. Salary costs will rise in line with cost of living increases agreed in national pay deals.

7.1.3.2 Accommodation:

The present accommodation was first occupied in 1996 as a tenant. The IMB purchased this building in December 2004. It is approx. 22,500 sq. ft. and accommodates approx. 160 staff. Since 2004 we have rented an additional 5,000 sq.ft. in an adjoining building. The overall cost of mortgage repayments and rent is approximately €1.2 million per annum. The space in the main building requires upgrading and this work, which commenced in 2006, should be substantially completed in 2007. The purchase of the building reduces our exposure to future cost increases and helps to fix the costs of accommodation going forward.

Off site storage costs for archived material are also quite significant. This issue is kept under review.

7.1.3.3 Capital Items:

This chiefly relates to IT equipment for expanded information technology activities and other office equipment and is based upon currently budgeted requirements.

7.1.3.4 Other Expenses:

These include travel, training and miscellaneous operating costs. These increase in line with inflation, volume of activity or, proportionately to staff depending on the specific item. We have appointed a Training and Development manager and will continue to commit significant resources to our training budget to ensure staff competencies and skills continue to develop

7.1.3.5 IT Services:

IT and Telecommunications systems are of particular importance to the IMB. Technology is changing rapidly and we continue to develop new systems. We are presently implementing a major project which will significantly enhance our business practices. This technology will be rolled out across other business areas in the organisation over the coming years. Ensuring timely compliance with EU initiatives supporting e-submissions, pharmacovigillance and improved communications with our partners and customers is a further challenge.

7.2 Intangible Assets

Intangible assets can be difficult to quantify but for the IMB these are of particular importance. These include reputation, accumulated learning and accumulated experience. We continue to invest in this area and since 2003 have employed a Training and Development Manager in our HR function to allow us to better coordinate training activities and continue to leverage resources and skills available from our staff and to enhance these for the future. Teamwork and sharing of collective knowledge is particularly important for us and individuals will be encouraged and enabled to share knowledge by the on going development of the Training and Development function.
We will continue to develop our organisational capabilities and management structures and the skills and capabilities of our staff with a strong emphasis on effective management and support of colleagues. In this regard management commitment to on going change is particularly important and we will continue to focus on this competency.
A further particular challenge is the management of effective relationships with Government Departments and State Agencies, EU Institutions and other Member States.

7.3 Resource Constraints.

Space, Finance and Staffing

In common with many organisations, resource constraints exist in the areas of space, finance and staffing.

Regarding available space, this matter is dealt with earlier in the paragraph headed accommodation.
There are particular constraints regarding finance and these matters are referred to in the section on revenues. The Board is statutorily obliged to manage its affairs so that revenue at least covers expenditure, taking one year with the next. Regarding Government funded areas of activity, the Board will manage each of these areas prudently within the strict constraint of Government funding provided. Regular communication will be needed with the DoHC to ensure that funding keeps pace with the development of each of these funded areas and that the IMB, as Competent Authority, can function as required by the relevant legislation.
The majority of the work of the IMB is funded by fee income and, as outlined earlier, we will continue to engage in an annual planning cycle with industry and Government to agree service levels and the related staffing/cost requirements for the following years. This process will also feed into an annual review of fee levels. We need on going Government support to then ensure that fee levels proposed are implemented by way of Statutory Instrument in a timely and efficient way so that new fees are effective from January 1st each year.

The issue of the process of agreeing the staffing allocation at the IMB with Government is particularly problematic. As part of normal development of services, management make proposals to the Board if and when additional staffing is required. An integral part of such submissions is always specific clarification on the availability of fee income to fund such posts. When posts are approved by the Board, a submission is then made to the DoHC to have the posts and grading approved. The DoHC reviews this submission and makes its recommendations to the Department of Finance, which department has the final imprimatur on approving such posts or otherwise. This process has posed significant challenges for the Board in the past and can take considerable amounts of what is essentially unproductive resource and time. While fully accepting the legal position and policy regarding public service staffing policies, having regard to the self funding nature of the Board and the health critical area in which we operate, it is difficult to understand why a more enabling and efficient system could not be put in place. We are in ongoing dialogue with the DoHC on this matter and will endeavour, with its assistance, to have a more efficient and effective mechanism for approving staff numbers and grades, having regard to the nature of the positions, the status of the IMB, and, in particular, the fact that all of these posts are self financing.

