IRISH MEDICINES BOARD

Annual Report and Accounts 1997

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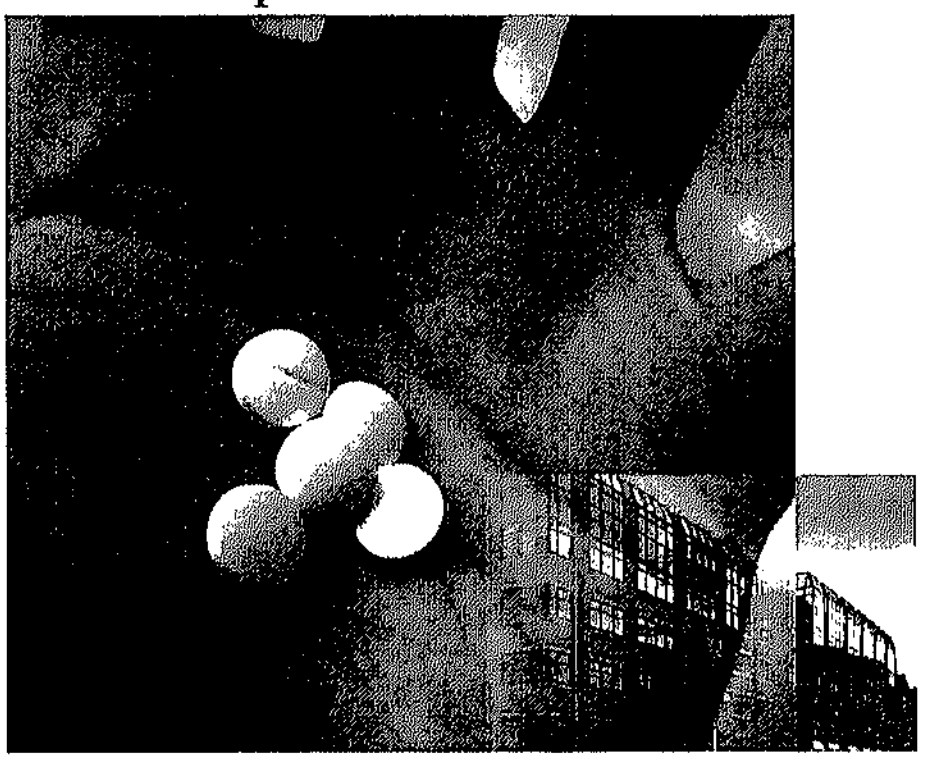
IRISH MEDICINES BOARD

Annual Report 1997



PAT O'MAHONY

Chairman's Report

I am pleased to report continuing progress and also to report that this was achieved with no cost to the taxpayer.

It gives me pleasure to introduce the 1997 Annual Report of the Irish Medicines Board, which is the second annual report of this new agency. The report contains a summary of activities during 1997, details of anticipated events for 1998 and the financial report. I am pleased to report continuing progress and also to report that this was achieved with no cost to the taxpayer.

The Irish Medicines Board operates in a very sensitive area. All those involved, namely the Board, management, staff and experts are very aware of the importance of the organisation in public health. The nature of the work is technically highly demanding and often at the forefront of medical knowledge. Ultimate decisions must balance the benefits of treatments against their risk, sometimes in the presence of much public debate. The role must balance several interests, notably public and commercial and inevitably this leads on occasion to conflict.

The Irish Medicines Board seeks to move forward in a consensus manner where possible, recognising its ultimate responsibilities to public health. In this context I welcome our new Service Charter.

I want to take this opportunity to express both my own and the Board's regret at the intended departure of our Chief Executive, Dr. John Kelly, during 1998. His contribution to the new organisation has been immeasurable and he will be greatly missed both at a personal and operating level. I wish him well in his future career.

Finally, I would like to express my appreciation of the continuing hard work and dedication of the staff. I would also like to thank the experts who have contributed during the year to the Irish Medicines Board's essential role in public health.

Pat O'Mahony
Chairman

Board Members

MR. PAT O'MAHONY (CHAIRMAN)

MS. RITA CLANCY

MR. ALBERT COSTELLOE

MR. DENIS CRONIN

MS. MARIE HOGAN

MS. ANNE NOLAN

MR. MARTIN HIGGINS

PROF. KEVIN O'MALLEY

MS. MAURA WATERS

COMPOSITION OF THE BOARD & OTHER INFORMATION

The Board was appointed on 1st January 1996 by the Minister for Health and Children, Mr. Michael Noonan TD in accordance with the powers conferred on him by subsection 2 of section 7 of the Irish Medicines Board Act, 1995.

DR. JOHN KELLY

Chief Executive's Report

The second year of the Irish Medicines Board has seen continuing change both within the Irish Medicines Board as we continue to build structures and improve efficiencies but also outside the Irish Medicines Board as we move towards greater harmonisation.

EUROPEAN MEDICINES REGULATORY SYSTEMS

December 31st 1997 marked the end of a transition period during which applicants seeking to market a medicinal product in more than one member state had a choice of making multiple separate national applications or application to one member state followed by application for mutual recognition by other member states. From January 1st 1998, there are only two systems by which the European market may be accessed outside of a single member state.

THE CENTRALISED SYSTEM

This route is mandatory for biotechnology products and optional for certain other new products.
The application is made to the European Medicines Evaluation Agency (EMEA), based in London.
The EMEA contracts the assessment to individual member state agencies. The resulting assessment report is reviewed by the remaining member states via the Committee for Proprietary Medicinal Products (CPMP) or the Committee for Veterinary Medicinal Products (CVMP). The resulting decision is binding upon all member states.

THE DECENTRALISED SYSTEM

The remainder of products must use this system. An application for authorisation is made to an individual member state. Following authorisation that member state may act as the reference member state (RMS) under the Mutual Recognition system.

A valid application under the mutual recognition procedure can only be refused by the concerned member states on the basis of significant risks to public health. Such concerns must be raised by the 60th day following receipt of an application. Otherwise the review must be complete by the 90th day and an authorisation issued by the 120th day.

NATIONAL SYSTEMS

Applications to individual member states under existing national systems may still be made but applications to additional member states must be made under the Mutual Recognition system.

