IRISH MEDICINES BOARD

Irish Medicines Board
Annual Report 2002

Protecting public health

Mission Statement

"To protect and enhance public and animal health through the regulation of human and veterinary medicines and medical devices available in Ireland, or manufactured in Ireland for Irish or export markets"

Contents

Chairman's Report

I am pleased to present the seventh annual report of the Irish Medicines Board (IMB). The report details the activities and financial statements of the IMB during 2002 and I am happy to advise that the IMB continues to be able to fund its core business without recourse to Government.

It is the working objective of the IMB to protect and enhance public and animal health through the regulation of human and veterinary medicinal products and medical devices on the Irish market and exported from this country. In undertaking this role, IMB staff continue to see a greater interest in this area from all facets of society. The increased awareness of issues and interest in areas of human and veterinary medicines and medical devices has translated into greater demands being placed on the staff at the IMB and I am happy to report that they continue to meet this challenge with professionalism, competency and enthusiasm.

Their consistent effectiveness and efficiency is demonstrated by the fact that following a competitive tender process involving other EU Member States, the IMB was contracted to assist the Maltese Government in establishing a functioning medicines authority for the island of Malta. The IMB led a joint tender with the United Kingdom Medicines Control Agency (now known as the Medicines and Healthcare Products Regulatory Agency - our counterpart in the UK). The project will result in the Maltese Government emulating the IMB's structures and procedures to ensure the safety, quality and efficacy of medicines on the Maltese market. We aim to seek other such income generating projects.

Our efficiencies will be even further enhanced following the completion of the N**IMB**us project, a major information technology development, which incorporates organisational and technological changes for the IMB. Overall these new processes, embarked on in 2002, are designed to streamline licensing activities and ensure the most effective and efficient use of resources in providing a quality service to all stakeholders. Due for completion in 2004, the new systems will bring about many benefits to ensure that we meet the challenges ahead in the most efficient manner possible.

I would like to take this opportunity to welcome the new Chief Executive of the IMB, Mr. Pat O'Mahony, who joined us in December 2002 and who brings a unique proficiency and leadership to the role, complementing the existing strong executive management team in place. We are grateful to the former CEO, Professor Frank Hallinan, who made a significant contribution to the IMB during his four year term in overseeing extensive organisational and managerial changes which provided huge benefits for the efficient and smooth running of the IMB. Professor Hallinan has left us to join Wyeth Biopharma, where we wish him every success.

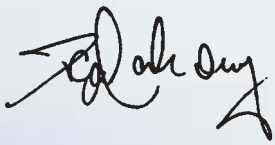
Our efficiencies will be even further enhanced following the completion of the N**IMB**us project, a major information technology development, which incorporates organisational and technological changes for the IMB.

On the financial situation, the IMB continued to conduct its core activities at no cost to the State. We achieved a reasonable surplus for the year – €306,455 (2001: €379,194) before write-back of staff superannuation contributions. Fee income increased by 7.5%, primarily reflecting the fee increase on 1st June 2002. Costs increased by 17.2%. Inflation for the year was running at 4.6%, although increases tended to be in excess of that in labour intensive services. In the main, the cost increase is attributable to increased staff numbers and related staff costs. In particular, general pay increases accounted for a 6.1% increase, staff numbers increased by 9% and the first 25% of benchmarking, backdated to 1st December 2001, was provided for in full. As with previous years, cash flow remained strong and the IMB is in a healthy position facing into 2003. However, payment of the remainder of the benchmarking pay awards will create a major financial challenge in 2004 and subsequent years, particularly as we are required to meet our obligations to remain self-financing. Clearly we must focus very rigorously on cost control.

Throughout 2002 the Board members of the IMB continuously demonstrated their commitment and dedication to the organisation through their greatly valued breadth and depth of expertise. I also very much appreciate the work undertaken by our various expert sub-committees who give the IMB unique access to best advice and who give that access generously.

To safeguard public and animal health, the sharing of information in the field of human and veterinary medicinal products and medical devices for human use is crucial. To this end we are grateful to the various scientific bodies, professional groups and representative organisations, as well as industry, the EU and international scientific and medical organisations whose co-operation is vital to ensuring the highest standards of all medicinal products and medical devices for human use on the Irish market and produced in Ireland for export worldwide.

In addition, the on-going support from the Minister for Health and Children and the Minister for Agriculture and Food is greatly appreciated and valued. The continued co-operation of the dedicated professionals in both departments has, and will continue to contribute to the effective operation of the IMB.



Pat O'Mahony
Chairman

Board Members

Back row (L-R) Dr. Rory Lehane; Mr. Denis Cronin; Ms. Anne Nolan; Mr. PJ O'Connor; Mr. Aidan Murray;
Front row (L-R) Prof. Kevin O'Malley; Ms. Aideen Murphy; Mr. Pat O'Mahony (Chairman); Ms. Breda Dooley

The Board of the IMB was appointed on 2nd March 2001 by the Minister for Health and Children, Mr. Micheál Martin TD in accordance with the powers conferred on him by subsection 2 of section 7 of the IMB Act, 1995 for the period ending 31st December 2005. The Board members are:

Mr. Pat O'Mahony (Chairman)

Mr. Denis Cronin

Ms. Breda Dooley

Dr. Rory Lehane

Ms. Aideen Murphy

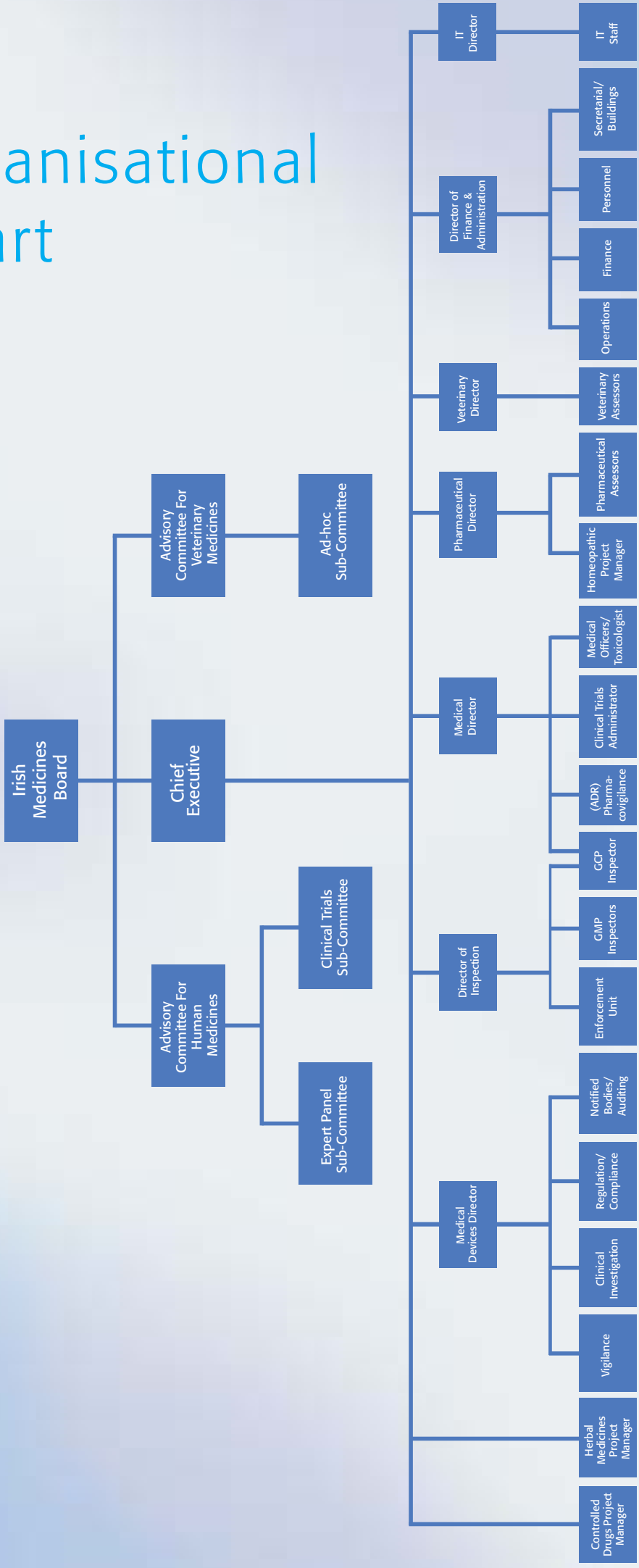
Mr. Aidan Murray

Ms. Anne Nolan

Mr. PJ O'Connor

Prof. Kevin O'Malley

Organisational Chart



Chief Executive's Report

Overview of 2002

2002 was another very interesting year for the IMB, with licensing and inspection activities continuing across the various sectors. In human medicines in excess of 6,500 products are approved while in veterinary medicines, the number of approved products stands at 1,100. Seventy companies maintain manufacturing sites and a similar number of companies operate in the medical devices sector. A total of 1,715 medical devices were registered during the year.

A major item in 2002 was the approval by the Board in January of the IMB's three-year IT strategic plan embracing both information technology and organisational change. The entire planned programme of work is known as N**IMB**us.

The European Medicines Regulatory System

The IMB continued to participate actively in the European Medicines Regulatory System through its involvement in many committees and working parties, in addition to its authorisation activities. The IMB also continued to represent Ireland at the European Pharmacopoeia.

Under the Centralised System, the IMB acted as Rapporteur/Co-Rapporteur for one human medicinal product and one veterinary medicinal product.

In the Decentralised System, the IMB received applications to act as Reference Member State for 55 (2001:19) human medicines applications and 14 (2001:14) applications for veterinary medicines. The IMB completed 20 (2001:13) such applications in the human medicines area as well as 11 (2001:10) in the veterinary medicines area.

In accordance with EC Directive 2001/83, a valid application under the Mutual Recognition procedure can only be refused by a Member State by raising a concern on the basis of significant risks to public health by day 55 of the procedure. The IMB continued to meet all timelines in this procedure in 2002.

Information technology continues to be an important topic on the EU agenda. The Common Technical Document (CTD) and associated eCTD, will bring new demands to the national system. The growth in electronic exchange of information across the EU in areas such as pharmacovigilance also brings challenges to the organisation.

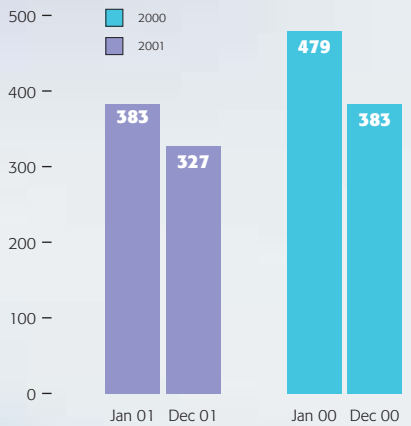
The IMB's Information Technology (IT) department was actively involved in a number of EU information technology initiatives in 2002, including EudraVigilance, eCTD and eDatabase technical implementation groups.

National Regulatory System

In the National Regulatory System, the IMB received 209 national applications compared with 174 in 2001, 153 in 2000 and 108 in 1999, indicating that new national applications continue to increase following the introduction of the European licensing legislation in 1997.

A major item in 2002 was the approval by the Board in January of the IMB's three-year IT strategic plan embracing both information technology and organisational change. The entire planned programme of work is known as N**IMB**us.

While the IMB continues to place a high priority on reducing the backlog of national applications, the total number of applications still in progress increased slightly from 327 in January 2002 to 335 by the end of December 2002. This reflects the increase in national products received, particularly in the latter part of 2002, as depicted in the graph below.



In addition the age profile of this work in progress has changed considerably with 62% of the products being received in the current year.

Communications

A new version of the IMB web site was published in September 2002. The new site incorporates improved functionality and has been warmly welcomed by our stakeholders. The web address is *http://www.imb.ie*.

Industry

During the year, the Board continued to enhance its communication with various groups with an interest in healthcare products. Five information days for industry stakeholders were held. These meetings attracted over 1,000 attendees and positive feedback was received in all cases.

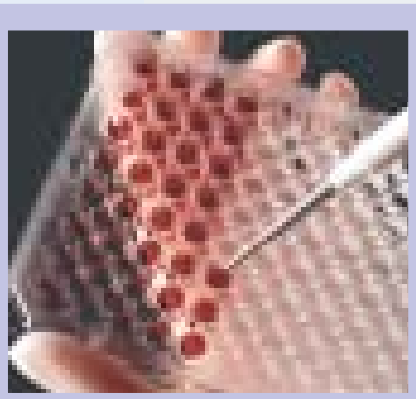
A number of other meetings with organisations and individuals with particular interests in healthcare products were hosted by the IMB during the year. These included meetings with the Animal & Plant Health Association (APHA), the Association of Pharmaceutical Manufacturers of Ireland (APMI), the Irish Association of Health Stores (IAHS), the Irish Health Trade Association (IHTA), the Irish Medical Devices Association (IMDA), the Irish Pharmaceutical Healthcare Association (IPHA), and the Irish Pharmaceutical and Chemical Manufacturers Federation (IPCMF).

Publications

The IMB launched a number of valuable guidance documents as part of its communications efforts during 2002, all of which are available from our web site.

Three editions of the IMB's Medicinal Products newsletter were published and circulated to all PA and VPA holders, manufacturing and wholesale licence holders as well as other interested parties.

The IMB is committed to supporting the regulatory systems in the countries joining the EU as part of the forthcoming enlargement and we hope to continue our support of PERF and other mechanisms in this regard in 2003.

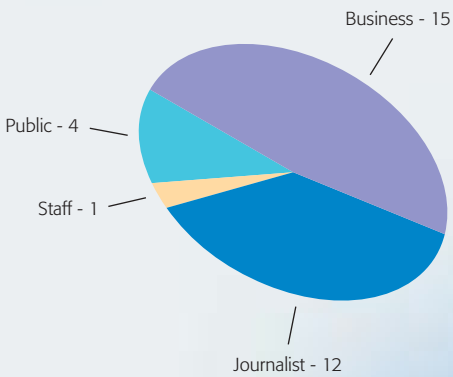


Three editions of the Drug Safety Newsletter were published and circulated to all registered medical and dental practitioners and pharmacists. Two editions of the Medical Devices Newsletter were also published and distributed electronically.

Freedom of Information

Thirty two requests were received under the Freedom of Information (FOI) Act in 2002, four of which could be dealt with outside the FOI Act. This compares to 42 during 2001.

Breakdown of Requests by Source



One request was appealed to the Information Commissioner and a decision on this is pending. In addition, one appeal to the Information Commissioner from 2001 also remains pending.

The Future

A range of issues will, in the future, lead to greater demands and challenges in meeting our mission to protect public health efficiently and effectively.

Provision for payment of the benchmarking pay awards will create a major financial challenge for the IMB in 2004 and subsequent years, and appropriate planning will be undertaken to deal with this issue during 2003.