Delays in obtaining approval for new posts have a number of adverse effects. Firstly, inadequate staffing can cause delays in licensing medicines, which has two significant

impacts. The first impact is on overall public health in the population. Delays in the licensing process can mean that new medicines, or additional indications for existing medicines, are denied to patients for an unacceptable period of time. The second impact regarding delays in licensing medicines, particularly generic medicines, is on the overall cost to the Exchequer of medicines and the cost to patients generally and the wider economy. Adequate staffing of the licensing agency will reduce the cost of medicines to the public and to the State in its reimbursement schemes.

Secondly, we are aware of Government policy in the area of reducing the State's exposure to litigation and of the work of the State Claims Agency under the National Treasury Management Agency in this regard. Government policy is that we should avoid any unnecessary exposure to claims in the future. The IMB is obliged to ensure that the principles of prudent risk management are taken on board in our planning, management and running of the agency. It may be very difficult to defend future actions where failure to act in a particular area related solely to lack of adequate staffing and not the capacity to have funded such positions at the time.

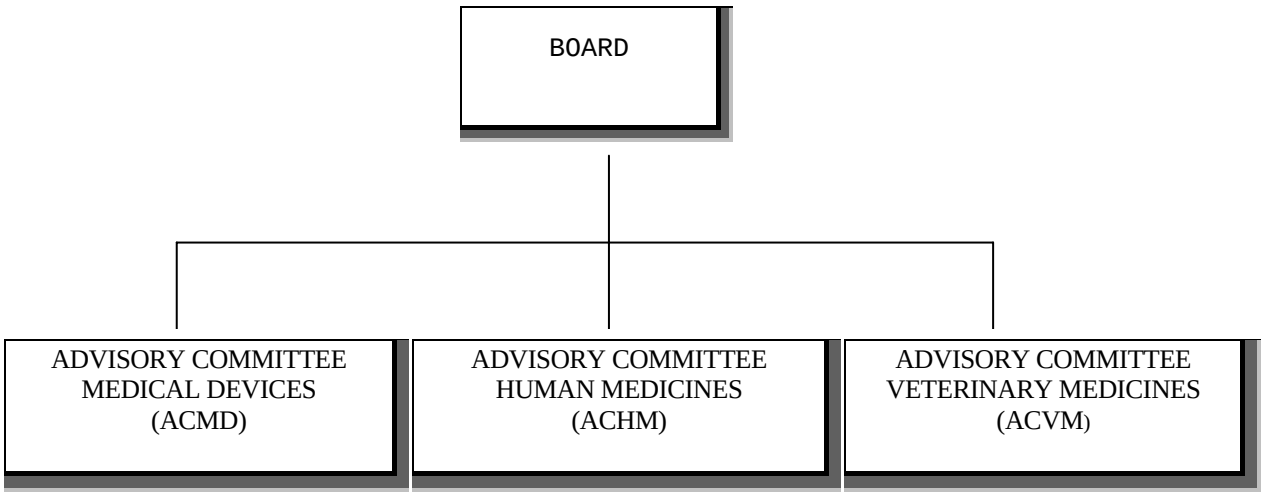
Finally, the third specific area of concern relates to the competitive environment in Ireland for the pharmaceutical and medical devices industries. We are well aware of Government policy in developing a competitive environment across a range of headings to encourage the development of existing companies in the pharmaceutical and medical devices sectors and to encourage new entrants. One of the essential building blocks of a competitive environment in these sectors is an efficient regulatory environment. Industry contacts have outlined on many occasions that the quantum of fees charged by the Irish Medicines Board is of little consequence in the overall context of companies making strategic investment decisions, but rather that the real issue is the ability of the Irish Medicines Board to provide adequate staffing resources to inspect premises and assess and license products in a timely, efficient and effective manner.