CONTRIBUTION OF THE IRISH MEDICINES BOARD TO EUROPEAN SYSTEMS

The IMB takes seriously its participation in European medicines regulatory systems. This participation however uses significant and expensive resources. The IMB participates in the formal committees such as the Pharmaceutical Committee of the European Commission, the Board of the EMEA, the CPMP and the CVMP. The latter are the two senior medicines advisory committees to the Commission (for human and veterinary medicines respectively). Beginning in 1998, IMB staff members hold the vice-chairmanship of both these committees. This is a significant achievement for a single agency. I must pay tribute to the IMB's Medical Director, Dr. Mary Teeling and its Veterinary Director, Mr. Cyril O'Sullivan in recognition

of being appointed to these important positions. There are a large number of additional committees to which the IMB contributes.

REVIEW OF 1997

The year began with the continuation of the work of the Tribunal of Inquiry into the circumstances surrounding the contamination with Hepatitis C of the blood product Anti-D Immunoglobulin. This consumed a significant proportion of resources for the first quarter of the year. The report of the Tribunal of Inquiry was published on 6th March 1997. The report addressed the role of the predecessor body to the Irish Medicines Board, that is the National Drugs Advisory Board (NDAB) and considered if the NDAB could have prevented this infection as part of its inspection and supervisory roles. The report concluded that 'It is clear that it was not the process being used for the manufacture of that product nor the systems availed of for its storage, distribution or dispatch that caused this infection, but rather the clearest breaches of:

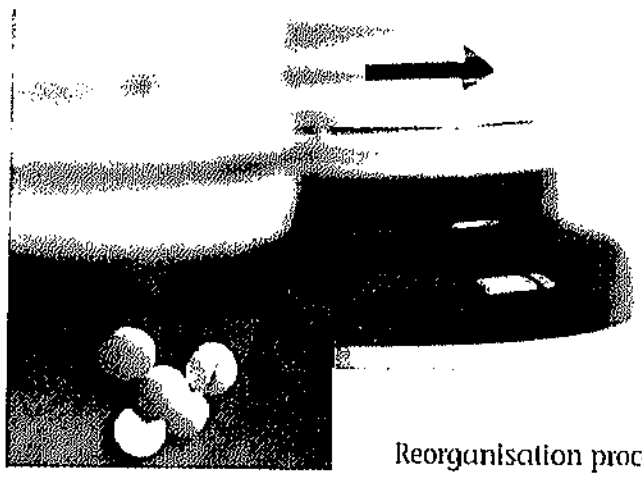
i) a number of standard operating procedures...
ii) well established rules for action resulting from complaints of abnormal reaction...
iii) a total ignoring of the proper standard of recall and destruction...'

This is a suitable opportunity to remind manufacturers of medicinal products of the need for appropriate procedures and of the need to follow these procedures and to inform the regulatory agency of any important matter with safety implications. The regulatory agency cannot physically supervise production of every batch manufactured in every plant in the country. There is an onus on the manufacturer to disclose relevant facts to the agency.

The IMB introduced regular newsletters during the year. These were circulated to holders of product authorisations and to health care professionals and included up-to-date lists of recently authorised products. During 1997, the IMB began work on a web site which will provide an electronic information source for those interested or involved with medicines regulation. This will be available at around the time of publication of this annual report. Included will be details of the IMB, details of the methods for making applications for product authorisation, fees and copies of reports.

Also during 1997, preparations were made for the requirements of the Freedom of Information Act, which became applicable to the IMB on April 21st 1998.

The IMB has committed to complying with the requirements of the Act and has produced an FOI document which is available on request (Section 15 document).



Reorganisation proceeded during 1997 and a new structure will be in place by the time this annual report is published. Completion of this required considerable work and inevitably some disruption involving interim structures and procedures. The task was eased by the willing and committed participation of all those involved and I appreciate that commitment to the future of the organisation.

I hope that industry has seen overall continuing progress in their regulatory contacts. A priority during 1997 was addressing areas of backlog. Files of all products subject to the veterinary review process had been opened by the year end. By the time of publication of this report, only a small number of products requiring outstanding technical issues to be addressed will remain. In the case of human medicines, a task force was established which will continue to address areas of backlog during 1998. In many cases, review of these products will require applicants to address outstanding technical issues within defined time frames. Failure to do this has historically contributed considerably to longer average authorisation times and the need to continuously revisit files has been a barrier to reduction of average assessment times. Completion of this review, together with the increased availability of resources will permit more timely reviews.

A feature of the year was preparation for new European Systems from January 1st 1998. These are reviewed elsewhere. Many applicants wished to take advantage of the time remaining for applications under the existing system which resulted in a steady increase in application numbers from August onwards, culminating in a busy December. The IMB was pleased to be able to facilitate these requests by examining and validating all applications by the European system deadline of 31st December.

FINANCE

The statement of accounts for the year is contained in a later section. The IMB continued to conduct its activities with no cost to the State. Financial targets for the year were exceeded, mainly for two reasons. Firstly, increased income due to increased numbers of applications in the latter half of the year and to increased regulatory activities following company merger activity. Secondly, lower costs than budgeted due to the bulk of the structural changes falling into 1998. In the longer term, changing European systems will have significant implications for the income of national agencies including the IMB. Harmonisation, centralisation and mutual recognition may reduce incomes and it is important to monitor any trends in this area.

CLOSING REMARKS

Publication of this annual report will coincide with the end of my period as Chief Executive of the IMB. I took up my appointment during the final year of operation of the NDAB with the task of establishing the new organisation. The IMB is a very different organisation to the NDAB and is a major guardian of public health. Within a very short time the IMB has established itself as a professional organisation with a creditable reputation for its technical excellence within Europe and further afield. Much credit is due to the staff of the IMB for their commitment to the new organisation. I would like to thank Board members for their help and advice, members of our advisory committees who provide an invaluable resource which is a real contribution to public health and staff at the Department of Health and Children for their willing help.

I have enjoyed my time at the Irish Medicines Board. I am pleased to have been involved in its establishment and I would like to leave my good wishes for the future with the staff and with those associated with its activities.

Dr. John G. Kelly
Chief Executive

Human Medicines

Irish authorisation times continue to compare favourably with those of other countries...

LICENSING

During 1997, the IMB issued 676 product authorisations. The following table shows the distribution of these:

New products, national	225
New products, European mutual recognition	95
New products, European centralised	10
Transfers	346
Total	676

The median authorisation time for new product authorisations was 74 weeks. Most applications for new chemical entities now proceed through the European Centralised system/mutual recognition system. At a national level, the Irish Medicines Board authorised 19 new chemical entities. During 1997 there was considerable activity related to company mergers resulting in increased requests for product transfers. The median time for review and issue of these authorisations was six weeks. During the year 3,051 variations to product authorisations were issued.

