EASTERN HEALTH BOARD

Report of

Food and Medicine Control Committee

Report presented to the Programme Manager, Community Care - April 1995.

A Task Group was appointed by the Programme Manager, Community Care, Eastern Health Board and held its first meeting on March 1st 1995.

Terms of Reference:

To report on the key areas of food and medicine control as highlighted in the Health Strategy (Shaping a Healthier Future) and to formulate relevant targets and objectives for the Board's area with detailed costings to include existing and future resource needs.

Members of the Committee:

Dr. Rosaleen Corcoran	A/DCCMOH (Chairperson)
Dr. Brendan O'Donnell	DMOH
Dr. Fergus Hill	Public Analyst, Eastern Health Board
Mr. Martin Devine	Principal E.H.O.
Dr. Eibhlin Connolly	Registrar Public Health Medicine
Ms. Carmel Hickey	Administrator
Ms. Claire Kerr	Community Pharmacist
Mr. Tom Prendergast	Principal E.H.O.
Ms. Dervala Comiskey (Secretary)	

The Four Year Action Plan for Food and Medicine Control outlined in the Health Strategy is as follows:

"The Department of Health will update the legislative controls relating to food and medicine in Ireland. A national surveillance programme for controlling food-borne diseases will be developed and safe practices for the use of drugs and medicines will be further encouraged".

FOOD CONTROLS

Target 1:

"To develop a national surveillance programme for the control of food-borne infections"

Recommendations:

The committee would endorse the rapid establishment of a national surveillance programme for the control of food-borne infections in line with the recommendations of the Food Safety Advisory Committee (see Appendix A).

The Committee recommends that it would be desirable and cost-effective to develop such a programme in the context of an overall national disease surveillance unit to avoid duplication.

It is envisaged that this unit would be an independent autonomous body working across all departments with inputs from various agencies.

Target 2:

"To meet EU obligations for the harmonisation of legislation and the modernisation of control measures, and in the process to revise and update existing legislation such as the Sale of Food and Drugs Acts and Provisions under the Health Act, 1947"

Harmonisation of Legislation:

Recommendations:

The Committee is of the opinion that existing legislation with regard to the control of food is confusing and requires to be co-ordinated and updated.

The Committee recognises that harmonisation is only possible in conjunction with the Department of Agriculture which has a significant responsibility in the area of food control, especially in relation to control of milk, meat and fish.

The Committee would endorse the use of three instruments in the control of food:

(i) Official Control of Foodstuffs Regulations
(ii) A New Bill to regulate the Sale of Food, as outlined below
(iii) New EC Directive on the Hygiene of Foodstuffs (93/43/EEC) which is due to come into effect at the end of 1995

The Committee endorses the introduction of a new Bill to regulate the sale of food to replace the existing Sale of Food & Drugs Act 1875 to 1936 and under Part V of the Health Act 1947, as recommended by the Food Safety Advisory Committee.

Modernisation of control measures

To be achieved by:

"Establishing a new food unit in the Department of Health and a Food Safety Advisory Board"

The Committee will support initiatives in regard of the establishment of a new food unit in the Department of Health and a Food Safety Advisory Board.

"Achieving accreditation to international standards of the food laboratories designated for the purpose of EU Directives"

The Committee is of the opinion that the achievement of accreditation to international standards is essential in order to have appropriate quality assurance. Over 500 accreditation tests will require to be carried out in food control laboratories. However, the cost of accreditation is significant running into several thousands of pounds.

The Committee recommends that expenditure on this aspect of the laboratory service should be spread over a number of years as resources permit.

"Conducting negotiations at EU level for new legislation and scientific co-operation"

The Committee agrees that negotiations should take place at EU level for new legislation and scientific co-operation.

Although this is the responsibility of the Department of health, **the Committee recommends that any draft directives should be discussed with the Health Boards before the enactment of same.**

The Dublin Region Public Analyst is a participant in the Scientific Co-operation by member states in the examination of questions relating to food, in the preparation of reports for the Scientific Committee for Food risk evaluation of dietary exposure to contaminants. A description of the Scientific Co-operation Programme and Irish involvement in it has been prepared by Dr. Fergus Hill and is appended at Appendix B.