The Department of Health and Children approved increased staffing for the IMB at the end of 2006. In the context of this strategic plan, the numbers approved provide for adequate resourcing of the agency for 2007. Staffing levels will be critically reviewed on an ongoing basis.

Chapter 8: Structure

8.1 Organogram of Board and Committees.

The Organogram of the Board and Committees of the IMB is set out below.



The Board of the IMB supervises in general the overall operation of the IMB. The Board comprises nine members appointed by the Minister for Health and Children under the terms of the Irish Medicines Board Act, 1995. The chairman is also appointed by the Minister.

The Advisory Committees, which are composed of external experts, and are Statutory Committees appointed by the Minister for Health and Children, have been established under the Irish Medicines Board Acts, 1995 and 2006, to advise the Board and management on technical and scientific matters.

Sub or Ad Hoc Committees and Working Groups may be constituted on the request of any of the committees to complete a particular task.

The following are the current permanent committees of the IMB:

- Advisory Committee for Human Medicines (ACHM)
- Advisory Committee for Medical Devices (ACMD)
- Advisory Committee for Veterinary Medicines (ACVM**).**

8.2 Management Structure

The executive is organised into the following departments:

- Human Medicines
- Veterinary Medicines
- Compliance
- Medical Devices
- Information Technology and Change Management
- Finance and Corporate Services.

The Management Committee comprises of the Chief Executive, the Director of each department and the Senior Scientific Advisor.

Chapter 9: Systems and Processes

Systems/Policies/Processes and Informal Elements of Activity.

A wide range of formal systems is in place for the operation of the Board and Committees, and activities in the various departments. These include, for example, an integrated Quality Management System which is being extended to all relevant processes across the IMB, an externally audited Quality Management System in the Compliance Department and formal systems of Standard Operating Procedures and Guidance Documents in all Departments. Another example is a detailed handbook available to all staff, which sets out HR processes and practices in all relevant areas. This has recently been revised and complemented by the addition of a Manager's Guide to implementing HR practices.

We will continue developments in this area to facilitate continuous improvement across the entire organisation.

Communications:

In the past the work of agencies like the IMB was carried on in a less public way. Today as a result of legislative change (e.g. Freedom of Information (FOI) Act), technological

change (e.g. the Internet), and the altered expectations of the public, the work of State Agencies is carried on in a very open environment. We welcome this change. This requires careful management to ensure that confidence is not unnecessarily lost in the system as a result of unbalanced reporting, and the media has a major responsibility in this regard.

Our primary role is to ensure that medicinal products and medical devices available to the Irish public are safe, effective and of high quality. Since risk/benefit management depends on timely communication and accurate information, communication is one of our principal tools in achieving our mission. The IMB encourages timely, open communication between management and staff, and with all outside stakeholders and clients.

Effective communication improves the Irish public's understanding of our role and functions. Therefore, we will continue to support and develop our use of communications technology by employing a wide variety of mechanisms to communicate with our clients and stakeholders.

The technologies used to support our focus on communication were traditionally based around printed media such as our newsletters and other publications, but will in the future be increasingly web based to maximise the use of new technologies and the availability of the maximum amount of information to all stakeholders.

Independence and transparency:

The IMB ensures that decisions taken on regulatory matters are based only on scientific and legal considerations and are entirely impartial. Staff members are prohibited from having any financial interest in the pharmaceutical or medical devices industries under the terms of their employment contracts. In addition, any other relevant relationship or those of their family members must be disclosed to the IMB. Members of the Management Committee and Board also complete Annual Statements of Interests, as required under the Ethics in Public Office Act, 1995.

Experts and committee members who are consulted by the IMB in the conduct of its business are obliged to declare any potential areas of conflict of interest and to absent themselves from discussions on any such matters.

In the event of a proposal to refuse any product authorisation or licence, mechanisms are in place to allow applicants appeal that proposal.