Irish authorisation times continue to compare favourably with those of other countries both inside and outside of the European Community. It is important to note however, that the authorisation times above are whole times, that is, they reflect the time from receipt of an application to issue of an authorisation and also include periods of dialogue with the applicant and the times taken for the applicant to respond. These can be long. Approximately 20% of new products (national) fall into this category.

As mentioned earlier, a task force has been established to address products with outstanding queries. It is intended that each of these files be reviewed during 1998.

The new year marks the beginning of the new European system for mutual recognition. This resulted in the receipt of a large number of applications for national product authorisations during the last quarter of 1997, seeking to avail of the existing national system.

Three final items should be pointed out:

i) When a medicinal product is authorised, it is an indication that the quality, safety and efficacy of that product has been examined and that the likely benefits are considered to outweigh any possible risks. The prescription of a product which does not carry an authorisation, or outside the terms of the authorisation (e.g. different doses or indications) is provided for under Section 4 of the Medical Preparations (Licensing and Sale) Regulations, 1996 (S.I. No.43 of 1996). The responsibility for such use rests with the prescriber.

ii) The definition of a medicinal product is contained in European Council Directive 65/65/EEC. This is reprinted below:-

- 'Any substance or combination of substances

presented for treating or preventing disease in human beings or animals.

- Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product'.

Thus products presented as medicines, making medicinal claims or containing substances having pharmacological effects are likely to be medicinal products requiring authorisation. It is not permitted to advertise or sell medicinal products without such authorisation. The pharmaceutical profession has a particular responsibility to ensure that the public are protected from products making unsubstantiated claims or for which quality, safety and efficacy cannot be adequately guaranteed.

iii) The IMB takes seriously its role in the protection of public health. The Irish Medicines Board Act 1995 refers to the role of the Irish Medicines Board in enforcing and execution of the various regulations. The IMB intends to be active in this area.

CLINICAL TRIALS

The Control of Clinical Trials Act is intended to protect the interests of participants in clinical trials. It forbids the conduct of a clinical trial unless the requisite permission has been obtained. 'Conduct a clinical trial' is defined as 'the conducting of a systematic investigation or series of investigations for the purpose of ascertaining the effects (including kinetic effects) of the administration of one or more substances or preparations on persons where such administration may have a pharmacological or harmful effect...'.

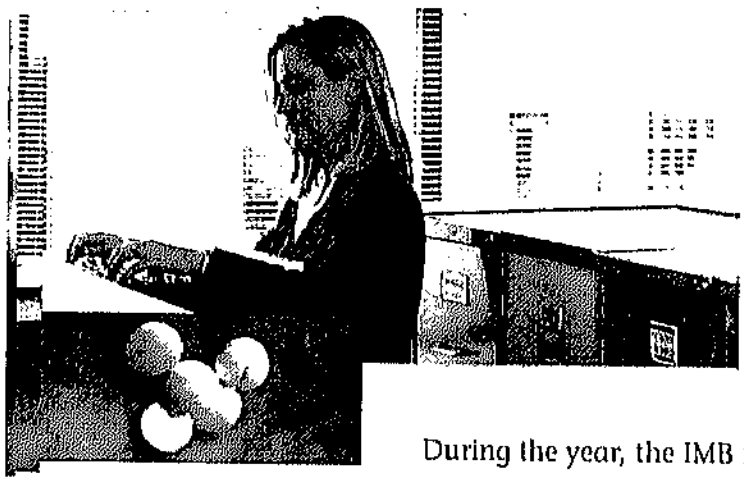
Permissions to conduct 243 clinical trials were granted during 1997. There were 201 permissions to amend clinical trials.

A European Directive relating to Good Clinical Practice in the conduct of clinical trials is expected to be adopted late in 1998. This will introduce harmonised requirements for clinical trials throughout the Community, including systems for ensuring compliance with Good Clinical Practice. The Irish Medicines Board is making arrangements to fulfil this function.

PHARMACOVIGILANCE

During 1997 the Irish Medicines Board received 1,175 adverse reaction reports of national origin. The distribution of sources was as follows:

General Practitioners	34.7%
Product Authorisation Holders	42.4%
Hospital Doctors	11.7%
Pharmacists	7.9%
Nurses	3.0%
Dentists	0.3%



During the year, the IMB reviewed and updated its guidelines for reporting of adverse drug reactions by companies in line with international activities in this area. All product authorisation holders received details. Further copies are available on request or via the IMB web site. The IMB communicated with doctors and pharmacists on the following topics:

ACE Inhibitors
Co-Amoxiclav (Augmentin)
Combined Oral Contraceptives (COCs)
Fenfluramine and Dexfenfluramine
Grapefruit Juice
Hormone Replacement Therapy (HRT)
Lamotrigine (Lamictal)
Malathion
Nucleoside Analogues
Paracetamol
Terbinafine (Lamisil)
Terfenadine
Tolrestat (Alrestat)
Vigabatrin (Sabril)
Vitamin B6

Further information on any of these is available on request from the IMB.

SAFETY OF MEDICINES

The proper use of a medicine involves a decision which balances the benefit attached to its use against any risk. Any medicine can be the cause of an adverse reaction and the prompt reporting of these by health care professionals using the yellow card system is a major source of information to the Irish Medicines Board in monitoring the safety of medicines.

QUALITY DEFECTS

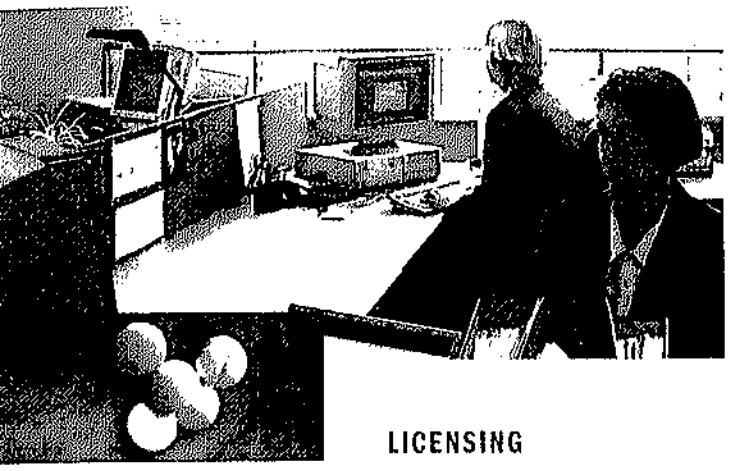
A total of 64 reports were received during 1997, the highest number submitted in any year. Eight of the complaints were found on examination not to be justified and in a further case, it was not possible to conclusively determine the origin of the defect.