The IT strategic plan and linked organisational change is the single biggest project ever undertaken by the IMB. We hope that it can transform our information technology systems and assessment activity with consequential major benefits to the IMB and its fee paying stakeholders. In the longer term, the IMB envisages an ever increasing proportion of its communication being carried out via electronic means.

2003 should see the transfer of more responsibilities from the Department of Health and Children in the area of controlled drugs. A simplified registration scheme for homeopathic medicines will be implemented and we await implementation of a licensing system for herbal products.

The IMB is committed to supporting the regulatory systems in the countries joining the EU as part of the forthcoming enlargement and we hope to continue our support of PERF and other mechanisms in this regard in 2003. In addition, the IMB will make particular efforts to work with other EU Agencies in ensuring our staff receive harmonised training in new areas.

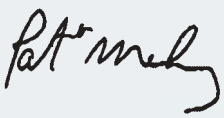
Board and Staff Matters

I want to express my appreciation for the help and advice of the Board members and the members of our Advisory Committees and Sub-Committees throughout the year. I also wish to acknowledge the support of the staff of the Departments of Health and Children, and Agriculture and Food.

IMB staff continue to make important contributions to the various EU committees involved in the regulation of medicinal products and medical devices. Staff members also made a number of presentations relevant to the mission of the IMB. (See Appendices II and III.)

Ms. Suzanne McDonald was appointed Director of Information Technology in April 2002. This appointment is consistent with the Board's commitment to optimising technology in the provision of improved services and organisational efficiency.

I wish to welcome all new staff members who joined during 2002 and to express my personal appreciation to all the staff of the IMB for their continued support in achieving the Board's objectives during the year. A particular word of thanks to all staff who made me very welcome when I took up my new role at the IMB. I look forward to the support of all staff in dealing effectively with the various challenges ahead as we continue to strive for excellence in all aspects of our daily activities.



Pat O'Mahony
Chief Executive

Human Medicines

Licensing

During 2002, the IMB issued 682 product authorisations. The following table shows the distribution of these over the last number of years:

Year	2000	2001	2002
New Products National	174	199	98
New Products EU Mutual Recognition	184	158	147
New Products EU Centralised*	45	35	38
Transfers	280	254	399
Total	**683**	**646**	**682**

*(*Total number of centralised authorisations issued by the European Commission)*

The median time for new product authorisations issued (excluding transfers) in 2002 was 45 weeks which was the same as 2001 and 2000, but compares to 73 weeks in 1999. This reflects the maintenance of improvements in timelines by the Board in 2002.

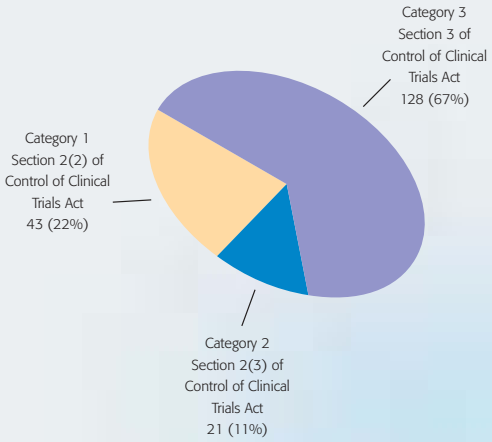
During the year, 5,365 variations to product authorisations were issued for products authorised through the national or MR systems.

Clinical Trials

The IMB's role in the Control of Clinical Trials Act 1987 and 1990 is focused on protecting the interests of participants. Clinical trials may not be carried out legally unless the requisite permission has been obtained from the Board. The Board continued to meet the statutory timelines defined in the legislation and benefited greatly from the advice and expertise of the members of its Clinical Trials Sub-Committee.

There were 192 applications to conduct clinical trials during 2002, which was a increase on the figure of 184 received during 2001.

These can be categorised as follows:



Two hundred and sixty four amendment applications were received.

The European Clinical Trials Directive (2001/20/EC) was published in April 2001. Member States are required to legislate nationally in order to comply with the provisions of the Directive before May 2003 and to apply the Directive's provisions with effect from 1st May 2004. The European Commission held four meetings during 2002 aimed at developing EU guidelines to support the Directive.

Nine Good Clinical Practice inspections were conducted during 2002.

Pharmacovigilance

During 2002, the IMB received 1,661 adverse drug reaction (ADR) reports of national origin. This figure represents a decrease on the number of reports received in 2001 (2,282). However, analysis of the 2001 figures shows a significant number of reports received during the period were associated with stimulated reporting following introduction of the meningitis C immunisation campaign. When adjustment is made for these reports, the overall figure for 2002 represents a continued, steady increase in the volume of ADR reports received. This increase in ADR reporting is very much welcomed as a sign of increasing awareness of pharmacovigilance on the part of healthcare professionals and a response to initiatives taken by the IMB to stimulate reporting.

During 2002, the IMB continued to encourage ADR reporting using the downloadable version of the report form (from the website) and provided regular reminders about reporting in the Drug Safety Newsletter and in MIMS (Ireland). A series of presentations on pharmacovigilance and ADR reporting were also made to post-graduate pharmacists as part of a continuing education programme.

Breakdown of Reports by Source

Marketing Authorisation Holders	30.6%
General Practitioners	19.9%
Clinical Trials	18.4%
Community Care Doctor	14.0%
Hospital Doctor	7.6%
Community Pharmacists	5.4%
Nurses	2.3%
Hospital Pharmacists	1.6%
Dentists	0.2%

All ADR reports were followed up, with feedback information provided to reporters, as appropriate. Relevant ADR reports (i.e. all serious, suspected cases) notified directly to the IMB by healthcare professionals were forwarded to the appropriate Marketing Authorisation Holders (MAHs) and to the EMEA within the agreed timeframes. An update of all reports received was also provided to the World Health Organisation (WHO) on a monthly basis, for inclusion on the international database.

Drugs Withdrawn for Safety Reasons

There were no withdrawals for safety reasons in 2002.

International Collaboration

There were a total of eight meetings of the Committee for Proprietary Medicinal Products (CPMPs) Pharmacovigilance Working Party (PhVWP) during 2002. During these meetings the PhVWP considered product related issues at the request of CPMP. Issues considered related to centrally authorised products, products subject to referral procedures, and nationally authorised products for which no referral has been made. Product related issues were also considered at the request of the competent authorities of the Member States. Over the year an increased number of issues were referred to the PhVWP both by CPMP and Member States. The PhVWP continued its regular interaction with the U.S. Food and Drug Administration (FDA) through video conferences held during Working Party meetings.

PhVWP sub-groups continued to develop and review guidance on organisational issues and to consider relevant class-related effects.

Staff from the Pharmacovigilance and IT Units of the IMB participated in the Joint Pilot Project meetings, which were held at the EMEA, to facilitate participation with implementation of the EU-mandated system of electronic reporting of Individual Case Safety Reports (ICSRs) by pharmaceutical companies and regulatory agencies.

Information was provided in respect of all requests circulated via the rapid alert/infofax system by other Member States. All suspected serious Irish ADRs notified to the IMB in association with centrally authorised products were provided to the EMEA at the designated intervals throughout the year.

Drug Safety Newsletter

Three issues of the IMB's Drug Safety Newsletter were circulated to doctors, dentists and pharmacists in January, July and December 2002. Topics reviewed in the newsletter are listed below and this information from the newsletters is available to interested parties.

- fluoroquinolone antibiotics
- infliximab
- cyproterone acetate
- non-steroidal anti-inflammatory drugs
- levofloxacin
- hepatitis A vaccine
- topiramate
- nimesulide
- hormone replacement therapy
- dopaminergic substances
- HMG-CoA reductase inhibitors
- angiotension-converting enzyme inhibitors
- erythropoietins
- single component vaccines
- the Privacy Directive
- ADR reporting

Company Liaison

Advice on IMB ADR reporting requirements and provision of Periodic Safety Update Reports (PSURs) was provided on request throughout the year. Anonymised ADR information was provided, on request, to Marketing Authorisation holders in respect of their products, and in respect of serious ADRs associated with use of their products, on an expedited basis.

Ongoing discussions were held with the National Haemovigilance Office (NHO) regarding the progress and activities of the National Haemovigilance Programme.

EU/International Activities

During the year IMB staff continued to devote significant effort to the international dimension of human medicines within the CPMP and its working parties, European Pharmacopoeia, European Commission and the International Conference on Harmonisation (ICH), as outlined in Appendix II.

In addition, the IMB continued to support the following meetings:

- Annual Meeting of the WHO Collaborating Centre
- Irish Society of Toxicology
- European Society of Toxicology

The IMB hosted a training course on Biotechnology in Kinsale in May 2002. This was the first in a series of EU assessor training seminars arising from an initiative championed by the IMB and was attended by assessors and inspectors from a number of EU Member States and from some of the candidate countries.

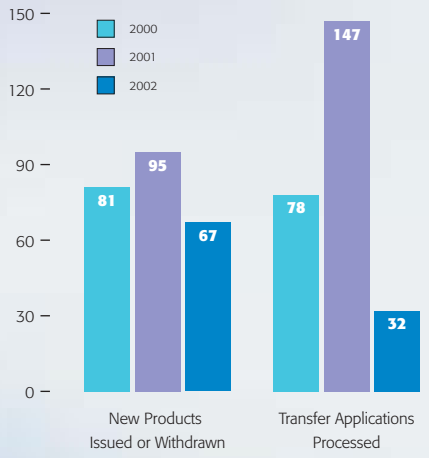
Staff

Dr. Marie Burns resigned from her post in October 2002. Marie joined the NDAB in 1978 and made an enormous contribution in her various roles as medical assessor, deputy medical director and medical director during her long service. More recently, she represented the medical department at the Lindsay Tribunal.

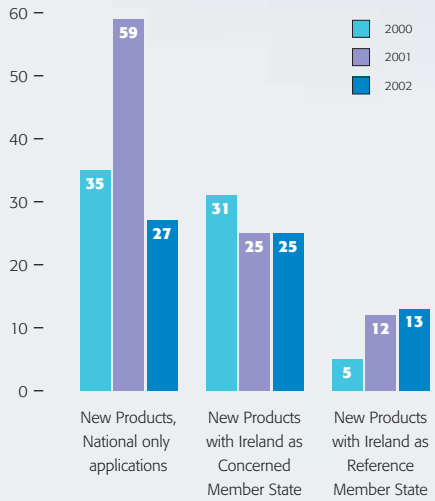
Veterinary Medicines

Licensing

Throughout 2002, the efficiencies of the licensing processes achieved over recent years were maintained. During the year, 67 new product authorisations were issued or withdrawn compared to 95 in 2001 and 81 in 2000. These figures in part represent the success of the IMB in the years 2000 and 2001 in clearing backlogs of applications for veterinary medicines nationally and in part by a decline in the number of new applications being developed by the animal health industry globally. A major success was the virtual elimination of the number of transfer applications awaiting approval during the year with only one single application pending by year end as is displayed graphically below:

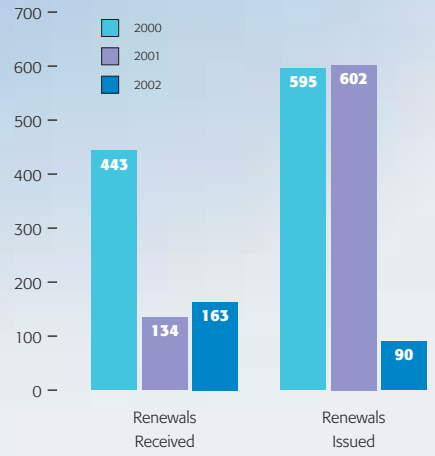


In relation to new product authorisations issued, the following graph illustrates the changes over the period 2000 – 2002.

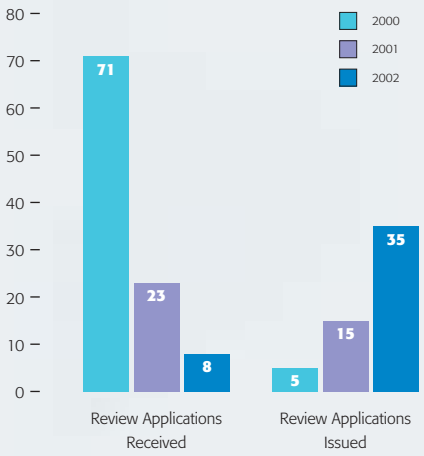


While the number of Mutual Recognition (MR) procedures involving Ireland as a Concerned Member State (CMS) or a Reference Member State (MS) was on par with 2001, the complexity of the applications increased insofar as the average number of CMSs per procedure and the number of questions raised on individual applications increased. The IMB met all its targets for timelines for the evaluation of applications submitted under the MR and centralised procedures.

Progress in renewal of pharmaceutical applications was also maintained during the year, albeit that the backlog of applications had been all but eliminated in the previous period. While a nadir for the work-in-progress figure of 42 was reached by mid-year, more than three times the number of applications for renewal of veterinary product authorisations (VPAs) was received in the second half of the year resulting in a year end closing figure of 137. The progress in the receipt and issue of renewal of applications for product renewals is illustrated in the following graph.

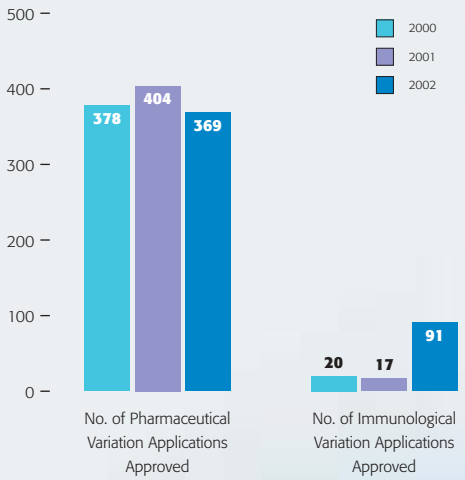


In relation to veterinary vaccines, progress on the review of existing products (conducted on behalf of the Department of Agriculture and Food), has been steady with the work-in-progress figure declining from 123 at the end of 2001 to 88 at the end of 2002. The progress in the receipt and issue of renewal of applications for vaccine review is graphically illustrated below.



The call-up of review applications for vaccines has now been completed. Every effort will be made to maintain the progress towards the goal of achieving closure of the review as soon as possible. The evaluation of vaccines for compliance with the EU directive on Transmissible Spongiform Encephalopathies (TSEs) was also completed during the year.

The number of variation applications approved for the year under review was 460. This compares favourably with 421 variations approved in 2001 and 398 in 2000 as graphically outlined below.



As in previous years, approximately 80% of the variations to VPAs related to the quality or manufacturing details. The increased activity in relation to veterinary vaccines reflects the fact that more vaccines are authorised than in previous years.

The increased complexity of the regulatory environment is also evidenced by a trend for an increased number and duration of meetings of the scientific committees of the European Medicines Evaluation Agency (EMEA) and, similarly, of regulatory meetings such as the Veterinary Mutual Recognition Facilitation Group (VMRFG). This development may reflect the state-of-the-art increases in the regulatory standards themselves as well as the preparation for EU enlargement to the central and eastern European Candidate Countries in 2004. Nationally, the regulatory climate also remains challenging.