The IMB is also committed to ensuring that its activities are carried out with the maximum degree of transparency, which balances the requirements of commercial confidentiality with the public's right to know the basis for our decisions, and the Board's statutory obligations under the terms of the Freedom of Information (FOI) Act (1997). Under this Act the public has the right to access records held by the IMB and receive explanations for decisions affecting them.

Performance Development Programme:

Performance Development Programme (PDP), as operated in the IMB, is essentially a framework to help all staff to be aware of the challenges facing the IMB and to see how these challenges translate into a plan for their own department, work team and the individual. It also deals with recognising the behaviours that must be displayed to achieve our vision for the IMB and, in particular, captures individual development needs of all staff. This process is now embedded in the culture of the IMB and extensive on going training programmes are provided.

Chapter 10: Vision and Values

10.1. Vision: The contribution we make to Society.

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 IMB will strive to maintain and further develop its position as one of the leading medicines and medical devices regulatory authorities, which is science-driven, and transparent in the way it operates. Our aim is to provide for better protected and informed patients and users of medicines, medical devices, blood and tissues, and health care products whilst encouraging and facilitating innovation and research in Ireland and playing a significant role in the regulation of medicinal products and medical devices in an enlarged EU.

The IMB is supported by high quality scientific resources and a high standard IT infrastructure which provides an adequate and secure network between IMB and client companies, EMEA and all other European Regulatory bodies in order to meet such a target.

10.1.1 Prerequisites to be fulfilled

In order to allow the IMB to successfully achieve the above vision, the following prerequisites should be fulfilled:

a. Provision of high-quality scientific resources.

The continuation and ever strengthening of the provision of high-quality scientific resources is key for the success of the IMB. The availability, retention and further development of highly qualified, efficient and effective staff will be key. Important choices will have to be made also at national level on how best to contribute to the overall EU regulatory system for medicinal products and medical devices. The EU may wish to move into a direction whereby centres of assessment for medicinal products are established in the EU.

b. Availability of an adequate Quality Management System (QMS).
The overall quality and efficiency of operation will be key for the IMB to position itself successfully in the regulatory environment and to meet its stakeholders' expectations. This necessitates an integrated QMS at the IMB in order to achieve an adequate level of scientific and regulatory consistency in the outcome of the scientific evaluation processes.
The requirements for good governance, good regulatory practices and integrated quality management extend to all scientific committees and working parties. HMA conducted a benchmarking of systems in relation to medicinal products in all Member States during 2005. This should result in a regular cycle of benchmarking and a strengthening of the quality systems in place in of all European medicinal products regulatory authorities.

c. Availability of a high quality IT infrastructure.
The quality of the overall IT infrastructure underpinning the IMB regulatory system is vital for our success. Recent investments in IT systems leave us very well placed in this regard.

d. Efficient and effective operation.
The continued efficient and effective operation of all processes and procedures delivered to customers by the IMB is a key element for our future success.

10.2 Values: the principles and standards by which we operate.

The IMB must continue to attract, involve, train and develop high calibre staff. The IMB recognises that training and development must encompass relevant technical areas and management skills with particular emphasis on enlightened people management skills. In support of these principles, all IMB personnel will foster a work environment where excellence is recognised and acknowledged, accountability is commensurate with responsibility, and creativity and the free exchange of ideas are encouraged. In addition, all managers and staff of the IMB are responsible and accountable for creating and fostering a work environment in which the following common values guide our actions on an ongoing basis:

10.2.1 Excellence

(a) Operating to the highest standards and focusing on results and value for money.
(b) Recognising that, as an evolving organisation, we must continually assess our systems and structures to ensure best practice.

10.2.2 Dignity and Respect

(a) Treating employees, clients and stakeholders with dignity and respect at all times.
(b) Ensuring that staff are aware of the expected standard of behaviour.
(c) Actively ensuring that the workplace is free of discrimination, prejudice, harassment and any other unacceptable behaviour.

10.2.3 Diversity

(a) Recognising, accepting, respecting and valuing diversity.