"Upgrading Food Laboratory Services"

The Committee will support the upgrading of the food laboratory services. The resource implications of such upgrading are discussed below.

"Guiding local management on their obligations for the enforcement of new controls"

The Committee recommends that a standardised enforcement protocol be drawn up within the Board with regard to food control.

The Committee is of the opinion that accountability can be achieved through a scheme of performance reviews as recommended in "Staff Motivation and Performance Review" a report on the Action Learning Project prepared for the Health Service Managers' Development Programme of the Eastern Health Board, October 1992.

The introduction of new EU Directives regarding food control, in particular food sampling requirements, will increase substantially the workload of the Public Analyst Laboratory, the Public Health Laboratory in Cherry Orchard Hospital and the Environmental Health Officers within the Board.

The Committee accepts that new controls will have cost and staff implications and recommends that this matter should be kept under regular review.

Laboratory Services:

The Committee noted the complementary nature of the services provided by the Public Analyst Laboratory and the Public Health Laboratory.

The Committee recommends the introduction of integrated information systems between the two Laboratories and food control centres. After consultation with the Laboratory services the cost of such systems would appear to be in the region of £80,000. Obviously a more exact costing would require detailed analysis.

The Public Health Laboratory at Cherry Orchard Hospital needs upgrading in line with that presently being provided for the Public Analyst Laboratory if the requirements of new EU directives are to be met.

The Committee would recommend upgrading of this service as proposed at Appendix C.

The Committee would support the further development of the Public Analyst Laboratory by the provision of new equipment, which it is estimated will cost in the region of £150,000 per year over the next three years, and the development of a library service for the laboratory as proposed at Appendix D.

The Committee suggests that the possibility of offsetting some of the extra costs of laboratory development by providing additional laboratory services to outside agencies and Health Boards should be explored.

EHO Service:

The Committee recommends the appointment of additional EHO's and clerical staff to the EHO service to allow it to meet the food control requirements of the new EU directives, as outlined at Appendix E.

These requirements will have to be reviewed when the new directives are in operation.

The Committee would support the appointment of specialist EHO's to the Board, which is under negotiation with the Department of Health at present, and would further support the sharing of this specialist expertise between Health Boards.

The Committee also recommends the appointment of a senior grade Research Officer to the EHO service who would be responsible for enforcement of control food regulations.

The Committee would like to highlight the extra clerical and administrative staff requirement of the development of the laboratory and EHO services.

PHARMACY AND MEDICINE CONTROLS

Target 1:

"To update the legal controls on pharmacy and medicines"

To be achieved by:

"A new Pharmacy Act to consolidate existing legislation, to introduce more effective controls on the practice of pharmacy and to conform to current international standards"

The Committee would welcome the general thrust of the proposed new Pharmacy Act which would regulate and control standards.

We recommend that this matter be kept under review, particularly with regard to future cost implications.

"A New Medicines Act to update and expand the existing controls under the Sale of Food and Drugs Acts 1875-1936 and the Health Act of 1947 and to have regard to our obligations as a member of the EU"

The Committee would welcome the updating and expansion of the Regulations under the Sale of Food And Drugs Acts 1875 -1936 and the Health Act 1947, as there are problems with the definitions of "food" and "medicine" under these Acts.

The Committee discussed the proliferation of "health foods" for public retail and the reported risks to the public of overdosing with some vitamins. The Committee recognises the need for both a policy and a means of control regarding micronutrients and food fortification. The Committee welcomes the recommendations of the Food Safety Advisory Committee regarding food supplements and health foods (see Appendix F) and would endorse the implementation of these recommendations.

The Committee recommends that the Department of Health expedite a report on the control of micronutrients.

The Committee recommends that the Poisons Regulations 1982-1986 should be examined and amended to correct anomalies in the existing legislation.

The Committee is of the opinion that regulatory responsibilities in this regard should not lie solely with EHO's, but should include a role for the Pharmaceutical Society and the Department of Agriculture.

The Committee recommends that a Committee should be set up to review the Poisons Regulations with a view to rationalisation vis a vis the roles of the Departments of Agriculture, Health and the Pharmaceutical Society.

The Committee recommends that the views from an EHO's perspective as appended in Appendix G should be given consideration.