Other Business Activities

Performance in the delivery of other business activities by the Veterinary Department was satisfactory. Some 11 applications for harmonisation of product labelling with products authorised in the UK were received during 2002, compared to nine for the previous year. During the year, the Veterinary Department received 80 classification enquiries for borderline products compared to 66 in 2001. By year-end, discussions were taking place between the IMB and the Department of Agriculture and Food on the borderline between the definition of an 'Animal Remedy' and the definition of a 'biocidal' product. It is expected that once these discussions are concluded, the IMB will issue an update to its Guide to the Definition of an Animal Remedy.

The Veterinary Department received two applications from the Department of Agriculture and Food for a recommendation on clinical trials in animals. This compares with five applications in 2001.

Pharmacovigilance

The IMB received 62 reports of Suspected Adverse Reactions (SARs) to veterinary medicinal products (VMPs) in 2002. Fifty reports were received from the marketing authorisation holder (MAH), five directly from veterinary surgeons in practice, four from veterinary surgeons in the regional veterinary laboratories, two directly from animal owners and one from a pharmaceutical company not responsible for the VMP that was the subject of the report.

Of the total number of SARs reported, 46 involved veterinary medicinal products and 21 concerned vaccines. The majority of SAR reports (n=58) related to an individual VMP, with two or more VMPs identified in only four reports. SARs were reported in the following species: human (1), cattle (25), horses (4), sheep (10), pigs (4), dogs (14), cats (3) and rabbit (1).

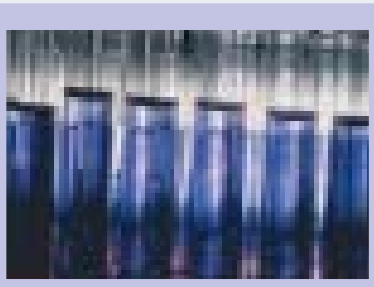
Lack of expected efficacy was reported for 20 VMPs. These included three reports relating to inefficacy of triclabendazole against *Fasciola hepatica* in sheep; one report of inefficacy of fenbendazole against nematodes in lambs; and, two reports of inefficacy of synthetic pyrethroids against lice in cattle. In all cases, it was indicated that the VMP in question was used in accordance with label recommendations and a positive response to treatment with alternative classes of active substance was reported. It is possible, although not confirmed, that resistance was responsible for the reported lack of expected efficacy in some of those cases.

Of the remaining reports, the product(s) used was considered to have been probably, or possibly, associated with the observed reaction in 21 cases. In a further 14 cases there was insufficient information on which to base a conclusion relating to causality and, in the remaining seven cases, it was concluded that the VMP(s) was definitely not the cause of the observed reaction.

A more detailed report of the SARs for 2002 will be made available on the IMB website *(www.imb.ie)*, or on request from the veterinary department.

During 2002, the IMB was also active in dealing with issues of lack of compliance by marketing authorisation holders, both in relation to the labelling and promotion of authorised products and also in investigating reports of possible adverse reactions.

The IMB made an oral presentation to the Dáil Committee on Agriculture and Food in February 2002 on the subject of the regulation of intramammary antibiotics and veterinary vaccines in Ireland.



Communications

The IMB made an oral presentation to the Dáil Committee on Agriculture and Food in February 2002 on the subject of the regulation of intramammary antibiotics and veterinary vaccines in Ireland.

An IMB Veterinary Information Day was held on 14th June 2002 in Dublin. This meeting considered the proposed changes in the veterinary medicines legislation, medicines availability, and updates of progress on licensing activities in the Veterinary Department.

During the year, the Veterinary Department issued various advices to its stakeholders, including the following:

- The importance of disclosing information on authorised veterinary medicines, which affect the quality, safety or efficacy of the product as well as any restrictions applied to the product by other regulatory authorities.
- The operation of the MR procedure where a product has been authorised by another Member State.
- The policy in relation to the implementation of packaging changes to veterinary medicinal products in Ireland.
- The policy in relation to the provision of mock-ups of product labelling and packaging.

Inspectorate

Summary of Activity

A summary of the main activities in 2002 is shown in the tables below with comparative figures for preceding years.

	2000	2001	2002
Inspections in Ireland	77	53 manufacturers 108 wholesalers	44 manufacturers 36 wholesalers
Manufacturer's/wholesaler's licence revocations	0	1 veterinary manufacturer	0
New human manufacturers' licences issued	4	6	6
New veterinary manufacturers' licences issued	1	2	3
New wholesaler's licence issued	6	5	4
Variations issued to human manufacturers' licences	69	136	191
Variations issued to veterinary manufacturers' licences	10	31	27
Variations issued to wholesaler's licences	10	23	19
Total number of manufacturers of medicinal products for human use	75	74	77
Total number of manufacturers of medicinal products for veterinary use	22	24	27
Total number of wholesalers	73	84	83

2002 saw a significant increase in the number of inspections in non-European Economic Area (EEA) countries.

	2000	2001	2002
Foreign inspections	5	7	15

Product Certification Activity

During 2002, the IMB issued 2,217 export certificates as shown below with the corresponding numbers for preceding years. The number of certificates issued during 2002 was down on the figure for 2001. However, the figure for 2001 was considerably boosted by a major project undertaken by one company in relation to registration of products in a number of export markets.

	2000	2001	2002
Certification of Documents	372	525	432
Certificates of Free Sale	64	170	72
Certificates of Manufacture and Free Sale	28	10	6
Certificates of Good Manufacturing Practice for Finished Products	171	242	196
Certificate of Good Manufacturing Practice for Active Pharmaceutical Ingredients (new category 2002)	-	-	40
Certificates of a Pharmaceutical Product (Human and Veterinary)	1,228	-	-
Certificates of a Pharmaceutical Product for Human Use	-	1,403	1,207
Certificates of a Pharmaceutical Product for Veterinary Use	-	369	246
Other	14	11	18
Total	**1,877**	**2,730**	**2,217**

Quality Defects on Human and Veterinary Medicinal Products

The Inspectorate Department coordinates the IMB's activities in relation to quality defects in both human and veterinary medicinal products. A total of 125 quality defects in human and veterinary medicinal products were reported to, or identified by, the IMB in 2002. This represents a very substantial increase from 2001 (an increase of 300%).

The IMB has worked to promote awareness among healthcare professionals and industry on the need to report quality defects in medicinal products to the IMB , and this may help explain in part the large increase in quality defects reported and identified during 2002.

The IMB's quality defect, product recall, and market-surveillance programmes are strongly interlinked, and they are also integrated fully with other inspection activities. These topics were discussed during the Inspectorate Information Days which took place in late 2001 and 2002. These Information Days provided an opportunity for the IMB to highlight the work in these areas and feedback obtained suggests that there is improved understanding of when quality defects need to be reported.

In 2002, 101 reports of quality defects concerning human medicines and 24 reports concerning veterinary medicines were received. The tables below show how the quality defects were classified, and for comparison, the corresponding figures for 2000 and 2001 are also presented. Note that a number of these quality defect reports resulted in product recalls being requested by the IMB during 2002, or in the issuance of Rapid Alert Notifications of a quality defect to other competent authorities. The information presented in the section below on Product Recalls includes recalls that were requested by IMB as a result of quality defect investigations.

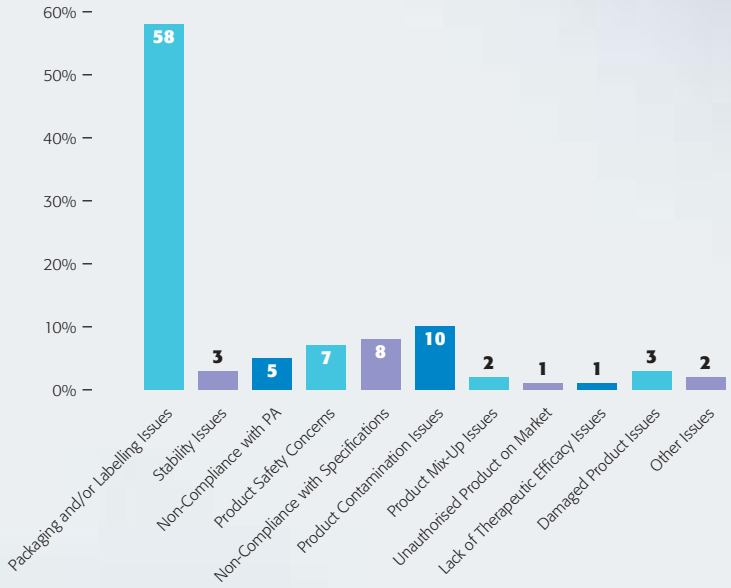
	Human Medicinal Products			Veterinary Medicinal Products		
Year	**2000**	**2001**	**2002**	**2000**	**2001**	**2002**
Minor Quality Defects	16	21	24	0	0	3
Major Quality Defects	5	5	67	0	1	19
Critical Quality Defects	0	1	6	0	0	0
Number of Quality Defect Reports Not Justified	16	3	4	0	0	1
Number of Quality Defect Reports Not Yet Classified	0	0	0	0	0	1
Total Number Quality Defects Reported/ Identified for the Year	**37**	**30**	**101**	**0**	**1**	**24**

Regarding the six human medicine quality defect reports received and investigated during 2002 that were classified as Critical Defects, each report was investigated, and none of the affected batches from any of these products was distributed on the Irish market.

One of these critical quality defects involved a product manufactured in Ireland. This related to a product mix-up in which the labels used on a batch of a paediatric product did not match the contents of the packs. While the product in question had not been marketed in Ireland, a Rapid Alert Notification of a quality defect was issued by the IMB to the competent authorities of the relevant export markets, so that the batch could be recalled in those markets.

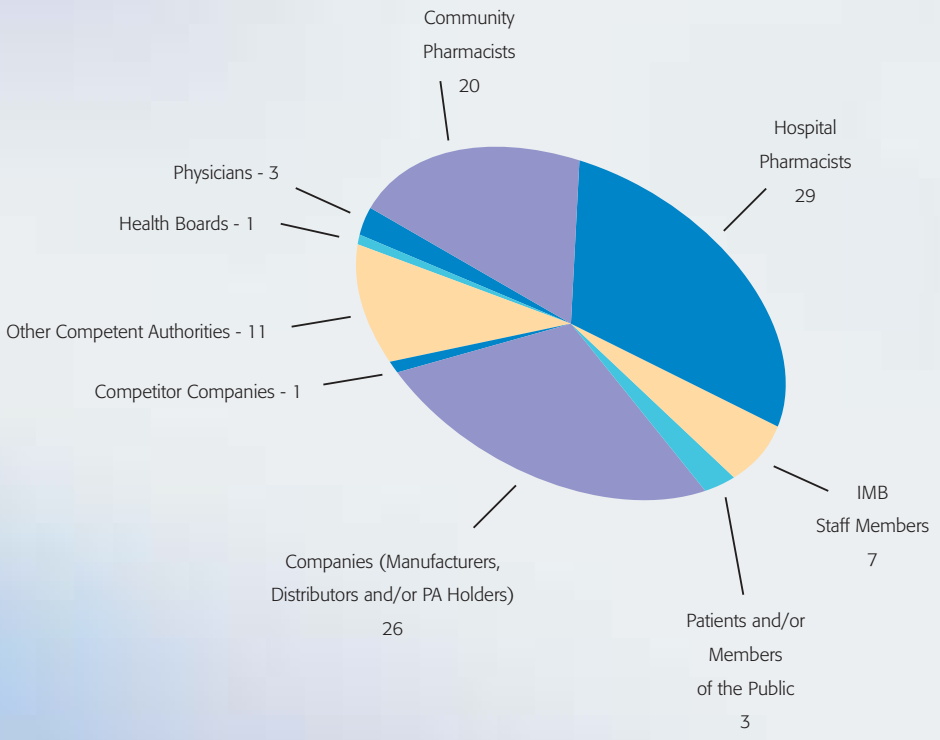
In 2002, 58% of the total number of quality defects reported and identified concerned packaging and labelling issues. Other quality defects related to contamination issues, non-compliance with specification issues, product safety concerns, non-compliance with product authorisation requirements, and others. The following chart provides details in this regard.

Areas of Quality Defects for 2002

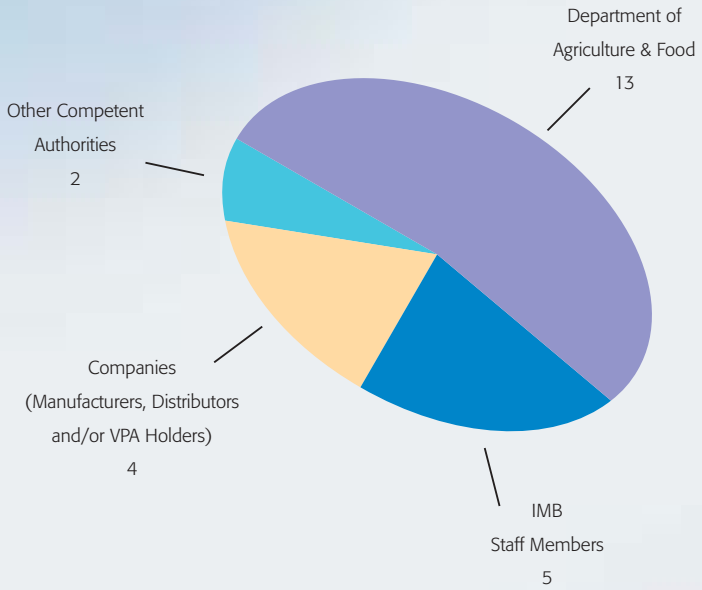


Five quality defect reports were found to be *unjustified*, in that no defect was found with the products and/or the complaint could not be substantiated. One quality defect report for 2002 has not yet been classified, because analytical work is continuing on this product.

The reports of human medicinal product quality defects came from:



The reports of veterinary medicinal product quality defects came from:



Recalls of Human and Veterinary Medicinal Products

A total of 70 recalls of medicinal products took place in Ireland during 2002. This represents an increase of 22% over 2001, and again, packaging and labelling errors were the largest single contributor to the total number of recalls.

Recalls of Medicinal Products for Human Use

The following table shows the total number and distribution of recalls of medicinal products for human use that took place in 2002 compared with 2001 and 2000.

Human Medicinal Product Recalls

Year	2000	2001	2002
Packaging issue	8	15	15
Stability issue	8	5	6
Non-compliance with Authorisation	13	1	6
Product safety concerns	7	3	8
Non-compliance with specification	4	7	7
Other	6	7	9
Total No	**46**	**38**	**51**

Recalls of Veterinary Medicinal Products

The following table shows the total number and distribution of recalls of veterinary medicinal products that took place in 2002 compared with 2001 and 2000.