Of the remaining 55 reports, four related to major defects resulted in batch recalls and involved a parenteral product which failed stability testing and tablets which had an extensive problem of colour-bleeding in the coating. The other two major defects related to incorrect label texts and resulted in a caution-in-use letter.

Over half of the reports came from community pharmacists and the remainder from PA holders, physicians and members of the public.

Veterinary Medicines

During 1998 the IMB anticipates taking responsibility for the assessment of veterinary vaccines...



LICENSING

There were 179 veterinary product authorisations issued during 1997. Of these 53 were for new products and 126 were issued under the veterinary review process. The median authorisation time for new product authorisations was 57 weeks. As for human medicines, these are whole figures from receipt of an application to issue of the authorisation and include periods when applications are held pending receipt of further data. The veterinary review process was drawing to a close at year end with all outstanding files opened. A proportion of these will carry into 1998 pending resolution of outstanding issues and to provide applicants with time to address questions. The number of variations to veterinary product authorisations issued during the year was 414, a considerable increase on the 1996 figure of 108.

During 1998 the IMB anticipates taking responsibility for the assessment of veterinary vaccines, beginning with a review of existing products. The veterinary department will be in touch with companies following completion of the planning process.

PHARMACOVIGILANCE

The IMB's pharmacovigilance system is a continuing source of valuable information on adverse drug reactions to veterinary medicinal products. However, many adverse reactions go unreported by veterinary surgeons, pharmacists and other healthcare professionals. The greater the input into the system, the more timely and effective will be the benefits brought about.

The main highlight of the year was the use of anthelmintic boli in cattle, which led to a meeting with the marketing authorisation holders to review what further steps could be taken to increase awareness of the safe use of the products (i.e. in animals of the correct age and weight and administration using the appropriate technique). A new educational campaign to this effect will be mounted early in 1998.

Other events of note were the occurrence of suspected adverse reaction to mineral and vitamin preparations in cattle and to various antimicrobial compounds in several species. Arising from the reports received, label changes were introduced on a number of products.

Adverse reactions in four humans following use of veterinary medicinal products were also reported. These related to the use of pyrethroids, organophosphates and fipronil. In all of the cases reported, no or inadequate protective clothing was worn or directions for safe use were not followed.

A full report of the reported adverse reactions for 1996/97 will be published during 1998.

Also during the year, a sub-Committee of the Advisory Committee for Veterinary Medicines was set up to advise the ACVM on the Sale and Supply of Intramammary Veterinary Medicines. The sub-Committee expects to prepare a report during 1998.

AVAILABILITY OF VETERINARY MEDICINES

With the dual impact of the Residue Regulation 2377/90 on the availability of active substances used in veterinary medicines and the commercial limitations of a small market size in Ireland, several potentially useful and important drugs are being lost. This is a serious concern which has obvious animal welfare and public health implications.

IMB staff members are working with colleagues from the Department of Agriculture, Veterinary Organisations and colleagues from overseas authorities to identify potential gaps in the therapeutic armoury and to take steps to ameliorate the situation.

EUROPEAN ACTIVITIES

The IMB continues to play a full part in the Committee for Veterinary Medicinal Products (CVMP) of the European Medicines Evaluation Agency (EMEA) and its sub-Committees.

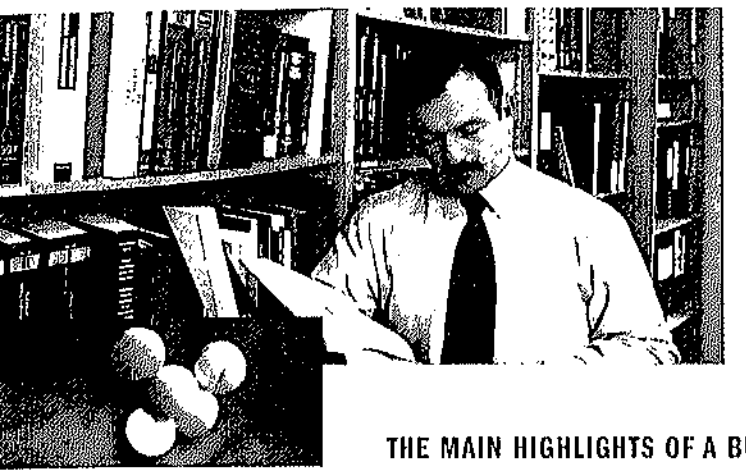
During the year Ireland acted as rapporteur for three Centralised procedures and as Co-Ordinator for Scientific Advice for one application.

The work of establishing maximum residue levels (MRLs) as required by regulation 2377/90 continues with significant progress being made in the review of all substances. Ireland was Rapporteur for four applications and Co-Rapporteur for two applications for MRLs for new actives as well as acting as Rapporteur for the review of several of the old actives.

Use of the mutual recognition procedure continues to expand. Ireland acted as Reference Member State for three applications during the year.

Inspections

During 1997 the Inspectorate paid particular attention to the validation status of manufacturing processes.



THE MAIN HIGHLIGHTS OF A BUSY YEAR ARE SHOWN BELOW:

Inspections and Licensing

Inspections in Ireland	57
Inspections of Foreign Sites	3

Licence revocations:

One veterinary manufacturer's licence was revoked due to critical GMP deficiencies.

New licences issued:

Human manufacturer	4
Veterinary manufacturer	3
Wholesaler	3

Variations to existing licences:

Human manufacturer	49
Veterinary manufacturer	15
Wholesaler	2

Numbers of licences at year end:

Human manufacturer	72
Veterinary manufacturer	16
Wholesaler	83

RAPID ALERTS

The IMB received a total of 20 Rapid Alerts from EU and/or PIC/S Member States in relation to recalls of defective medicinal products. Of these 20 alerts, 4 were relevant to products which were on the Irish market. Appropriate recall action was instituted in each of the 4 cases.

RECALLS

Medicinal Products for Human Use:

There was a total of 43 recalls of medicinal products for human use during 1997. The breakdown of these was as follows:

Packaging error	11
Stability problems	8
Non-compliance with PA	6
Precautionary withdrawal due to possible safety risks	4
Non-compliance with specification	3
Change from over the counter to prescription status	2
Withdrawal due to safety risks	2
Incorrect details on Patient Information Leaflet	1
Precautionary withdrawal of a blood product due to lack of a specific viral inactivation step	1
Product deterioration due to incorrect transportation conditions	1
Sterility test failure	1
Cosmetic defect	1
Leaking containers	1
Precautionary recall of product containing a plasma derivative due to donor to plasma developing new variant CJD	1

Veterinary Medicinal Products

There was a total of 33 recalls of veterinary medicinal products during 1997. The breakdown of these was as follows:

Lack of sterility assurance	31
Stability problem	1
Non-compliance with VPA	1

NATIONAL

A number of companies constructed new facilities or upgraded existing facilities during 1997. The need for regular review and if necessary, upgrading of facilities and systems is stressed to all manufacturers and wholesalers.