10.2.4 Open Honest Communication

(a) Ensure open, honest, transparent and timely communication.

10.2.5 Integrity

(a) Behaving ethically, honestly, fairly and impartially at all times.
(b) Being open and accountable and recognising that we serve the citizens of Ireland and Europe.
(c) Being familiar with and exercising inherent responsibilities concerning relevant Human Resource legislation, policies, regulations, directives and practices.

10.2.6 Health and Safety

(a) Valuing and respecting the need for employees to balance work, personal, family and community lives.
(b) Taking appropriate steps to ensure a safe and healthy work environment.

Finally, the IMB embraces a partnership philosophy, whereby employees are encouraged to be involved in the decision-making processes that affect them and our service to our clients. We seek to create an environment that enables staff and stakeholders to acknowledge each other's roles and contributions, and to work together effectively to protect and further the public health and safety of the Irish people and the health and welfare of farmed and domestic animal populations.

Chapter 11: Objectives and Goals

11.1 Balance between the Planned and Unplanned:

This Strategic Plan and the Board's Annual Work Plans are being implemented to facilitate the work of the Board in meeting our vision. However, unanticipated events will occur throughout the lifetime of any plan and these will also require our attention. Hence, at all times an appropriate balance must be struck between the day to day national and EU operational work and those activities which are required to plan, develop, monitor and review new work which it has been necessary to undertake as a consequence of unplanned occurrences.

To ensure this balance is achieved, the IMB needs at all times to possess the organisational capability to **manage change** while effectively managing current responsibilities and effectively communicating these challenges with our stakeholders. At all times the highest priority of the IMB must be the resolution of issues with potential adverse public or animal health impact.

11.2 Performance Indicators:

Performance Indicators are defined as specific, measurable, time based indicators of success related to particular objectives. They can include quantitative and qualitative descriptions of the services the IMB provides. Performance indicators are essential to a well-managed organisation.

The establishment and implementation of performance indicators each year will be crucial to the success of the IMB. In the future, as part of continuous improvement, existing targets will be refined and new targets developed in all areas of activity so that we will be better able to compare our standards and performance with previous years and with those of similar regulatory agencies who are striving for continuous improvement and excellence. More accurately defined standards will also provide the management information that we need to further refine our processes and resources. Finally, meeting performance standards is critical in allowing us to set fees that are accurate and appropriate.

11.3 Objectives

A number of objectives have been defined based on the mission and vision outlined earlier. It is anticipated that the achievement of these objectives will help to assure that the Irish people will be healthier and the health care system more cost-effective, and that the animal population is healthy, productive and well cared for. These objectives serve as the starting point for the definition of various goals as outlined below and provide the basis for individual departmental objectives and goals. They are:

11. 3.1 Effective Risk Management and Improving Consumer Safety.

1. Provide timely, high quality, cost effective processes for the review of licence applications for medicinal products within agreed timelines to ensure that high quality, safe and effective products are available to the Irish public in a timely manner.

2. Provide timely, high quality, cost effective processes for the review of new technologies/ pre-market submissions/ scientific advice.

3. Develop plans and priorities and manage operations based on the relevant risks and benefits of the medicinal products and medical devices available to the public.

4. Provide timely, high quality, cost effective processes to ensure that medical devices on the market are of safe design, of appropriate quality, perform as intended, and are properly used.

5. Maintain an efficient and effective post-market surveillance system for medicinal products and medical devices based on the analysis and prompt investigation of adverse incident reports, and take any necessary action to safeguard public health.

6. Maintain an efficient and effective post-market surveillance system for medicinal products for human and veterinary use based on pharmacovigilance programmes, investigation of quality defects and a programme of sampling and analysis.

7. Provide timely, high quality, cost effective processes for evaluating whether or not a product should be categorised as a medicinal product or a medical device.

8. Provide a regulatory environment which supports the development and maintenance of an adequate range of authorised veterinary medicinal products for minor species and for minor indications.