Veterinary Medicinal Product Recalls

Year	2000	2001	2002
Sterility issue	0	0	0
Packaging and/or Labelling issue*	0	0	9
Stability issue	0	1	1
Product Contamination issues*	0	0	7
Product Safety Concerns*	0	0	1
Non-compliance with Authorisation	2	4	1
Other	0	11	0
Total No	**2**	**16**	**19**

*New categories introduced for the 2002 Annual Report to provide more explanatory information.

Sampling and Analysis of Medicinal Products

Surveillance of the marketplace by the IMB is achieved through the implementation of the sampling and analysis programme. This programme monitors the quality of authorised medicinal products, the quality of medicinal products that are the subject of applications for product authorisations, medicinal products manufactured in Ireland and intended for export, and compliance to legislation governing the authorisation of medicinal products.

The programme is based on an annual sampling and analysis plan drawn up by the sampling and analysis committee of the IMB. The committee is comprised of representatives from the Pharmaceutical Department (human and veterinary), the Inspectorate Unit, the Enforcement Unit and Herbal Medicines. Input is also received from the laboratories.

Eighty five medicinal and other products available on the Irish marketplace were examined in 2002. The figure for 2001 was 54. Five centrally authorised medicinal products were also tested on behalf of the European Directorate for the Quality of Medicines (EDQM). Additionally, four centrally authorised medicinal products available in Ireland were sampled by the IMB on behalf of the EDQM for testing by EU Official Medicines Control Laboratories (OMCLs).

Four proficiency testing studies were successfully undertaken in 2002 by the Public Analyst's Laboratory, Galway, as part of the EDQM's Proficiency Testing Study (PTS) scheme. This scheme is designed to measure the technical competence of the laboratories used in the testing of centrally authorised medicinal products.

A breakdown of the medicinal product categories that were physico-chemically analysed in 2002 is given in Figure1.

Two out-of-specification results were found. One product sample was found to be out-of-specification with respect to its content of active ingredient per unit dose and one product sample was found to be out-of-specification with respect to the appearance of the tablets. All issues were followed-up with the authorisation holders/ manufacturers involved.

The sampling and analysis programme also identified a large number of deficiencies associated with the analytical methods provided by companies for analysis work. During 2002, a total of thirteen medicinal products selected for physico-chemical testing were associated with analytical method deficiencies. This is an increase of more than 80% when compared with 2001. While this increase may be due in part to the increased market surveillance work performed by the IMB in 2002, it is recognised that analytical method deficiencies is an area that must be addressed by companies, and the IMB is following up with all companies concerned in this regard.

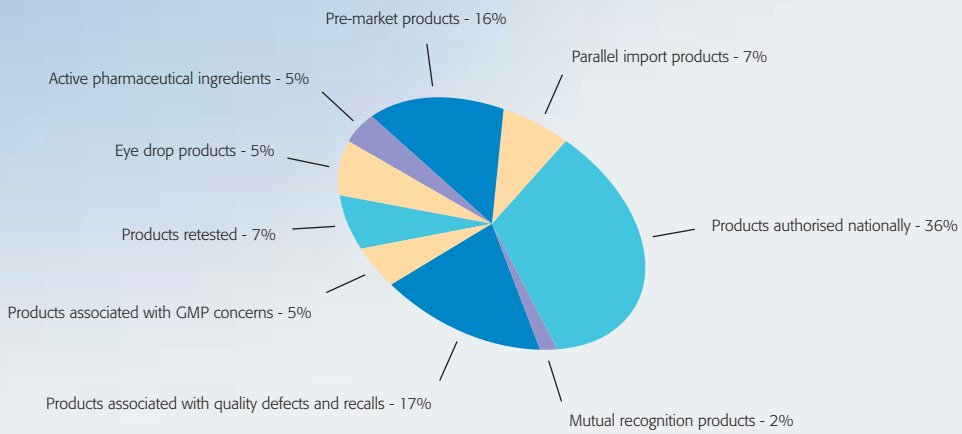


Figure 1: Product categories sent for physico-chemical testing during 2002.

Microbiological testing was carried out on eight medicinal products sampled from the marketplace during 2002. The majority of these products were eye drop formulations (see Figure 2). One sterile product was found to fail the preservative efficacy test, and this product is the subject of ongoing follow-up work with the product authorisation holder.

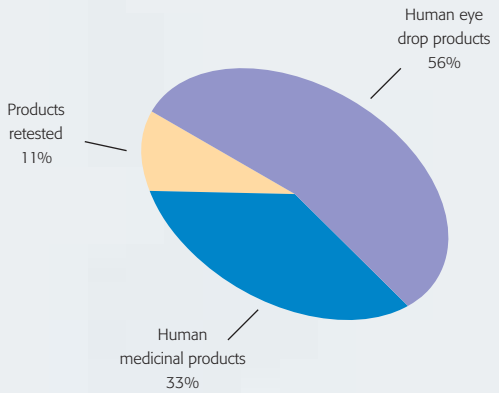


Figure 2: Product categories sent for microbiological testing in 2002.

During 2002, 22 medicinal products were also inspected at the premises of the IMB for labelling and packaging compliance as part of the IMB's post-marketing surveillance work.

The IMB would like to acknowledge co-operation received in relation to the operation of the sampling and analysis programme and to especially thank the staff of the Public Analyst's Laboratory, Galway, for their invaluable contribution to the IMB sampling and analysis programme. Additionally, thanks to the Public Analyst's Laboratory, Galway, the State Laboratory, Abbotstown, Dublin 15, Microchem, Dungarvan, Co. Waterford, and the Toxicology Laboratory, Beaumont Hospital, Dublin 9 for conducting the analytical work.

National

One of the key issues during 2002 was checking on compliance with the product/marketing authorisation. In one instance, the failure of a product authorisation holder to report out of specification stability data to the IMB led to the recall of a number of batches and the suspension of the product authorisation.

The IMB emphasises the need for manufacturers to ensure that stability data are available to key personnel and, particularly, to qualified persons.

Assessment of adherence of manufacturers and marketing authorisation holders to pharmacovigilance requirements continued during 2002. In one instance, it was found that a significant number of adverse reactions relating to one product had not been reported due to a software problem.

Inspections of manufacturers of Active Pharmaceutical Ingredients continued during 2002 and, in general, the standard of GMP compliance of

such manufacturers was found to be acceptable and a number of GMP certificates were issued.

Regular liaison meetings continued with the Animal and Plant Health Association (APHA), the Association of Pharmaceutical Manufacturers of Ireland (APMI) and the Irish Pharmaceutical and Chemical Manufacturers Federation (IPCMF).

An Information Day for manufacturers was held on the 27th September, at which a range of national and international issues was covered.

One inspection each of the National Blood Centre and the Cork Centre of the Irish Blood Transfusion Service were carried out during 2002. Two inspections of mobile clinics and one inspection of a storage site for raw materials for a mobile clinic were also carried out.

EU/International Activities

The following was the status at year-end of the Mutual Recognition Agreements (MRAs) which had not been fully implemented at the end of 2001:

Canada

Progress was made towards implementation of this MRA and it was anticipated that implementation would take place early in 2003.

Japan

An eighteen-month preparatory phase commenced on the 1st January 2002. Mutual assessment of legislation and GMP guidelines progressed during 2002.

Switzerland

Full implementation of this MRA took place on the 1st June 2002.

USA

Implementation of this MRA did not progress to any appreciable extent during 2002.

Members of the inspectorate continued to participate actively in the ad hoc working party of GMP Inspection Services and in the Committee of Officials of the Pharmaceutical Inspection Co-Operation Scheme (PIC/S).

The following new Annexes to the EU Guide to GMP were implemented on the 1st January 2002:

- Annex 16 'Certification by a Qualified Person and Batch Release'.
- Annex 17 'Parametric Release'.

Consultation relating to proposed revision to two Annexes was completed during 2002. These were:

- Annex 1 'Manufacture of Sterile Medicinal Products'.
- Annex 13 'Manufacture of Investigational Medicinal Products'.

It was anticipated that revised texts for these two Annexes would be formally adopted during 2003.

Greece and Malaysia became members of the PIC/S at the beginning of 2002. Re-evaluation of two Member States was carried out under the Joint Reassessment Programme.

The Committee of Officials of the PIC/S endorsed a proposal for an International Medicines Inspectorates Database.

An EU Directive on Blood Transfusion, 2002/98/EC, was adopted during 2002.

A PERF meeting for GMP Inspectors from Candidate Countries was organised by the EMEA in Dublin, in 2002. IMB personnel made a number of presentations and facilitated workshops at the meeting.

Enforcement

The IMB's enforcement unit initiated 515 cases involving breaches of Medicinal Product Regulations during 2002 as compared to 244 in 2001. Public awareness of the IMB's role in safeguarding public health has led to an increased reporting and detection of breaches of the legislation. The closure of enforcement cases in 2002 increased to 29.6 cases per month compared with 13.1 per month in 2001 and 5.8 per month in 2000. There was an increased level of cooperation and more timely willingness to comply in some of the areas targeted for action and this enabled a timelier conclusion of investigations.

The breakdown of cases in 2001 and 2002 is shown in Figure 1.

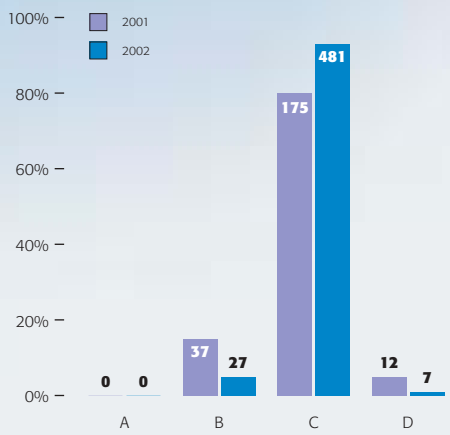


Figure 1: Case Categories

Outlined in Figure 2 is the distribution of cases by sector in 2002:

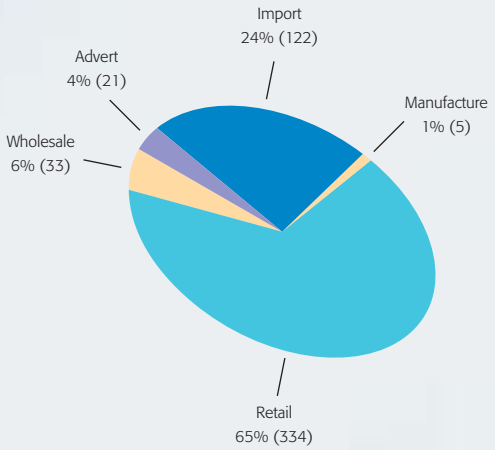


Figure 2: Breakdown of Breaches 2002

Category A: Urgent. A serious health risk which potentially involves a large number of persons.

Category B: Immediate. Serious health risk but not involving a large number of persons.

Category C: No immediate health risk involved.

Category D: Routine complaints without specific information or evidence which do not merit Category A, B or C.

The IMB targeted the unauthorised supply by unlicensed wholesalers and by grocery retail outlets of both unauthorised and authorised medicinal products. This project accounted for 65% (284) of all cases investigated in 2002. Seventy percent (199) of these cases involved the sale, from grocery retail outlets, of pharmacy confined medicinal products, both authorised and unauthorised. In 74% (211) of these cases the medicinal products detected were unauthorised medicinal products. The remaining 26% (73) involved authorised products restricted to sale from pharmacy outlets only.

Wholesale breaches accounted for 6% (33) of all cases investigated in 2002. The majority, of these 76% (25), involved unlicensed wholesalers. The remaining 24% comprised of licensed wholesalers acting in breach of the conditions of their wholesaler's license.

Manufacturing accounted for 1% of cases investigated. All these cases involved unlicensed manufacturing. This figure does not include unauthorised importations.

Inappropriate advertising of medicinal products accounted for 4% (21) of all cases in 2002. This compares favourably with 39% (95) in 2001 and reflects IMB targeted action in the advertising sector in 2001. This decrease reflects a greatly increased level of compliance and cooperation by both advertisers and publishers during 2002. Ninety six percent of all products involved in advertising breaches were prescription only medicines.

Public awareness of the IMB's role in safeguarding public health has led to an increased reporting and detection of breaches of the legislation.

The unauthorised importation of medicinal products includes those originating from outside the EU and those resulting from mail order advertisements, mainly from the Internet. This sector accounted for 24% (122) of all investigations in 2002. Mail order supply of medicinal products accounted for 53% (65) of cases involving importations. While this equates to 12.5% of all the 2002 cases, as compared to 18% (43) in 2001 and 27% (41) in 2000, the actual number of cases at 64 is greater than in each of the preceding two years. However, with increased international liaison and cooperation the potential for breaches facilitated by the Internet is constantly being restricted. This illegal trade in the mail order supply of medicinal products continues to be a significant issue. International liaison action resulted in one Dutch based Internet site and one UK based site ceasing to supply Ireland with medicinal products by Internet. One Irish supplier supplying into the EU for a US based Internet site ceased such supply following IMB action. The IMB will continue to cooperate with colleagues in other law enforcement and Regulatory agencies at home and abroad in monitoring this area.

During 2002, the IMB seized a total of 44,000 tablets and capsules, 209 litres of liquids and 13 kgs of creams. In 3 investigations, legal proceedings were initiated. All 3 cases are due for hearing in 2003.

Medical Devices

Summary of Activity

In the year 2002, in the newly formed Medical Devices department of the IMB, the recruitment and training of staff was a key priority to ensure the functions of the IMB as the Competent Authority (CA) for medical devices were fulfilled.

Registration

In the year 2002, manufacturers registered a total of 1,715 medical devices with the IMB. A total of 700 *in-vitro* diagnostic medical devices (IVDs) and 1,015 general medical devices (GMDs) were registered.

The following tables represent summaries of the registrations made in 2001 and 2002.

Table 1: Number of devices, grouped by device product family, placed on the register in 2002

General Medical Devices – Total Devices Registered = 1,015

Device Product Family	Number of Devices	
	Oct-Dec 2001	2002
Reusable Instruments	2	78
Active Implantable Devices	0	0
Non-Active Implantable Devices	0	14
Dental Devices	16	413
Ophthalmic and Optical Devices	7	23
Diagnostic and Therapeutic Radiation Devices	0	1
Anaesthetic and Respiratory Devices	0	25
Electro-Mechanical Medical Devices	0	12
Technical Aids for Disabled People	0	242
Hospital Hardware	4	65
Single Use Devices	3	142
Total	**32**	**1,015**

***In-vitro* Diagnostic Medical Devices – Total Devices Registered = 700**

Device Product Family	Number of Devices	
	Oct-Dec 2001	2002
In-vitro Diagnostic Medical Devices	782	700

Table 2: Classification of devices registered in 2002

Device Group	GMD		IVD	
	Oct-Dec 2001	2002	Oct-Dec 2001	2002
Class I Devices	15	413	-	-
Custom-Made Devices	14	565	-	-
System & Procedure Pack	3	22	-	-
Other (GMD)	0	15	-	-
List A	-	-	41	46
List B	-	-	43	56
Self Test	-	-	2	2
Other (IVD)	-	-	696	596
Total	**32**	**1,015**	**782**	**700**

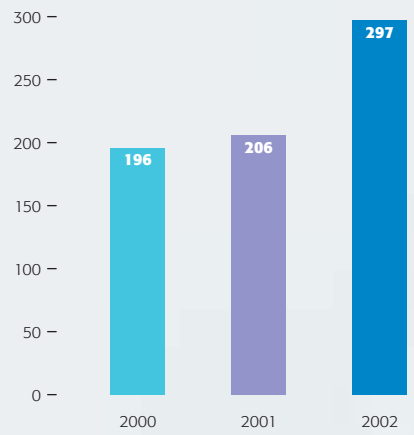
Certificates of Free Sale

In 2002, 222 Certificates of Free Sale were issued by the IMB. While paper based and electronic submissions of applications were accepted during 2002, all manufacturers were submitting their completed application forms electronically by the end of the year. With regard to the expiry date on Certificates of Free Sale, policy in this area was reviewed and it was decided to extend the expiry date of Certificates of Free Sale from one to two years. This applies to all Certificates of Free Sale issued from the 1st January 2003. It is the responsibility of the manufacturer/authorised representative to inform the IMB of any changes made to their Notified Body Certificate or if the Notified Body Certificate for a product has been withdrawn.