During 1997 the Inspectorate paid particular attention to the validation status of manufacturing processes. Key points which manufacturers should bear in mind at all times are:

- process validation should not commence until equipment has been fully qualified,
- raw materials should be fully characterised with regard to their properties which are likely to effect the finished products, e.g. particle size etc.,
- process optimisation is not the same as process validation,
- for the manufacture of validation batches the manufacturing parameters should be clearly defined and should not be altered throughout the manufacturing process.

The report of the Hepatitis C Tribunal recommended that the IMB should 'carry out not less than two separate full inspections .... each year of the premises and procedures of the Blood Transfusion Service Board'. This recommendation was complied with during 1997 with both fixed Centres in Ireland being inspected three times. A mobile blood collection clinic and a contract laboratory were also inspected.

EU/INTERNATIONAL

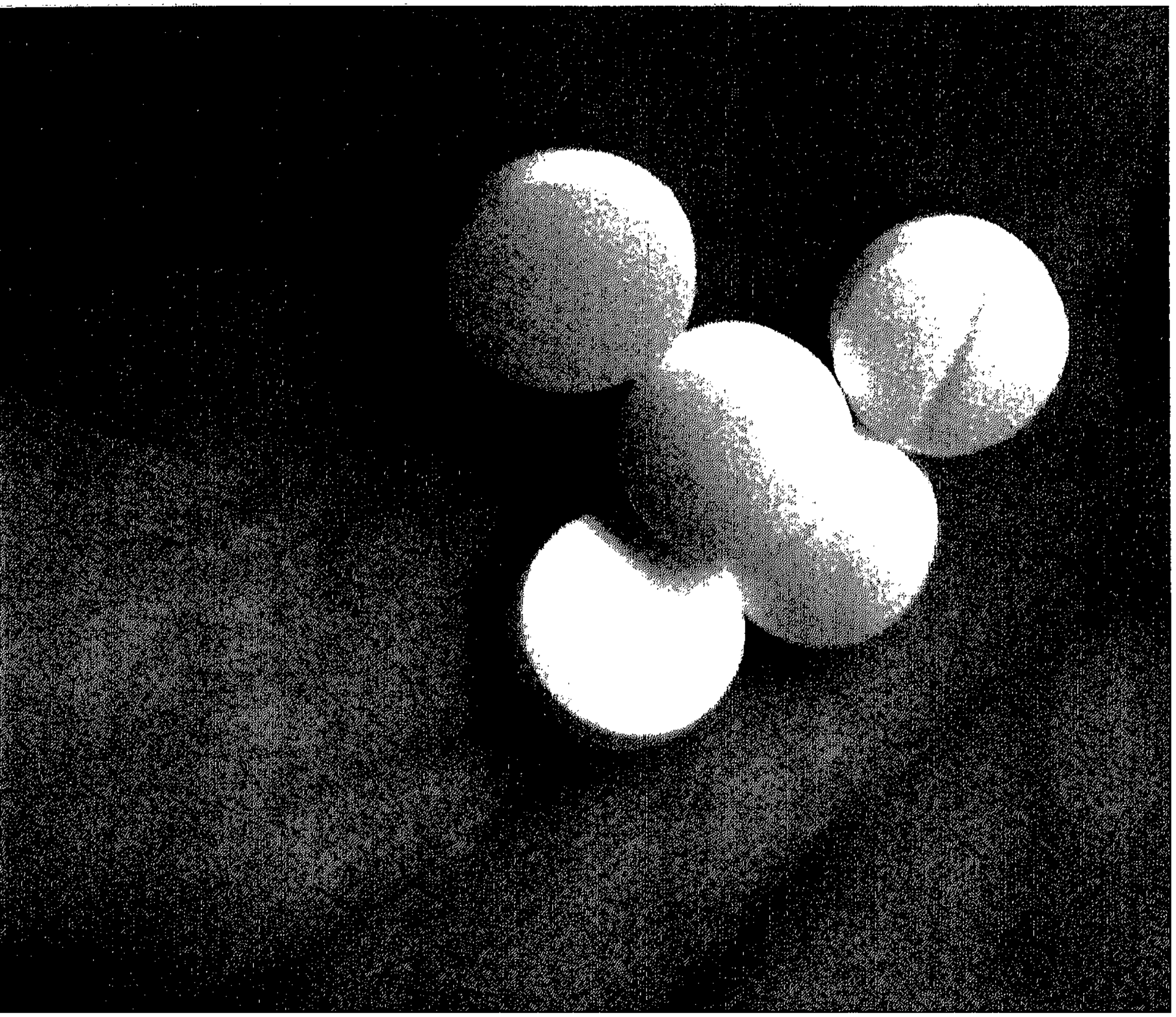
Negotiations on Mutual Recognition Agreements (MRAs) on GMP inspection continued during 1997. By the end of the year it had emerged that the transition periods for the MRAs with Canada and the USA would be 18 months and three years, respectively, from the date of their coming into force. It was envisaged that these MRAs, along with those with Australia, New Zealand and Switzerland, would be signed during 1998.

Proposals to amend Directives 75/319/EEC and 81/851/EEC to provide for inspection of the manufacture of starting materials were out for consultation with interested parties at the end of 1997.

A draft Internationally Harmonised GMP Guide for Active Pharmaceutical Ingredients, prepared under the auspices of the Pharmaceutical Inspection Co-Operation Scheme (PIC/S), was out for consultation with interested parties at the end of 1997.

IRISH MEDICINES BOARD

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
Maura Waters, Board Member

Report of the Comptroller and Auditor General

I have audited the financial statements on pages 19 to 26.

RESPONSIBILITIES OF THE BOARD AND OF 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 17. It is my responsibility, under Section 18 of the Irish Medicines Board Act 1995, to audit the financial statements presented to me by the Board and to report on them. As a result of my audit I form an independent opinion on the financial statements.

BASIS OF OPINION

In the exercise of my functions as Comptroller and Auditor General I plan and perform my audit in a way which takes account of 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 and 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, consistently applied and adequately disclosed.