9. Provide high quality timely assessment of clinical trial applications for human and veterinary medicines and clinical investigations for medical devices.

10. Provide timely, high quality, cost effective oversight of manufacturing, processing and distribution of human and veterinary medicinal products, blood and blood components, and tissues and cells to reduce risk.

11. Set, and meet, internationally competitive performance standards, which meet stakeholders' needs in all activities.

12. Actively contribute to the development of European and global standards and policies on the quality, safety, efficacy and usefulness of medicines and medical devices.

13. Monitor the safety of medicines, medical devices and blood and blood components.

14. Enhance our ability to identify risks associated with medicinal products and medical devices.

15. Provide timely, high quality, cost effective advice on safe residue limits for veterinary medicinal products used in food producing animals.

16. Take appropriate action to communicate risks and correct problems associated with medicinal products and medical devices.

17. Provide contingency for unplanned urgent activities where public or animal health may be compromised.

18. Actively participate in the European medicinal products and medical devices regulatory regimes.

19. Ensure timely notification of issues to agencies in other countries likely to be affected.

20. Develop enforcement of legislation governing medicinal products and medical devices for human use, in order to meet the challenges posed by illegal activities, and with the primary aim of ensuring that public health is protected.

11.3.2 Effective regulation through the on going development of our work force and non-staff resources.

1. Ensure a high quality, diverse and motivated work force that performs enthusiastically to ensure client satisfaction in a work environment that is flexible and meets their needs and concerns.

2. Maximise efficiencies from effective teamwork between individuals, work units and departments.

3. Ensure fairness and transparency in recruitment and selection of additional staff, and recognition of performance in selection for internal promotion.

4. Increase efficiency and effectiveness of IMB Management.

5. Optimise the use of IT as a strategic tool for realising IMB policy goals and objectives.

6. Provide stable funding.

7. Effectively and efficiently manage resources.

8. Provide appropriate IMB corporate accommodation to improve operations for employees and customers.

11.3.3 Effective communication with all stakeholders.

1. Further develop the IMB communications infrastructure.

2. Operate with the maximum degree of transparency.

3. Ensure effective communication and working relationships with key external stakeholders to enhance health outcomes.

4. Ensure effective communication and knowledge exchange with internal stakeholders to enhance health outcomes.

5. Meet stakeholder needs with the provision of timely, quality services.

6. Disseminate information to all stakeholders in the most comprehensive and effective manner possible making best use of IT resources and developments.

11.4 Work Plans.

Individual annual work plans are developed for each department including:

Human Medicines

Veterinary Medicines

Compliance

Medical Devices

Information Technology

Finance and Corporate Services

Senior Scientific Advisor.

The plan for each function is divided into a number of different areas, specifically these are:

- **Operational Planning:** The 'nuts and bolts' of the business plan. It details the major outputs and processes that the unit performs on a regular basis which could be deemed business as usual.

- **Internal Processes:** The objectives in terms of internal processes, namely those activities that are key to service delivery.

- **People Management:** The objectives in terms of people management and development.

- **Customer Management:** The objectives in terms of customer management.

- **Financial Management:** This section covers the objectives in terms of financial management.

- **Assumptions, Opportunities and Vulnerabilities:** This section provides documentation of assumptions and other factors which could impact on delivery.

Chapter 12: Monitoring and Review

How we implement and monitor/ adapt the Strategic Plan.

This Strategic Plan sets out our mission, vision, values and goals and objectives for the coming years. The successful implementation of these strategies will require the dedication and commitment of all our staff, committees and Board. Annual work plans, prepared by all departments, will build up a concrete annual programme of actions to implement strategies and achieve our goals. In turn, these work plans are used as a basis for the individual work programmes of staff members in the Performance Development Programme (PDP). Annual work plans also help us to integrate strategy and planning as an on-going exercise, which must ensure a flexible response to sudden changes in focus, while allowing us to retain an overall sense of mission.

Work plans will be kept under continuous review with formal reviews at mid-year and year-end. Results of these reviews will be presented to the Board.