Vigilance

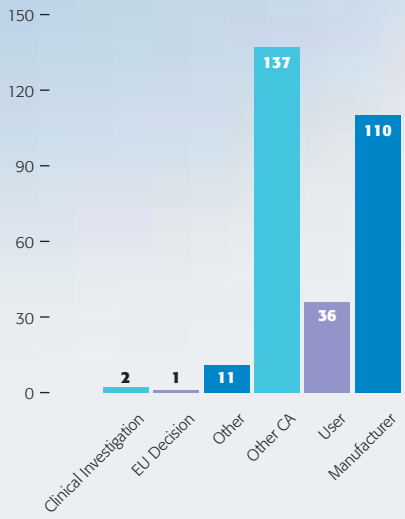
In the year 2002, there was a marked increase in the number of vigilance reports received by the IMB. Two hundred and ninety seven reports in total were received, an increase of approximately 50% on 2001.

Number of Vigilance Reports Received during 2000 to 2002



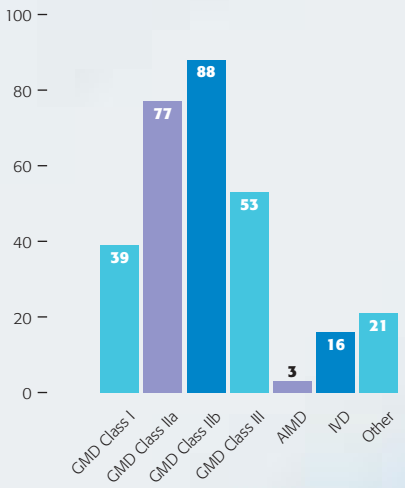
While the majority of reports received were from the Competent Authorities for medical devices in other Member States and manufacturers, a significant increase in the number of user reports was evident.

Sources of the Vigilance Reports in 2002



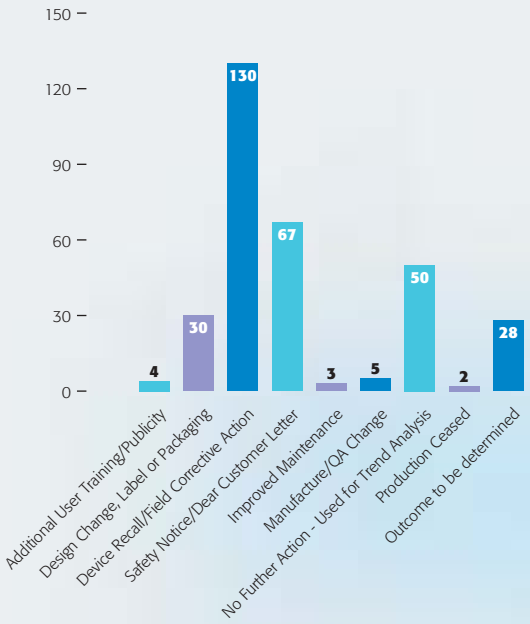
The majority of reports received related to valid incidents, with only two reports not fulfilling the vigilance system criteria. A greater number of those reports received related to near incidents rather than incidents. Fatalities were associated with two reported incidents in Ireland, but on investigation, it was found that these were not device related. Incidents relating to Class IIb, Electro Mechanical Devices, Single Use Devices and Non-active Implantable Devices constituted the majority of those reports received.

Class of Device Implicated in Vigilance Reports in 2002



The outcomes of completed investigations have varied, with the majority resulting in a notification to the user followed by either a recall or on site corrective action. Investigation outcomes which indicated a production error have, in some cases, led to post market surveillance audits or technical file reviews.

Outcome of the Investigation of Vigilance Reports in 2002



During the course of 2002, the IMB issued seven Competent Authority reports to colleagues in other Member States. A monthly circulation of safety and advisory notices to the health services was initiated in March 2002. Five IMB safety notices, 1 FDA and 51 MRHA (formerly the UK Medical Devices Agency (MDA)) safety notices have been circulated.

In October 2002, the IMB joined the Global Vigilance reporting system (under the Global Harmonisation Task Force (GHTF)), which has opened up the receipt from and distribution of Competent Authority Reports to Australia, United States, Canada and Japan.

Communication/Industry Liaison

In 2002, user reporting for medical devices was promoted and has developed significantly with users reporting critical vigilance issues within hospitals on a regular basis. The majority of these issues were valid and have provided a useful means for the IMB to get the information required to prevent re-occurrence of serious issues within the Irish healthcare sector. The initial development of the user on-line reporting system for vigilance issues started in Autumn 2002. It is hoped that the pilot testing of this system will occur in the second quarter of 2003. A working group of Dublin area teaching hospitals was put in place to look at the area of user vigilance reporting and to ensure that the monthly circulation of all safety and advisory notices is targeted appropriately. It is hoped that this will lead to increased awareness and to improved communications between users and the IMB. The development of a new draft Guidance Note on adverse incident reporting was also initiated and feedback was received from both the medical device sector and the professional users. This will be published in 2003.

In preparation for the implementation of the *in-vitro* diagnostics legislation on 7th December 2003, many IVD manufacturers submitted registration applications, vigilance and recalls reports for the *in-vitro* diagnostics area during 2002.

The IMB hosted two educational fora for dental technicians and for the general medical device sector. Both were successful and well attended. In addition, a number of lectures were given to professional groups in relation to the Competent Authority activities particularly on the area of vigilance. During 2002, a number of post-market surveillance audits were carried out on manufacturers of dental products and a number of technical files reviewed. Two working groups were also set up; for dental technicians and for manufacturers of custom made devices. As part of a planned series of Guidance Notes two were issued during the year, namely, Guidance Note 10: *Guidance Note to Custom Made Dental Devices Manufacturers regarding Compliance with the Requirements as outlined in S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994*, and Guidance Note 14: *Guidance Note to Custom Made Medical Device Manufacturers regarding Compliance with the Requirements as outlined in S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994*.

One statutory instrument affecting medical devices was published in 2002, namely S.I. No. 576, European Communities (Medical Devices) (Amendment) Regulations 2002, which transposed Council Directive 2000/70/EC of the 16th November 2000 and Council Directive 2001/104/EC of 7th December 2001 in relation to medical devices incorporating stable derivatives of human blood or human plasma. This also amended the IMB Act, 1995 to allow for the formation of an Advisory Committee for Medical Devices.

A number of meetings were held with the Irish Medical Device Association (IMDA) in relation to the requirements of the legislation and also in relation to sharing information on areas of mutual interest. Twenty-eight meetings were held with medical device manufacturers in 2002.

Finally, a specific newsletter was first published in Summer 2002. This is now being issued on a quarterly basis to the sector and has been welcomed by the medical device sector.

Notified Body Issues

During 2002, the IMB, as Competent Authority, designated the NSAI as a notified body under Article 15 of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1999 on *in-vitro* diagnostic medical devices, and article 11 of S.I. No. 304 of 2001, European Communities (*in-vitro* Diagnostic Medical Devices) Regulations, 2001. The scope of the designation includes Annex II List A virology

products, Annex II List B products and self test devices. This followed a lengthy review and site audit at the NSAI premises. This was the first designation by the IMB in its role as Competent Authority for medical devices. The NSAI had previously been designated by the Department of Health and Children (DoHC) as Notified Body for the Medical Devices Directive 93/42/EEC and for the Active Implantable Medical Devices Directive 90/385/EEC. Additionally, for the first time in Ireland, observed audits were carried out on the NSAI, in its role as notified body for general medical devices.

EU/International Activities

IMB staff attended a number of expert meetings for IVDs and general medical devices (GMDs), where the IMB represented Ireland as a Member State for the purposes of the Competent Authority obligations under the Medical Devices Directives. Furthermore, staff actively participated in a number of working groups namely, Notified Bodies Operations Group (NBOG), Market Surveillance Operations Group, (MSOG), Clinical Investigation Working Group, Vigilance Working Group, IVD Borderline Working Group, Eudamed Database Working Group, Transparency Working Group, IVD Annex II Working Group and TSE Working Group.

Clinical Investigations

During 2002, three clinical investigation submissions were received from Irish and multinational manufacturers. All three applications were approved and a further four amendments to the clinical investigation protocols were also received and approved. All initial applications were reviewed within the 60-day time period.

Post-Market Surveillance Issues

Over the year 2002, the IMB conducted both proactive and reactive post-market surveillance audits. The proactive audits were part of a programme to address the Custom-Made Device Manufacturing Sector.

The custom made manufacturer grouping addressed was dental technicians, acting as manufacturers of medical devices, and dental laboratories. This group manufactures a range of custom made devices including dentures, dental crowns and orthodontic retainers. Audits of these manufacturers demonstrated the need for attention to several areas of manufacturing practice. The common issues found amongst the Dental Technicians and Laboratories, acting as manufacturers, included the following:

- Lack of methods to reduce the risk of cross-contamination
- Use of non-CE marked materials
- No work instructions and repeatable manufacturing methods
- Inadequate labelling and records with the device to allow traceability
- No statement of conformity to the Essential Requirements of Schedule 1 of S.I. No. 252 of 1994.

Reactive audits to EU Directive 93/42/EEC were also conducted following concerns resulting from recalls of high-risk medical devices.

Information Technology

IT Strategic Plan

In January 2002 the Board of the IMB approved a three-year IT strategic plan embracing both information technology and organisational change. The entire programme of work planned is known as N**IMB**us.

A feasibility study was carried out in 2001 to identify the potential usage of information technology to provide improved services to stakeholders. This study highlighted the potential to streamline a number of licensing processes and to use technology to improve methods of exchanging information with stakeholders. The human medicines area was identified as an immediate priority and work commenced on the various projects following the Board's approval of the work programme in January 2002.

The principal components of the strategy are as follows:

- Business Architecture & Organisational Structure Review
- Quality Systems Improvement
- Business Transformation & associated Technology services.

These components are further broken down into individual projects supporting the IMB's objective of an improved quality of service to stakeholders, incorporating organisational efficiencies and timeline management spanning a three-year implementation programme.

In Q1/2002 a request for tenders was published in the Official Journal of the European Union requesting interested parties to supply a comprehensive response to the IMB's request for a combined technology and business implementation solution. Tenders were received in June 2002 and evaluated during Q3.

Work commenced on the detailed analysis for the new systems and a project plan encompassing a 24-month implementation programme was established. The new systems and associated business practices will be implemented within the IMB during Q4/2003 and Q1/2004 respectively. External services will become available to stakeholders during Q1 and Q2, 2004.

The principal technologies employed within the N**IMB**us programme will include:

- Workflow technology
- Document Management Systems
- Web-based application facilities
- On-line tracking functionality for customers.

These systems will also be applicable outside the human medicines area, therefore maximising the Board's investment across the organisation over the coming five years.

A second project was also initiated in mid-2002 to examine the organisational structure and to recommend potential improvements. This study was carried out in the second half of 2002 and recommendations went to the Board in January 2003.

The combined technology and reorganisation projects work together to provide a comprehensive solution for the organisation. External factors also play a major role in deciding on the optimum solution, as the IMB must accommodate any changes introduced by the CTD, eCTD and electronic exchange of data in the pharamcovigilance area. All EU technology initiatives currently defined are scheduled for incorporation into N**IMB**us.

Veterinary Medicines – Document Management

Work began in 2001 on the introduction of improved document management systems to support the activities of the veterinary unit.

This project continued through 2002 to transfer paper-based documentation to electronic format and to eliminate paper wherever possible.

A web-based solution has now been developed and implemented to allow staff to save and retrieve documentation under a wide range of criteria. The solution is now planned for extension to other departments within the IMB.

The technology utilised for the project will be incorporated into the N**IMB**us project for use within the human medicines area. The veterinary project provided a very useful experience for the organisation in identifying the potential of document management solutions.

New IMB Website

A new version of the IMB website was published in September 2002. The new site incorporates improved functionality and has been warmly welcomed by stakeholders. Web monitoring has indicated that the various application forms are the most frequently sought documents from the site.

A number of further improvements are planned for the site, including comprehensive product listings for licensed products and 'on-line' application forms.

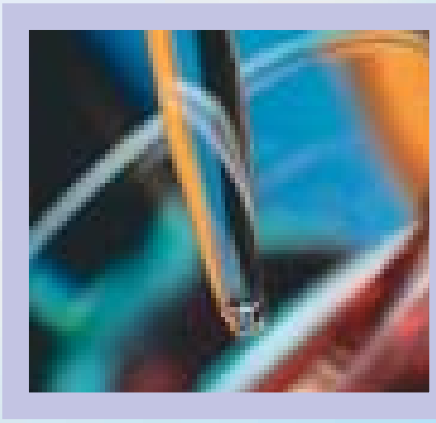
EU Activities – Technology

This has been a particularly busy area as a large number of EU technology initiatives are underway. Ireland has been very active in the various working groups and continues to participate in the on-going projects where possible.

The working groups requiring on-going support in 2002 included the following:

- EudraNet Technical Implementation Group
- EudraVigilance Technical Implementation Group
- PIM Project
- ESubmissions Technical Implementation Group
- European Database Project.

The IMB's involvement in these projects has proved valuable in the development of new technologies under the IT Strategic Plan.



New Activities

The IMB's work with the DoHC in relation to the extension of the Board's activities by the transfer of responsibilities from the Department continued in 2002. In addition, work on the Herbal Medicines Project continued.

Herbal Medicines

Herbal Medicines Project

Following submission of the Herbal Medicines Project final report to the Department of Health and Children on 22nd January 2002, the Minister for Health and Children, Micheál Martin TD, requested that the IMB hold a seminar on the 'Implications of the Proposed Interim National Licensing Scheme'.

A one-day seminar was held in May. Over a hundred people attended the seminar, with representatives from each organisation/company known to the IMB to be interested in herbal medicines. Representatives from the Food Safety Authority of Ireland and the Department of Health and Children were also present.