My audit was conducted in accordance with auditing standards which embrace the standards issued by the Auditing Practices Board and in order to provide sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement whether caused by fraud or other irregularity or error. I obtained all the information and explanations that I required to enable me to fulfil my function as Comptroller and Auditor General and, in forming my opinion, I also evaluated the overall adequacy of the presentation of information in the financial statements.

UNCERTAINTY

Attention is drawn to note 11 in the financial statements in relation to claims against the Board by persons who may have contracted Hepatitis C.
At present, it is not possible to assess or quantify the extent of legal liability, if any, which may attach to the Board, arising from legal proceedings.

OPINION

Subject to the foregoing uncertainty, the financial statements, in my opinion, give a true and fair view of the state of the affairs of the Board at 31st December 1997 and of its income and expenditure and cash flow for the year then ended. In my opinion, proper books of account have been kept by the Board and the financial statements are in agreement with them.

John Purcell
Comptroller and Auditor General
23 April 1998

Accounting Policies

HISTORICAL COST CONVENTION

The financial statements are prepared under the historical cost convention.

INCOME AND EXPENDITURE

Income and expenditure 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. Expenditure incurred on the processing of such applications is taken to accounts as it is incurred. The Board is committed to expenditure in future years arising out of such applications.
- 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. The related expenditure is accounted for on an accruals basis.

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:	28 years
Fixtures and Fittings:	5 years
Computer Equipment:	3 years

SUPERANNUATION

The superannuation scheme operated by the Irish Medicines Board is in accordance with the Local Government (Superannuation) Act, 1980. Benefits are met from current income as they arise. The charge to salaries and wages is stated net of superannuation deductions of IR£92,492 (1996 - IR£70,436).

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 31 December 1997

	Note	1997	1996
		IR£	IR£
Fee Income	2	**5,080,836**	3,835,835
Sundry Income		**29,468**	22,575
		5,110,304	3,858,410
Salaries and Wages	3	**2,097,224**	1,691,826
Other Operating Costs	4	**1,278,409**	1,672,725
Depreciation		**141,646**	203,154
		3,517,279	3,567,705
Surplus for the year		**1,593,025**	290,705
Reserves brought forward		**424,236**	133,531
Reserves carried forward		**2,017,261**	424,236

The accounting policies on page 19 and the notes on pages 23 to 26 form part of the financial statements.

Pat O'Mahony, Chairman

Maura Waters, Board Member

Balance Sheet

As at 31 December 1997

	Note	1997	1996
		IR£	IR£
Tangible Assets	1	**289,303**	247,866
Current Assets			
Debtors and Prepayments	5	**927,394**	193,773
Stock of Stationery		**7,898**	7,837
Cash at Bank and in Hand		**1,478,564**	625,984
		2,413,856	827,594
Creditors - Amounts falling due within one year			
Creditors and Accruals	6	**685,898**	651,224
Net Current Assets		**1,727,958**	176,370
Total Net Assets		**2,017,261**	424,236
Financed by			
Income and Expenditure Account		**2,017,261**	424,236
		2,017,261	424,236

The accounting policies on page 19 and the notes on pages 23 to 26 form part of the financial statements.

Pat O'Mahony, Chairman

Maura Waters, Board Member

Cash Flow Statement

For the year ended 31 December 1997

	Note	1997 IR£	1996 IR£
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for year		**1,593,025**	290,705
Depreciation charge		**141,646**	203,154
(Increase) in Debtors		**(733,621)**	(173,659)
(Increase) in Stocks		**(61)**	(2,526)
Increase in Creditors - amounts falling due within one year		**34,674**	625,447
Deposit interest		**(23,087)**	(825)
Bank interest and charges		**2,155**	7,941
Gain on Disposal of Fixed Assets		**(4,006)**	(5,800)
Net Cash Inflow from Operating Activities		**1,010,725**	944,437
Cash Flow Statement			
Net Cash Inflow from Operating Activities		**1,010,725**	944,437
Return on Investments and Servicing of Finance	7	**20,932**	(7,116)
Capital Expenditure	7	**(179,077)**	(249,239)
Increase in Cash		**852,580**	688,082
Reconciliation of net cash flow to movement in net funds/debt	8		
Net funds/debt at start of year		**625,984**	(62,098)
Net cash inflow		**852,580**	688,082
Net funds at end of year		**1,478,564**	625,984

The accounting policies on page 19 and the notes on pages 23 to 26 form part of the financial statements.

Notes to the Financial Statements

	Fixtures and Fittings IR£	Computer Equipment IR£	Leasehold Property IR£	**Total IR£**
1 Tangible Assets				
Cost				
Balance as at 1 January 1997	184,751	442,206	59,361	**686,318**
Additions for the year	80,827	102,256	–	**183,083**
Disposals for the year	(5,000)	(9,076)	–	**(14,076)**
As at 31 December 1997	260,578	535,386	59,361	**855,325**
Depreciation				
Balance as at 1 January 1997	93,426	342,025	3,001	**438,452**
Charge for the year	88,671	51,736	1,239	**141,646**
Disposals for the year	(5,000)	(9,076)	–	**(14,076)**
As at 31 December 1997	177,097	384,685	4,240	**566,022**
Net Book Value at 31 December 1997	**83,481**	**150,701**	**55,121**	**289,303**
Net Book Value at 1 January 1997	**91,325**	**100,181**	**56,360**	**247,866**

2 Fee Income	**1997 IR£**	1996 IR£
Clinical Trials	**136,433**	103,719
Human Medicine Licensing Fees	**3,962,086**	2,990,453
Veterinary Medicine Licensing Fees	**501,385**	207,075
European Fees	**146,787**	215,304
Inspectorate Department	**334,145**	319,284
	5,080,836	3,835,835

Notes to the Financial Statements continued

	1997	1996
	IR£	IR£
3 Salaries and Wages		
Staff costs are comprised of:		
Salaries and Wages	**1,934,734**	1,577,864
Social Welfare Costs	**162,490**	113,962
	2,097,224	1,691,826

The average number of staff employed during the year was 85 (1996 - 68).