Mr. Richard Woodfield from the Medicines Control Agency in the UK provided an update on the proposed Directive on Traditional Herbal Medicinal Products and Dr. Desmond Corrigan (School of Pharmacy, Trinity College, Dublin) presented the keynote address. In addition to the four IMB speakers, speakers representing the health trade, health food stores, herbalists and consumers made presentations on the day. Feedback from attendees indicated that the seminar was considered successful in its aim to provide a forum for discussion for all interested parties. A full report on the seminar was submitted to the Minister for Health and Children on 31st May 2002.

Herbal Medicinal Products Working Party at the European Medicines Evaluation Agency (EMEA)

The Herbal Medicinal Products Working Party at the EMEA, previously reporting to the EMEA Management Board, became a full working party of the Committee on Proprietary Medicinal Products (CPMP) in February 2002. The IMB is represented at the meetings of this group.

Proposed Directive on Traditional Herbal Medicinal Products

The first European Council working group meeting to discuss the proposed 'Directive on Traditional Herbal Medicinal Products' was held in June 2002, at which the IMB supported the introduction of European legislation in the area. Most other Member States also welcomed the proposed Directive and encouraged its expedited implementation. At the second Council Working Group meeting in October 2002, the two key issues raised were the scope of the Directive and the proposed definition of 'traditional use', which relies exclusively on the product having been available for 30 years on the European market with a derogation to 15 years for products from outside the EU. It was suggested that the proposed transitional period between agreement on the Directive and full compliance would facilitate many products in terms of their time on the market. It was also suggested that it might be possible that the proposed Committee on Herbal Medicinal Products (CHMP) could review individual products that did not satisfy the 30/15 years of use.

The DoHC is currently progressing the amendments to legislation necessary to confer responsibility for the controlled drug functions on the IMB. We anticipate that the functions will transfer in late 2003 or early 2004.

In parallel to the work of the Council Working Group, the European Parliament Committee for the Environment, Public Health and Consumer Policy proposed a number of amendments to the Directive, which were presented to the plenary session of the European Parliament on 6th November 2002. Twenty eight of these amendments were agreed by the Parliament in late November 2002 and submitted to the European Commission for consideration.

Amendment of the Medicinal Products (Prescription and Control of Supply) Regulations 1996. [S.I. No. 256 of 1996]

The Department of Health and Children published an amendment to the above regulations entitled the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulation 2002 [S.I. No. 627 of 2002]. This legislation includes a number of amendments relating to herbal substances that were agreed following discussion with the IMB. These include:

a) a general exemption allowing herbal practitioners to extemporaneously dispense *Hypericum perforatum* L. and *Ginkgo biloba* L. for the treatment of individual patients under their care as part of an individual consultation,

b) the listing of *Hypericum perforatum* L. in Schedule 3 Part 2 allowing non-prescription products containing this herb to be sold in non-pharmacy retail outlets, and

c) the listing of all herbal substances in the schedules to these regulations according to their scientific names rather than their common names.

Controlled Drugs Project

During 2002, considerable progress was made in preparing for the transfer of responsibility for the controlled drugs functions from the DoHC to the IMB. The functions to be transferred to the IMB include the responsibility for ensuring national compliance with regard to the licensing and inspection requirements under the Misuse of Drugs Acts, 1977 and 1984 and responsibility for providing statistical reports to the International Narcotics Control Board (INCB) of the United Nations (UN), as part of our national obligation under the terms of the various UN Conventions on controlled drugs and precursor chemicals.

The primary focus of the IMB during the past year has been the setting in place of systems necessary for undertaking these functions, which will ensure a smooth transfer of responsibilities.

The IMB has successfully tested and installed the 'National Drug Control System' (NDS), developed by the United Nations Office on Drugs and Crime (UNODC). This is an information management system that will provide more efficient methods of generating the various licences and providing statistical reports to the INCB, and will be used by the IMB once the transfer of responsibilities from the DoHC has been completed.

The development of systems has also included setting in place quality systems and related documentation that will be used by the IMB once the transfer of functions has been completed.

During 2002, the IMB expanded the staff assigned to the controlled drugs project so that necessary training and expertise in the legislative compliances could be developed in advance of the transfer of functions.

The IMB and the DoHC have liaised closely throughout 2002. Regular meetings have taken place to discuss and review progress. This has provided an opportunity for advancement of the key aspects of the project including legislative amendments, funding and the development of systems.

The IMB and the DoHC jointly hosted an information meeting on the transfer of the controlled drugs functions to the IMB in November 2002. The meeting was attended by representatives from the pharmaceutical and chemical industries and provided an overview of the current legislative requirements for controlled drugs and precursor chemicals, the legislative amendments necessary to transfer functions to the IMB, and new developments in functions after the transfer of responsibilities has been completed.

The DoHC is currently progressing the amendments to legislation necessary to confer responsibility for the controlled drug functions on the IMB. We anticipate that the functions will transfer in late 2003 or early 2004.

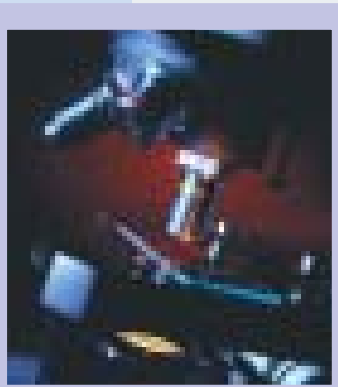
Homeopathic Medicines Project

This project was initiated in order to establish a regulatory mechanism for homeopathic medicines in Ireland, in line with both EU directives and Irish legislation. In particular, the goal of the project is to establish a Simplified Registration Scheme (SRS) for homeopathic products, which are placed on the market without therapeutic claim and in a form (oral and topical) and dosage that does not present risk to the patient.

Legislation

At the outset of the project a review of Irish legislation was carried out to ascertain if it was in compliance with the EU directives in this area.

An obstacle to SRS was identified in the Medicinal Products (Prescription and Control of Supply) Regulations, S.I. 256 of 1996. This legislation listed many commonly used homeopathic medicines e.g. Belladonna, Aconite; which have heretofore been sold over the counter, as prescription only and pharmacy restricted substances. In consultation with the Dept. of Health and Children an amendment was prepared. This included a schedule of substances which when included in homeopathic medicinal products, at a concentration of D6 or above, were exempt from prescription control. This amendment came into effect in November 2002 as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, S.I. 627 of 2002.



In order to inform all relevant parties of the establishment and purpose of the Homeopathic Medicines Project, contact was made with various organisations, both nationally and internationally.

Organisations/Manufacturing and Distribution Companies

In order to inform all relevant parties of the establishment and purpose of the Homeopathic Medicines Project, contact was made with various organisations, both nationally and internationally. These included professional organisations such as the Irish Association of Medical Homeopaths, the Irish Society of Homeopaths (ISH) and the European Council for Classical Homeopathy (ECCH); commercial organisations, such as the Irish Health Trade Association (IHTA), the Irish Association of Healthfood Stores (IAHS), as well as consumer and patient organisations. All organisations have expressed their full support for the proposed SRS.

Companies marketing homeopathic medicinal products (HMPs) were contacted and requested to submit lists of their products. In total, there are 18 manufacturing companies and nine distribution companies operating on the Irish market.

Information submitted by the companies was used to compile a database of HMPs. There are currently approximately 8,000 products on this IMB database.

Simplified Registration Scheme

Work commenced on the development of a series of Guidance Notes for the SRS. These include Guidance Notes for; 'Manufacturers and Suppliers', on the 'Control and Quality of Homeopathic Stocks' and on the 'Manufacture and Control of Dosage Forms'. These will be available for the launch of the SRS in 2003.

Financial Statements

Board Members and Other Information

Board Members:
Mr. Pat O'Mahony (Chairman)
Mr. Denis Cronin
Ms. Breda Dooley
Dr. Rory Lehane
Ms. Aideen Murphy
Mr. Aidan Murray
Ms. Anne Nolan
Mr. P.J. O'Connor
Professor Kevin O'Malley

Bankers:
Allied Irish Bank
Lower Baggot Street
Dublin 2

Solicitors:
Eugene F. Collins
Temple Chambers
3, Burlington Road
Dublin 4

Head Office:
Block A
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Auditor:
Comptroller and Auditor General
Dublin Castle
Dublin 2

Corporate Governance

The Irish Medicines Board (IMB) was established under the terms of the Irish Medicines Board Act, 1995, and is governed by a Board which was appointed by the Minister for Health & Children. The Board of the IMB (the Board) consists of a Chairman and eight unremunerated non executive members.

The IMB is committed to the highest standards of Corporate Governance and is in the process of implementing the Department of Finance 'Code of Practice for the Governance of State Bodies'. This Code of Practice, which was issued to the Irish Medicines Board in January 2002, incorporates many of the principles under which the IMB operates, taking account of the size and legal nature of the organisation. Initiatives that the IMB have taken include the finalisation in 2002 of an extensive Code of Conduct for all staff, committee and Board members. During 2002, an audit sub-committee of the Board was established by the IMB, comprising the Chairman, three Board members and the Chief Executive, which met on two occasions during 2002. A review of the internal audit needs of the organisation was also carried out during the year. The IMB already applies the highest standards of disclosure and transparency in respect of interests held by staff, committee and Board members.

Remuneration Policy - Board Members and Executive Directors

Remuneration and travel expenses paid to Board members are disclosed in note 15 to the financial statements. The Chairman receives remuneration in accordance with instructions received from the Minister for Health and Children, in accordance with the Irish Medicines Board Act, 1995. Other Board members receive travel expenses in accordance with circulars issued by the Department of Health and Children. The Chief Executive Officer is remunerated in accordance with guidelines issued from Government and other Executive Directors are paid in accordance with Department of Health and Children pay scales. The Chief Executive's salary is disclosed net of Superannuation contributions in note 16 to the financial statements.

Internal Control

The Board is responsible for the IMB's systems of internal control. Such systems can only provide reasonable and not absolute assurance against material misstatement or loss.

"Internal Control: Guidance for Directors on the Combined Code" (the "Turnbull Guidance") was published in September 1999. Although the guidance is primarily directed towards private and listed companies subject to the Companies Acts (1963 to 1996), the IMB applies the relevant sections of the guidance to its operations.

In addition, the Board confirms that there is an ongoing process for identifying, evaluating and managing the significant risks faced by the IMB. This process is regularly reviewed by the Board via the report of the Chief Executive Officer.

Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable internal controls. These risks are assessed on a continual basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory requirements.

Management report fortnightly on operational issues and risks and how they are managed to the Management Committee. The Management Committee's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the IMB and the system of actions necessary to manage such risks and to present their findings on significant matters via the Chief Executive Officer to the Board.

The Chief Executive reports to the Board on behalf of the executive management on significant changes in the work of the IMB and on the external environment which affects significant risks. The Director of Finance and Administration provides the Board with monthly financial information which includes key performance indicators. Where areas for improvement in the system are identified the Board considers the recommendations made by the Management Committee.

An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only or, as delegated by the Board, for appropriate Executive approval. The Board has delegated the day-to-day management of the IMB and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial control.

Going Concern

The Board has a reasonable expectation, at the time of approving the financial statements, that the IMB has adequate resources to continue its operations for the foreseeable future. For this reason, it continues to adopt the going concern basis in preparing the financial statements.

Statement of Board Members' Responsibilities

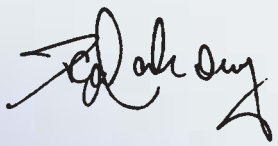
The Board is required by the Irish Medicines Board Act, 1995 to prepare financial statements for each financial year which give a true and fair view of the state of affairs of the Irish Medicines Board.

In preparing those statements the Board is required to:

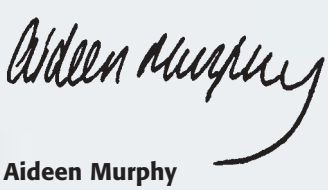
- select suitable accounting policies and apply them consistently
- make judgements and estimates that are reasonable and prudent
- disclose and explain any material departures from applicable accounting standards, and
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the Irish Medicines Board will continue in existence.

The Board is responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the Irish Medicines Board and which enable it to ensure that the financial statements comply with the Act. It is also responsible for safeguarding the assets of the Irish Medicines Board and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

On behalf of the Board



Pat O'Mahony
Chairman



Aideen Murphy
Board Member

Report of the Comptroller and Auditor General

for presentation to the Houses of the Oireachtas

I have audited the financial statements on pages 41 to 52 under Section 18 of the Irish Medicines Board Act, 1995.

Respective Responsibilities of the Board and the Comptroller and Auditor General

The accounting responsibilities of the members of the Board are set out in the Statement of Board Members' Responsibilities on page 39. It is my responsibility, based on my audit, to form an independent opinion on the financial statements presented to me by the Board and to report on them.

I review whether the statement of the system of internal financial control on pages 38 and 39 reflects the Board's compliance with applicable guidance on corporate governance and report any material instance where it does not do so, or if the statement is misleading or inconsistent with other information of which I am aware from my audit of the financial statements.

Basis of Audit Opinion

In the exercise of my function as Comptroller and Auditor General, I conducted my audit of the financial statements in accordance with auditing standards issued by the Auditing Practices Board and by reference to the special considerations which attach to State bodies in relation to their management and operation.

An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosures in the financial statements. It also includes an assessment of the significant estimates and judgements made in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Board's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations that I considered necessary to provide me with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement whether caused by fraud or other irregularity or error. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements.

Opinion

In my opinion, proper books of account have been kept by the Board and the financial statements, which are in agreement with them, give a true and fair view of the state of affairs of the Irish Medicines Board at 31st December 2002 and of its income and expenditure and cash flow for the year then ended.

Gerard Smith

For and on behalf of the
Comptroller and Auditor General

15th July 2003

Accounting Policies

Historical Cost Convention

The financial statements are prepared in accordance with generally accepted accounting principles under the historical cost convention and comply with the financial reporting standards of the Accounting Standards Board.

Income Recognition

Income is recognised in the financial statements on the following basis:

- In the case of applications for Product Authorisations (new applications, variations to existing authorisations, or transfers) and Clinical Trial applications, income is recognised in the financial statements when a valid application form is received.
- In the case of Wholesale and Manufacturing Licences and maintenance of Product Authorisations, fees are payable annually and a full year's income is accrued in each financial year.

Expenditure Recognition

Expenditure is recognised in the financial statements on an accruals basis as it is incurred.

Reporting Currency and Currency Translation

The financial statements are prepared in Euros.

Transactions in currencies other than Euro are recorded at the rates ruling at the date of the transactions or at a contracted date. Monetary assets and liabilities are translated into Euro at the balance sheet date or at a contracted date. Exchange differences are dealt with in the income and expenditure account.

Tangible Assets

Tangible Assets are stated at cost less accumulated depreciation. Depreciation is calculated in order to write off the cost of tangible assets over their estimated useful lives by equal annual instalments.

The estimated useful lives of tangible assets by reference to which depreciation has been calculated are as follows:

Leasehold Property:	Unexpired portion of the lease
Fixtures and Fittings:	5 years
Computer Equipment:	3 years

Taxation

The Irish Medicines Board is exempt from liability to Corporation Tax under Section 32 of the Finance Act, 1994.

Debtors

Known bad debts are written off and specific provision is made for any amount, the collection of which, is considered doubtful. A further general provision is also maintained.

Superannuation

The superannuation scheme operated by the Irish Medicines Board is in accordance with the Local Government (Superannuation Revision) (Consolidation) Scheme, 1986. It is an unfunded statutory scheme and benefits are met from current income as they arise.

The charge to salaries and wages is stated gross of superannuation deductions of €310,382 (2001 - €206,881). The surplus for the year on page 43 is then shown both before and after superannuation transactions for the year. The income and expenditure reserve on the balance sheet is split between retained reserves and superannuation reserves in note 11.

The above accounting treatment, which is consistent with all State Bodies under the Local Government Body Superannuation scheme, is not in accordance with the requirements of Financial Reporting Standard 17. For accounting periods ending on or after 1st January 2005 the Standard will require financial statements to reflect at fair value the assets and liabilities arising from an employer's superannuation obligations and any related funding and to recognise the costs of providing superannuation benefits in the accounting periods in which they are earned by employees. As a transitional measure the Standard requires that for accounting periods ending on or after 22nd June 2002, opening and closing balance sheet information and

Accounting Policies *(continued)*

performance statement information for the period (no comparatives required) is to be given in the notes only. This information is contained in note 19 to the financial statements.

Library

No value has been placed on the books, audio-visual resources and electronic databases in the library. Expenditure on these items is written off in the year in which it is incurred.

Leases

All leases are treated as operating leases and the rentals thereunder are charged to the Income and Expenditure account on a straight line basis over the lease period.

Statement of Income and Expenditure

For the year ended 31st December 2002

	Note	**2002**	2001
		€	€
Fee Income	2	8,410,538	7,817,728
Other Income	3	1,617,607	850,255
		10,028,145	8,667,983
Salaries and Wages	4	6,657,355	5,363,812
Other Operating Costs	5	2,660,855	2,634,968
Depreciation	1	403,480	290,009
		9,721,690	8,288,789
Surplus for the year before write back of Superannuation contributions		306,455	379,194
Staff Superannuation Contributions		310,382	206,881
Surplus for the year		616,837	586,075
Balance brought forward		4,271,980	3,685,905
Balance carried forward		**4,888,817**	4,271,980

All income and the surplus for the year arises from continuing activities. The IMB had no recognised gains or losses other than those dealt with in the Income and Expenditure Account.

Pat O'Mahony
Chairman

Aideen Murphy
Board Member

The accounting policies on pages 41 to 42 and the notes on pages 46 to 52 form part of the financial statements.

Balance Sheet

As at 31st December 2002

	Note	2002 €	2001 €
Tangible Assets	1	631,688	500,902
Current Assets			
Debtors and Prepayments	6	2,436,865	1,924,167
Stock of Stationery		3,959	5,172
Cash at Bank and in Hand	12	2,426,454	2,012,885
Short Term Deposits		2,184,689	2,124,073
		7,051,967	6,066,297
Creditors - Amounts falling due within one year			
Creditors and Accruals	7	2,794,838	2,295,219
Net Current Assets		4,257,129	3,771,078
TOTAL NET ASSETS		**4,888,817**	4,271,980
Financed by			
Income and Expenditure Reserve	11	4,888,817	4,271,980
		4,888,817	4,271,980

Pat O'Mahony
Chairman

Aideen Murphy
Board Member

The accounting policies on pages 41 to 42 and the notes on pages 46 to 52 form part of the financial statements.

Cash Flow Statement

For the year ended 31st December 2002

	Note	**2002**	2001
		€	€
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for Year		616,837	586,075
Depreciation Charge		403,480	290,009
Increase in Debtors		(512,698)	(677,384)
Decrease in Stocks		1,213	812
Increase in Creditors - amounts falling due within one year		499,619	347,222
Deposit Interest		(84,716)	(109,914)
Bank Interest and Charges		5,979	4,554
Gain on Disposal of Fixed Assets		(530)	(533)
Net Cash Inflow from Operating Activities		**929,184**	440,841
Cash Flow Statement			
Net Cash Inflow from Operating Activities		929,184	440,841
Return on Investments and Servicing of Finance	8	78,737	105,360
Capital Expenditure	8	(533,736)	(421,728)
Management of Liquid Resources	8	(60,616)	292,447
Increase in Cash		**413,569**	416,920
Reconciliation of net cash flow to movement in net funds			
Increase In Cash		413,569	416,920
Increase In Short Term Deposits		60,616	(292,447)
Change In Net Funds		474,185	124,473
Net Funds at start of year		4,136,958	4,012,485
Net funds at end of year	9	**4,611,143**	4,136,958

The accounting policies on pages 41 to 42 and the notes on pages 46 to 52 form part of the financial statements.

Notes to the Financial Statements

For the year ended 31st December 2002

1 Tangible Assets	Fixtures and Fittings	Computer Equipment	Leasehold Property	Total
	€	€	€	€
Cost				
Balance as at 1st January 2002	641,693	1,532,468	75,373	2,249,534
Additions for the year	126,245	408,021	-	534,266
Disposals for the year	-	(31,569)	-	(31,569)
As at 31st December 2002	**767,938**	**1,908,920**	**75,373**	**2,752,231**
Depreciation				
Balance as at 1st January 2002	480,928	1,251,553	16,151	1,748,632
Charge for the year	87,970	312,818	2,692	403,480
Disposals for the year	-	(31,569)	-	(31,569)
As at 31st December 2002	**568,898**	**1,532,802**	**18,843**	**2,120,543**
Net Book value at 31st December 2002	**199,040**	**376,118**	**56,530**	**631,688**
Net Book value at 1st January 2002	**160,765**	**280,915**	**59,222**	**500,902**

2 Fee Income	2002	2001
	€	€
Clinical Trials	112,123	128,539
Human Medicine - National Fees	4,297,134	3,580,038
Human Medicine - European Fees	2,056,649	2,623,195
Veterinary Medicine - National Fees	666,125	662,532
Veterinary Medicine - European Fees	258,042	264,782
Inspectorate Department	978,380	552,682
Medical Devices	42,085	5,960
	8,410,538	7,817,728
Fee Income can also be analysed as follows:		
Income recognised on a cash receipts basis	5,753,759	5,722,928
Income recognised on an accruals basis	2,656,779	2,094,800
	8,410,538	7,817,728

3 Other Income

	2002	2001
	€	€
Dept Of Health & Children Funding	1,413,178	670,945
Conference Fee Income	119,183	68,858
Deposit Interest	84,716	109,919
Gain on Disposal of Fixed Assets	530	533
	1,617,607	850,255

4 Salaries and Wages

	2002	2001
	€	€
Salaries and Wages	6,123,010	4,912,785
Social Welfare Costs	534,345	451,027
	6,657,355	5,363,812

The average number of staff employed during the year was 153 (2001 - 140)

Staff employed at 31st December 2002 can be analysed across the following departments:	2002	2001
Medical Technical	13	10
Pharmaceutical Technical	24	15
Veterinary Technical	5	6
Inspectorate Technical	8	7
Medical Devices Technical	5	2
Enforcement Technical	5	5
Herbal Medicines Technical	1	1
Controlled Drugs Technical	1	1
Administrative and Operational Staff	89	91
Pensioners	4	4
	155	142

5 Operating Costs	**2002**	2001
	€	€
Accommodation Costs	897,670	878,991
Travel, Representation and Training	496,378	408,186
Legal Costs	215,338	434,322
Stationery, Publications and Postage	276,488	240,849
Other Operating Costs	774,981	672,620
	2,660,855	2,634,968

6 Debtors (all due within one year)	**2002**	2001
	€	€
Trade Debtors	1,023,789	559,989
Prepayments	121,855	116,338
Other Debtors	1,291,221	1,247,840
	2,436,865	1,924,167

Included in Other Debtors is an amount of €1,172,325 in respect of legal costs incurred by the IMB in their participation in the Tribunal of Enquiry of Infection with HIV and Hepatitis (of persons with Haemophilia and related matters.) While the award of costs by the Chairperson of any Tribunal is a discretionary matter, solicitors to the IMB have expressed the view that it has been the unequivocal practice and custom of all similar tribunals to award costs to any party that is legally represented before it and who has co-operated in its dealings with the Tribunal. The IMB has co-operated fully with the Tribunal and are confident that it will recover all costs on the same basis as occurred in the case of the Tribunal of Enquiry into the Infection of Anti-D with Hepatitis C.

7 Creditors (amounts falling due within one year)	**2002**	2001
	€	€
Trade Creditors	349,721	267,133
Accruals	2,277,267	2,028,086
PAYE/PRSI	167,850	-
	2,794,838	2,295,219

8 Gross Cash Flows

	2002	2001
	€	€
Returns on Investment and Servicing of Finance		
Deposit Interest	84,716	109,914
Bank Interest and Charges	(5,979)	(4,554)
	78,737	105,360
Capital Expenditure		
Payments to acquire Tangible Fixed Assets	(534,266)	(422,261)
Receipts from sales of Tangible Fixed Assets	530	533
	(533,736)	(421,728)
Management of Liquid Resources		
Payments to acquire Short Term Deposits	(60,616)	292,447
	(60,616)	292,447

9 Analysis of Changes in Net Funds

	2002	2001
	€	€
Cash at Bank and in Hand	2,426,454	2,012,885
Short Term Deposits	2,184,689	2,124,073
	4,611,143	4,136,958

10 Administration Expenses

	2002	2001
	€	€
Surplus for the year was calculated having charged:		
Auditor's Remuneration	**9,750**	8,500

11 Income and Expenditure Reserves

	2002	2001
	€	€
The Income and Expenditure Reserve disclosed in the Balance Sheet on page 44 comprises the following:		
Retained Reserves	3,830,379	3,523,922
Staff Superannuation Contributions	1,058,438	748,058
	4,888,817	4,271,980

12 Cash and Bank Balances

	2002	2001
	€	€
Current Account Balances	963,595	280,587
Deposit Account Balances	1,462,209	1,731,656
Cash on Hand	650	642
	2,426,454	2,012,885

13 Lease Commitments

	2002	2001
	€	€
Operating Leases		
Amounts payable during the next twelve months in respect of leases which expire		
- within one year	-	859
- between two and five years	2,300	1,150
- after five years	606,300	606,300

The operating lease amounts include an annual commitment of €606,300 (2001 - €606,300) in respect of the Board's premises at Earlsfort Terrace, Dublin 2.

14 Capital Commitments

	2002	2001
	€	€
Contracted For (Contract Signed)	1,331,000	-
Not Contracted For	605,000	-
	1,936,000	-

15 Board Remuneration

	2002	2001
	€	€
Chairman's Salary	22,610	21,197
Board Member's Travel Expenses	9,908	4,665
	32,518	25,862

16 Staff Remuneration

	2002	2001
	€	€
Chief Executive's Salary (Stated net of Superannuation Contributions)	98,063	91,768
	98,063	91,768

17 Related Party Transactions

There have been no transactions with related parties which require disclosure under Financial Reporting Standard 8.

18 Contingent Liabilities

Anti-D Immunoglobulin

In early February 1994 the Irish Medicines Board was advised that Hepatitis C could have been transmitted through Anti-D Immunoglobulin produced from Irish blood plasma and manufactured by the Blood Transfusion Service Board. The Board has received letters before action and has been sued, with the Blood Transfusion Service Board, the Minister for Health and Children, Ireland and the Attorney General, in legal proceedings by a number of persons arising out of alleged infection by the Anti-D product. Further letters and proceedings are anticipated. The Board does not admit liability in these cases and thus will be defending them in full. In the settlements concluded to date, the IMB has not incurred any liability arising from the Anti-D Immunoglobulin cases and on that basis does not anticipate that any such liability will arise in the future.

The Department of Health and Children established a Tribunal of Enquiry to review the circumstances surrounding the infection of Anti-D with Hepatitis C. The Tribunal's findings were published in March 1997 and are available to the public from the Government Publications Office.

The Department of Health and Children also established a Tribunal for the purpose of providing ex-gratia compensation to persons infected with Hepatitis C through the use of the Anti-D Immunoglobulin product.

Where an award made by the tribunal has not been accepted the claimant can pursue legal action.

19 Financial Reporting Standard 17

A new accounting standard, Financial Reporting Standard No.17 - Retirement Benefits, was issued by the Accounting Standards Board in November 2000. Compliance with the new standard does not become mandatory until the financial year 2005. However, in accordance with the transitional provisions set down by the standard, the Irish Medicines Board is required to disclose the assets (if any) and liabilities related to the pension scheme for its employees by way of a note to the accounts. Members of the Irish Medicines Board participate in the Local Government (Superannuation) Scheme, which is unfunded. The results set out below are based on an actuarial valuation of the liabilities in respect of Irish Medicines Board staff as at 31st December 2002. This valuation was carried out using the projected unit method.

19 Financial Reporting Standard 17 *(continued)*

The financial assumptions used to calculate scheme liabilities were as follows:

Discount rate	**6%**
Salary increase assumption	**4%**
Pension increase assumption	**4%**
Price inflation	**2%**

On the basis of these assumptions, and using the projected unit method prescribed in FRS 17, the value of the accrued liabilities in respect of the Irish Medicines Board staff at 31st December 2002 was estimated at €11.1m.

There are no assets held in respect of the accrued pension liabilities of the Irish Medicines Board.

The Irish Medicines Board confirms that an actuarial review of its Superannuation Scheme will be carried out for the 2003 financial statements and that the disclosure requirements of FRS 17 will be fully complied with.

20 Prompt Payment Of Accounts Act 1997

The Irish Medicines Board (IMB) confirms that it is complying with the provisions of the Prompt Payment of Accounts Act, 1997.

21 Exchange Rates

The exchange rates used in preparing these financial statements were as follows:

2002 €1 = STG £0.6698

2001 €1 = STG £0.6000

22 Conversion to the Euro

All accounting systems in the IMB were converted over to the Euro on 1st November 2001. Detailed testing was carried out on test databases prior to the conversion and the changeover took place successfully. The costs associated with the changeover were not significant.

23 Approval of Financial Statements

The financial statements were approved by the Board on 4th June 2003.