4 Operating Costs		
Lease premium written off	**...**	200,000
Removal Costs	**174**	92,126
Accommodation Costs	**488,832**	654,723
Travel, Representation and Training	**176,770**	161,625
Legal Costs	**193,544**	192,506
Stationery, Publications and Postage	**182,418**	142,297
Other Operating Costs	**236,671**	229,448
	1,278,409	1,672,725

5 Debtors (all due within one year)		
Trade Debtors	**640,397**	63,698
Prepayments	**33,453**	61,214
Other Debtors	**253,544**	68,861
	927,394	193,773

Notes to the Financial Statements continued

	1997	1996
	IR£	IR£
6 Creditors (amounts falling due within one year)		
Trade Creditors	**131,597**	122,750
Accruals	**489,033**	476,644
PAYE/PRSI	**65,268**	51,830
	685,898	651,224
7 Gross Cash Flows		
Returns on Investment and Servicing of Finance:		
Deposit interest	**23,087**	825
Bank interest and charges	**(2,155)**	(7,941)
	20,932	(7,116)
Capital Expenditure:		
Payments to acquire tangible fixed assets	**(183,083)**	(255,039)
Receipts from sales of tangible fixed assets	**4,006**	5,800
	(179,077)	(249,239)
8 Analysis of Changes in Net Funds/(Debt)		
At 1 January:		
Cash at bank and in hand	**625,984**	–
Overdrafts	**–**	(62,098)
	625,984	(62,098)
Cash flows	**852,580**	688,082
At 31 December:		
Cash at bank and in hand	**1,478,564**	625,984
9 Administration Expenses		
Surplus for the year was calculated having charged		
Auditor's Remuneration	**4,000**	4,000

Notes to the Financial Statements continued

	1997 IR£	1996 IR£
10 Lease Commitments		
Operating Leases		
Amounts payable during the next twelve months in respect of leases which expire		
• within one year	–	–
• between two and five years	**19,656**	14,367
• after five years	**282,500**	280,000

The operating lease amounts include an annual commitment of IR£282,500 (1996- IR£280,000) in respect of the Board's premises at Earlsfort Centre, Earlsfort Terrace, Dublin 2.

11 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. It is not possible at this stage to assess or quantify the extent of legal liability, if any, which may attach to the Board in these threatened or actual proceedings.

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.

12 Approval of Financial Statements

The Financial Statements were approved by the Board on 22 April, 1998.

Appendix I: Principal Functions of the Irish Medicines Board

The principal functions of the Board, described in the Irish Medicines Board Act 1995 are:-

a) the licensing of the manufacture, preparation, importation, distribution and sale of medicinal products,

b) subject to subsection (4) to exercise the powers conferred on the competent authority by Council Directive No. 65/65/EEC of 26 January 1965, as amended, and any regulations under the Health Act, 1947, giving effect to that Directive as amended,

c) to exercise the powers conferred on the supervisory authority by Council Regulations (EEC) No. 2309/93 of 22 July 1993(3),

d) to exercise the powers conferred on the competent authority by Council Directive No. 81/851/EEC of 28 September 1981(4),

e) to exercise the powers specified in the Control of Clinical Trials Acts, 1987 and 1990, and conferred on the Board by *Section 35*,

f) to establish and administer a service for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products,

g) to establish and administer a service for obtaining and assessing reports on any adverse effects of medicinal products in use in the State,

h) to advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which medicinal products may be marketed or continued in use in the State,

i) to arrange for the collection and dissemination of information relating to medicinal products including, in particular, information concerning the pharmacological classification and therapeutic efficacy of such products,

j) to furnish, whenever it is so requested by the Minister, advice to the Minister in relation to the licensing of the manufacture, importation, distribution and sale of medicinal products and in relation to the standards of manufacturing practice (including quality control) of medicinal products,

k) to furnish, whenever it is so requested by the Minister, advice to the Minister in relation to the certification for export or any other purpose of medicinal products manufactured in the State,

Appendix 1 continued

l) to establish and administer a service for the inspection of any service for the collection, screening, processing and quality control facilities and procedures in respect of human blood, blood components, blood products and plasma derivatives for the purposes of ensuring the safety and quality of blood, blood components, blood products and plasma derivatives and to advise the Minister in relation to such general or particular matters arising out of the administration of such a service as the Minister may refer to the Board,

m) if so requested, to advise the Minister or others concerned on such matters relating to medical devices as may be referred to it and are connected with the functions or activities of, or the services provided by the Board,

n) to furnish, whenever it so thinks fit or is so requested by the Minister, advice to the Minister in relation to any matter connected with the functions or activities of, or the services provided by the Board.

Appendix II: Executive Board Members and Committees

EXECUTIVE BOARD

Dr. John G. Kelly	Chief Executive
Mr. John Lynch	Director of Inspection
Dr. J. Michael Morris	Pharmaceutical Director
Mr. Cyril O'Sullivan	Veterinary Director
Ms. Rita Purcell	Director of Finance and Administration
Dr. Mary Teeling	Medical Director

ADVISORY COMMITTEE FOR HUMAN MEDICINES

Professor Kevin O'Malley (Chairman)
Dr. Rosemary Boothman
Dr. Gerard Burke
Professor Owen Corrigan
Professor Desmond Fitzgerald
Mr. Declan Hickey
Dr. Kate McGarry
Mr. Tom McGuinn
Ms. Claire McSweeney
Dr. Owen Smith

ADVISORY COMMITTEE FOR VETERINARY MEDICINES

Mr. Albert Costelloe (Chairman)
Dr. Thomas Barragry
Ms. Eugenie Canavan
Dr. Anne Cullinane
Mr. Timothy Kyne
Professor Michael Lambert
Mr. George Lane
Mr. Desmond Leadon
Mr. Tom McGuinn
Dr. Grace Mulcahy
Mr. Patrick J. O'Connor
Dr. Iona Pratt

SUB-COMMITTEES

Clinical Trials Sub-Committee
Dr. Kate McGarry (Chairperson)
Dr. Liam T. Bannan
Dr. David Fennelly
Professor Desmond Fitzgerald
Dr. Michael Gill
* Mr. Austin Leahy
Dr. Noel G. McElvaney
Professor Fergus Shanahan
Dr. Patrick A. Sullivan

* Resigned 1997

EXPERT SUB-COMMITTEE ON THE ADVISORY COMMITTEE FOR HUMAN MEDICINES

Dr. Louise Barnes
Professor Hugh R. Brady
Mr. Patrick Broe
Ms. Ann Bruzzi
Dr. Owen Carey
Dr. Desmond N. Carney
Professor Martin Clynes
Professor Louis M. T. Collum
Dr. Kevin D. Connolly
Ms. Mary Donovan
Dr. George Duffy
Dr. Desmond Feeley
Dr. Oliver FitzGerald
Dr. Chris Fitzpatrick
Dr. Stephen Flint
* Professor W. Hall
* Mr. V. Harte
Dr. Owen Hensey
Professor Irene Hillary
Professor Hilary Humphreys
Dr. Gerry D. Hurley
Professor Conor Keane
Dr. Kevin Kelleher
Professor Brian Leonard
Dr. Patricia McCormack
Dr. David McInerney
Dr. Malachi McKenna
Dr. Kingston Mills
Dr. Fiona Mulcahy
Dr. Frank Murray
* Dr. J.R. O'Donnell
Dr. Dan P. O'Mahony
Dr. Brian Otridge
Dr. Janice Redmond
Professor Fergus Shanahan
Dr. John D. Sheehan
Dr. John Stack
* Dr. J.M. Stronge
Professor Richard F. Timoney

The IMB wishes to acknowledge the work of the experts without whose continuous support the IMB would have difficulty in carrying out its statutory functions. We wish those experts, who have left the committees during 1997 every success in the future.