Appendix I:
Executive Committee Members and Committees

Executive Committee

Mr. Pat O'Mahony	Chief Executive (Appointed 9th December 2002)
Dr. J. G. Beechinor	Veterinary Director
Dr. Joan Gilvarry	Medical Director
Mr. John Lynch	Director of Inspection
Ms. Suzanne McDonald	Director of Information Technology
Dr. J. Michael Morris	Pharmaceutical Director
Ms. Ann O'Connor	Medical Devices Director
Ms. Rita Purcell	Director of Finance and Administration

** Dr. Frank Hallinan Chief Executive (Resigned 30th September 2002)*

Advisory Committee for Human Medicines

Professor Kevin O'Malley (Chairman)
Ms. Eugenie Canavan
Dr. Kevin Connolly
Professor Owen Corrigan
Dr. Paule Cotter
Professor Ted Dinan
Professor Desmond Fitzgerald
Dr. Mary Horgan
Dr. Rory Lehane
Dr. Kate McGarry
Mr. Tom McGuinn
Dr. Patrick Sullivan

Advisory Committee for Veterinary Medicines

Mr. Patrick J O'Connor (Chairman)
Dr. Thomas Barragry
Mr. Patrick Brangan
Dr. Rory Breathnach
Ms. Eugenie Canavan
Dr. Anne Cullinane
Mr. Timothy Kyne
Mr. Desmond Leadon
Mr. John McArdle
Mr. Tom McGuinn
Mr. Paul Mulville

Clinical Trials Sub-Committee of Advisory Committee for Human Medicines

Dr. Patrick Sullivan (Chairman)
Dr. Liam T. Bannan
Professor David Bouchier-Hayes
Dr. Paul Browne
Professor Ted Dinan
Professor Desmond Fitzgerald
Dr. Liam Grogan
Dr. Tom Peirce

Expert Sub-Committee of the Advisory Committee for Human Medicines

Dr. Anne Bruzzi
Dr. Brendan Buckley
Dr. Colin Buckley
Dr. Mary Cafferkey
Dr. Owen Carey
Professor Martin Clynes
Professor Louis M. T. Collum
Dr. Peter Conlon
Dr. Kevin D. Connolly
Prof. Ted Dinan
Dr. George Duffy
Professor Des Fitzgerald
Dr. Stephen Flint
Dr. Owen Hensey
Dr. Mary Horgan
Professor Hilary Humphreys
Dr. Gerry D. Hurley
Dr. Kevin Kelleher
Dr. Mary Keogan
Dr. John McCaffrey
Dr. Patricia McCormack
Mr. T. McGuinn
Dr. David McInerney
Dr. Malachi McKenna
Professor Kingston Mills
Dr. Fiona Mulcahy
Dr. Frank Murray
Dr. John O'Connor
Dr. Rosemary O'Connor
Dr. Veronica O'Donoghue
Dr. Janice Redmond
Dr. Mark Rodgers
Dr. Martina Scallan
Professor Brian Sheppard
Dr. John Stack
Dr. Brion Sweeney
Dr. Douglas Veale

Scientific Committee on Herbal Medicinal Products

Dr. D. Corrigan (Chairperson)
Dr. D. Clare
Ms. N. Darrell
Prof. E. Ernst
Mrs. I. Hook
Ms. G. Lavelle
Ms. H. McCormack
Dr. K. Chan-Mullen
Dr. H. Sheridan

The Irish Medicines Board wishes to acknowledge the work of the experts without whose continuous support the Irish Medicines Board would have difficulty in carrying out its statutory functions. The Board wishes to acknowledge the contribution made to its Sampling and Analysis Programme and to the work of its Committees by Dr. Des Feeley who recently retired from his role as Public Analyst to the Western Health Board. The Board also acknowledges the contributions made by Dr. Kate McGarry and Professor Owen Corrigan who resigned from the Advisory Committee for Human Medicines.

Appendix II:
Meetings Attended by Staff on behalf of the IMB

The Committee for Proprietary Medicinal Products (CPMP)
The Committee for Orphan Medicinal Products (COMP)
The Committee for Veterinary Medicinal Products (CVMP)
Mutual Recognition Facilitation Group (MRFG) & 'Breakout' Meetings
CPMP Safety Working Party
CPMP Pharmacogenetics Working Party
CPMP Efficacy Working Party and Therapeutic Subgroup
CPMP Vaccine Expert Group
CPMP Ad hoc Expert Diabetes Group
CPMP Ad hoc Working Group on Comparability of Biotechnology Derived Products
CPMP Pharmacovigilance Working Party
CPMP Working Party of Good Clinical Practice
CPMP Scientific Advice Review Group
CPMP Ad hoc Working Party on Blood Products
CPMP Ad hoc Working Party on Anti-Cancer Agents
CPMP Ad hoc Working Party on Update on the Note for Guidance on the SPC
CPMP Ad hoc Working Party of GCP Inspectors
CPMP Herbal Medicinal Products Working Party
CPMP/CVMP Quality Working Party
CVMP Efficacy Working Party
CVMP Immunologicals Working Party
CVMP Pharmacovigilance Working Party
CVMP Ad hoc Group on Availability of Veterinary Medicines
EU Commission Meeting on CT Directive Guidelines
EU Commission Notice to Applicants Working Party
European Pharmacopoeia Commission
Council Working Party Meetings on Directive for Traditional Medicines
Annual Meeting of National Centres participating in the WHO Collaborating Programme
National Immunisation Committee (Ireland)
National Immunisation Steering Committee (Ireland)
WHO Meeting on Advertising
International Society of Pharmacovigilance
Joint Pilot Project on Implementation of Electronic Reporting
Emacolex
Informal EU Group of Competent Authorities for Homeopathic Medicinal Products
Official Medicines Control Laboratories (OMCL) Network
Permanent Forum on International Pharmaceutical Crime
First Global Forum on Pharmaceutical Anti-Counterfeiting
EMEA Ad Hoc Working Party of GMP Inspection Services
PIC/S Committee of Officials
EU Commission Notice to Applicants Working Party
EMEA Working Party on Quality Review of Documents
Meeting of Heads of Regulatory Agencies of Veterinary Medicinal Products
Pan European Regulatory Forum
Veterinary Mutual Recognition Facilitation Group

Appendix III:
Meetings Attended by Staff as Invited Speakers

Title	Event	Speaker
The IMB and Pharmacovigilance	Irish Centre for Continuing Pharmaceutical Education, Post Graduate Training for Pharmacists, Cork , Louth, Clare and Donegal; April, May, November 2002	Niamh Arthur
The CIOMS Communications Monograph	ICH, Brussels; February 2002	Niamh Arthur
Risk Communications and Crisis Management	Pan European Regulatory Forum, Bulgaria; April 2002	Niamh Arthur
Irish Pharmacovigilance Regulations and Guidelines and A Regulatory View of EU Pharmacovigilance Guidelines	University of Hertfordshire Training Course of Postgraduate Employees; September 2002	Niamh Arthur
Counterfeiting and Fraudulent Diversion of Pharmaceuticals	IPCMF Crisis Management Workshop by Risk Management, Cork; June 2002	Hugo Bonar
The IMB Herbal Medicines Project Final Report	Irish Herb Society, Galway; February 2002	Dairine Dempsey
Regulations of Traditional Medicinal Products	Irish Centre for Continuing Pharmaceutical Education; May, November 2002	Dairine Dempsey
Proposed Regulatory Actions on Paediatric Medicinal Products	European Forum of Good Clinical Practice Meeting, Brussels; 2002	Joan Gilvarry
Patient Leaflets: Content and Comprehension, a Regulatory Perspective	EAN Annual Conference, London; January 2002	Joan Gilvarry
Ensuring a Standardised Informed Consent Process	Clinical Trial Conference London; January 2002	Joan Gilvarry
EU Directive and Clinical Trials in Ireland	Irish Clinical Research Society Meeting; October 2002	Joan Gilvarry
Homeopathic Medicines at the IMB	The Annual Meeting of the Irish Health Trade Association; April 2002	Gwen Glasgow
The Regulation of Homeopathic Medicines – Ireland and the EU	Irish Society of Homeopaths – Western Branch; November 2002	Gwen Glasgow
The National Vigilance System for Medical Devices	National Risk Managers Group; August 2002	Andrea Hanson
IMB Guidance on Packaging and Leaflets	IIR Conference on Meeting the Changing Regulations of PILS, Packaging and Labelling, London	Sheila Killalea
Orphan Drugs	Fondaione Salvatore Maugeri Symposium, Pavia, Italy; February 2002	David Lyons
New Trends in Regulatory Affairs	Eudipharm Seminar, Brussels; April 2002	David Lyons
BIRA Training Day	London; June 2002	David Lyons
Human Genome: The Research Ethics Dimension	Irish College of General Practitioners, Dublin; February 2002	Teresa Mitchell
Regulatory Guidelines Covering the Use of Genotyping in Clinical Trials	Drug Information Association (DIA), Basel; March 2002	Teresa Mitchell

Meetings Attended by Staff as Invited Speakers *(continued)*

Title	Event	Speaker
Biotechnology Products from Transcription to Prescription	London; June 2002	Teresa Mitchell
Council on Cardiovascular Genetics Workshop	Tallaght Hospital, Dublin; July 2002	Teresa Mitchell
Participation in Endocrinology Summer School	University of Reading; September 2002	Teresa Mitchell
Specifications	IBC Ltd., London; January 2002	Mike Morris
Quality Aspects of Pharmaceutical Excipients	EDQM Seminar, Brussels; April 2002	Mike Morris
Specifications for Modified Release Dosage Form	IBC Ltd. London; May 2002	Mike Morris
Stability Testing	IIR Ltd., Dublin; May 2002	Mike Morris
New Quality Development and Guidance	IBC Seminar, London; July 2002	Mike Morris
Validation during Pharmaceutical Development	PCS Workshop, Amsterdam; November 2002	Mike Morris
Comparability of Biotechnology Derived Products	Drug Information Association (DIA) Basel; March 2002	Orla Nolan
Herbal Medicines: Worts and All	British Toxicology Society, London; May 2002	Orla Nolan
The Drug Device Divide	Irish Medical Devices Association Annual Meeting; May 2002	Ann O'Connor
IMB impact on Laboratory Practice	IEQAS Annual Meeting	Ann O'Connor
Regulatory Issues with New Medical Devices	Engineering Conference	Ann O'Connor
Tissue Engineering	EI Conference; November 2002	Ann O'Connor
The National Vigilance System for Medical Devices	DATH's Fora	Ann O'Connor Andrea Hanson
Pharmaceutical Quality Assurance	Dublin Institute of Technology, Dublin; March 2002	Kevin O'Donnell
Quality Defects on Drug Products and their Investigation	DIT Kevin Street: Lecture and Workshop to students in the MSc Degree course in Pharmaceutical Quality Assurance; March 7th and 14th 2002	Kevin O'Donnell
Sterilisation	Honeyman Sterilisation Course	Stan O'Neill
Process Deviations	TIPPSA	Stan O'Neill
ESRA Meeting	Brussels; October 2002	Patrick Salmon
Taiex Meeting	Nicosia; November 2002	Patrick Salmon
EU Assessor Training Course on Biopharmaceutical Quality Training	IMB, Kinsale; May 2002	Various IMB Personnel
IMB's Inspection and Enforcement Activities	PERF Meeting organised by EMEA, Dublin; June 2002	Various Inspectorate/ Enforcement Personnel

Appendix IV: Publications

Arthur N

Howlett A, Arthur N, Corrigan O.,
An analysis of ADR reporting by Pharmacists in Ireland
Irish Pharmacy Journal, December 2002: 519-527

Killalea S

Meaklim J, Yang J, Drummer OH, Killalea S, Staikos V, Horomidis S, Rutherford D, Ioannides-Demos LL, Lim S, McLean AJ, McNeil JJ. Fenitrothion: toxicokinetics and toxicologic evaluation in human volunteers. Environ Health Perspect. 2003 Mar; 111(3): 305-8.

Mitchell TH

Ireland's Health in Crisis: Do mothers hold the answer?
Modern Medicine 2002, 32, 12, 33-35

Human Genome – The Research Ethics Dimension Report prepared by Dr. David Smith for ICGP with contribution by Dr. T. M. Mitchell, IMB

A Prospective International Assessment of Policy Reactions to Concern regarding Combined Vaccines: Partnership for Prevention, Child Health Evaluation and Research Unit, University of Michigan with contribution by Dr. T. M. Mitchell, IMB

Glasgow G

Published articles in the Homeopathic Times, Quarterly Journal of the Irish Society of Homeopaths, Summer Issues. Titled 'Homeopathic Medicines Project at the IMB'.

Appendix V: Glossary

ADR:	Adverse Drug Reaction
AIMD:	Active Implantable Medical Device
APHA:	Animal and Plant Health Association
API:	Active Pharmaceutical Ingredient
APMI:	Association of Pharmaceutical Manufacturers of Ireland
BWP	Biotechnology Working Party
CA:	Competent Authority
COMP:	Committee for Orphan Medicinal Products
CPMP:	Committee for Proprietary Medicinal Products
CJD:	Creutzfeldt Jakob Disease
CTD:	Common Technical Document
CVMP:	Committee for Veterinary Medicinal Products
DAF:	Department of Agriculture and Food
DoHC:	Department of Health and Children
EC:	European Community
ECTD:	Electronic Common Technical Document
EDQM:	European Directorate for Quality of Medicines
EEA:	European Economic Area
EMEA:	European Agency for the Evaluation of Medicinal Products
EU:	European Union
FDA:	Food and Drug Administration
FEDESA:	European Federation of Animal Health
FOI:	Freedom of Information
GCP:	Good Clinical Practice
GDP	Good Distribution Practice
GMD:	General Medical Device
GMP:	Good Manufacturing Practice
HIV:	Human Immunodeficiency Virus
HRT:	Hormone Replacement Therapy
IAHS:	Irish Association of Health Stores
ICH:	International Conference on Harmonisation
IHTA:	Irish Health Trade Association
IMB:	Irish Medicines Board
IMDA:	Irish Medical Devices Association
IPCMF:	Irish Pharmaceutical and Chemical Manufacturers Federation
IPHA:	Irish Pharmaceutical Healthcare Association
IVD:	*In-Vitro* Diagnostic
MA:	Marketing Authorisation
MAH:	Marketing Authorisation Holder
MCA:	Medicines Control Agency
MDA:	Medical Devices Agency
MHRA:	Medicinal and Healthcare Products Regulatory Agency
MR:	Mutual Recognition
MRA:	Mutual Recognition Agreement
MRL:	Maximum Residue Limit
NBOG:	Notified Bodies Operations Group
NDAB:	National Drugs Advisory Board
NSAI:	National Standards Authority of Ireland
NSAID:	Non Steroidal Anti Inflammatory Drug
PA:	Product Authorisation
PERF:	Pan European Regulatory Forum
Ph.Eur.:	European Pharmacopoeia
PhVWP:	Pharmacovigilance Working Party
PIC/S:	Pharmaceutical Inspection Co-Operation Scheme
PIM:	Product Information Management
QWP:	Quality Working Party
SCHMP:	Scientific Committee on Herbal Medicinal Products
SWP:	Safety Working Party
TSE:	Transmissible Spongiform Encephalopathy
UN:	United Nations
VPA:	Veterinary Product Authorisation
WHO:	World Health Organisation

IRISH MEDICINES BOARD

Earlsfort Centre
Earlsfort Terrace
Dublin 2

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