* Resigned 1997

Appendix III: Irish Medicines Board Service Charter

1 INTRODUCTION

This document describes the nature and duties of the Irish Medicines Board. It defines the Irish Medicines Board's stakeholders and its commitments to them. Lastly it commits to ongoing development and improvement in the services which it provides.

2 THE ROLE OF THE IRISH MEDICINES BOARD

The primary duty of care of the Irish Medicines Board is the protection of public health. Its duties and activities are described in the Irish Medicines Board Act, 1995. The Irish Medicines Board is the Competent Authority responsible for the licensing of the manufacture, preparation, importation, distribution and sale of medicinal products for human use. It assesses the quality, safety and efficacy of medicines, regulates the conduct of clinical trials and inspects the processes of manufacturing and distribution of medicinal products. It is also the Competent Authority for medicinal products for veterinary use for the purposes of improving animal health and welfare and the protection of consumers of animal products.

3 COMMITMENTS OF THE IRISH MEDICINES BOARD

To ensure so far as possible, consistent with current medical and scientific knowledge, the quality, safety and efficacy of medicines available in Ireland. To play a full role in European systems for the regulation of medicines.

4 THE STAKEHOLDERS IN THE IRISH MEDICINES BOARD:

These are the following:

a) The public, who are the consumers and users of medicines.

b) Healthcare professionals, who prescribe, supply and administer medicines.

c) Applicants and holders of licences, who require our activities in assessment, authorisation and subsequent maintenance of their licences.

d) The Minister for Health and Children, who confers functions on the Irish Medicines Board and who is advised by the Irish Medicines Board on matters related to medicines.

e) The Minister for Agriculture and Food who is advised by the Irish Medicines Board on matters relating to animal remedies.

f) Our partners in the European medicines licensing system.

g) The Board members and the staff, Committee members and experts of the Board.

Appendix III continued

5. EXPECTATIONS OF STAKEHOLDERS

a) Patients who consume medicines should be able to do so on the basis that, while accepting that every medical treatment carries a risk, that the risk can be reasonably considered to be acceptable in the context of the condition being treated and of the likely benefit. The authorisation of a medicine implies that an appropriate review of the quality, safety and efficacy has taken place consistent with the existing state of medical and scientific knowledge. Reported side effects of medicines are reviewed and any resulting implications for their use are followed up. Where practicable appropriate information about medicines should be available to patients. Patients are entitled to timely access to important innovative therapy.

b) The healthcare professional who prescribes, supplies or administers an authorised medicine does so expecting that the claims made have been independently reviewed and that, based on existing medical and scientific knowledge, the information supplied as part of the agreed data sheet and summary of product characteristics can be used to form judgements concerning the properties and appropriateness of that product. The Irish Medicines Board provides a common point for integrating reports of adverse events and will communicate with healthcare professionals when necessary. The Irish Medicines Board provides an information resource for healthcare professionals.

c) Applicants for and holders of licences will be dealt with in an impartial fashion. Information disclosed to the Irish Medicines Board will be treated in confidence, consistent always with the Irish Medicines Board's overriding concern for public health. Applicants are entitled to information regarding the current status of an application. The Irish Medicines Board commits to instituting and adhering to measures designed to process applications in an efficient and speedy manner, consistent with safety to the patient and the public and the availability of resources.

d) The Minister for Health and Children shall be furnished with any information and advice requested and shall be kept informed of any matters which the Irish Medicines Board in its opinion considers should be reported to the Minister or which the Minister from time to time may ask to be informed of.

e) Likewise, the Minister for Agriculture and Food shall be furnished with information and advice on request and shall be kept informed of relevant matters in the area of animal remedies.

f) The Irish Medicines Board is committed to playing its full part in the processes of medicines regulation in the European Community including meeting the time scales required under the various Directives and Regulations.

g) All those who work in or give guidance or advice to the Irish Medicines Board shall be encouraged to contribute fully to its activities and staff members will be supported in training and career development.

6 PROVISION OF INFORMATION

The Irish Medicines Board fully supports access of all to information on its activities as provided in the Freedom of Information Act, 1997 where this does not conflict with rights of an individual to confidentiality in medical matters or with the rights of the owner of proprietary or commercially sensitive information.

7 PERFORMANCE TARGETS

The Irish Medicines Board will collect information on the conduct of its activities and will publish details of its performance. This information will permit targets for performance to be set and information on performance against these targets will be published. The Irish Medicines Board has a commitment to continuous improvement of its services.

8 EFFICIENCIES

The structures of the IMB will reflect an intention to provide an efficient service within the constraints of available resources. There is a commitment to control finances to ensure value for money in the Board's activities. The IMB is committed to being self financing and not a burden to the taxpayer.

9 CONSULTATION

Those subject to the Irish Medicines Board's activities will have opportunity for consultation on matters related to them.

10 COMPLAINTS

A formal complaint may be made by a person or organisation who has fair reason to disagree or be dissatisfied with any aspect of their interaction with the Irish Medicines Board. The Irish Medicines Board will investigate such complaints in an objective and timely manner and will provide a response to the matters raised. Any failure of service will be examined by the Irish Medicines Board with a view to improved service.

11 REVIEW

This Charter will be subject to regular review and update in the interests of providing a continuing improvement in services to stakeholders.

BANKERS

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1/3 Lower Baggot Street
Dublin 2

SOLICITORS

Eugene F. Collins
Temple Chambers
3 Burlington Road
Dublin 4

HEAD OFFICE

Block A
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Earlsfort Terrace
Dublin 2

AUDITORS

Comptroller
and Auditor General
Dublin Castle
Dublin 2

Notes

Notes

Designed and Produced by Visual Communications

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