The National Medicines Board:

The Committee welcomes the proposal from the Minister to establish a new health body - The National Medicines Board. It is proposed that the licensing of medicines will transfer from the Minister to the new Board.

Consequently the National Drugs Advisory Board will be abolished and its functions will then be undertaken by the new Board. It is foreseen that two new advisory Councils will be set up, one for human and the other for veterinary medicines. These Councils may appoint committees if they feel that it is necessary, similar to committees that are already in place in the National Drugs Advisory Board.

The European Medicines Evaluation Agency:

The European Medicines Evaluation Agency which came into operation in January 1995, and is based in London, will act as a co-ordinating centre for the scientific evaluation of medicinal products, both for human and veterinary use. The work of the Agency will be carried out through two main committees:

Committee on Proprietary Medicinal Products (CPMP)
Committee on Veterinary Medicinal Products (CVMP)

There are three registration procedures for human and veterinary medicines:-

(i) A centralised procedure for high technology products which leads to a single marketing authorisation valid throughout the EU.
(ii) A decentralised procedure based on the extension of a national authorisation to other member states if the applicant applies for this to happen
(iii) National procedures which are used for products intended for marketing in one country only.

Target 2:

"To encourage rational and safe use of drugs and medicines"

To be achieved by:

"The continuing emphasis on good quality prescribing by doctors"

The Committee is of the opinion that the continuing emphasis on good quality prescribing by doctors is essential to ensure the equitable and cost-effective use of resources.

The Committee recognises the value of research which has been undertaken to date in the area of prescribing by agencies such as the Department of Pharmacology and Therapeutics, University of Dublin and recommends that *such research should be supported in the future.*

Some of the findings to date include:

- GP's show a large reliance on hospitals and pharmaceutical representatives for their information on new drugs.
- GP's are concerned about the reliability, quality and labelling of generic products on the market and require reassurance in this regard.
- GP's are concerned that pharmacists may legally dispense more expensive proprietary preparations in the case of private prescriptions written generically.
- Prescribers in hospitals have a poor awareness of the cost of more expensive drugs.
- The introduction of a hospital formulary with active intervention comprising feedback, peer comparison and information significantly reduced drug costs and improved the quality of prescribing.

(More details of research carried out in the area of prescribing by the Department of Pharmacology and Therapeutics, University of Dublin are summarised in Appendix I).

These findings suggest there is a need for mechanisms for the ongoing training and support of prescribers, including the provision of feedback. These issues are covered in the Reports of the National Therapeutics Advisory Committee. The Committee endorses the recommendations of the first and second Reports of the National Therapeutics Advisory Committee to the Minister for Health with regard to encouraging safe and cost-effective prescribing (see Appendix I), **and recommends that the Department should expedite the implementation of these recommendations, particularly with regard to legislation governing generic prescribing.** The Committee is of the opinion that generic prescribing should be encouraged but professional autonomy should be maintained.

The Committee welcomes initiatives which have been taken to date to encourage safe and cost-effective prescribing including the establishment of the National Medicines Information Centre which provides information to professionals, the appointment of an Adviser to the Department of Health and the National Therapeutics Advisory Committee, the appointment of a Prescribing Fellow under the aegis of the National Therapeutics Advisory Committee and the publication of a booklet for GP's, "Recent Therapeutic Notes", in 1994.

The Committee supports the work of the GP Unit in promoting quality prescribing that is appropriate and cost-effective, by the provision of information on prescribing to GP's and visits to individual GP's by community pharmacists where requested.

The Committee recommends that prescribing information made available for GP's within the Board's area should be of high-quality, with a professional standard of layout, design and presentation.

The Committee would also endorse the distribution of information to GP's by the GMS Payments Board covering the costing of drugs.

The Committee endorses the initiatives that have already been undertaken to support the GP Unit, such as the establishment of the Regional Drugs Unit. The Regional Drugs Unit analyses the data produced by the GMS Payments Board to assess prescribing trends by GP's. This information is passed on to the GP Unit. Attention is presently focused on quality prescribing indicators. Examples of current activity include:

(i) the baseline pattern of prescribing of specific prescription items such as the ratio of inhaled steroids to bronchodilators
(ii) age-standardised prescription rates for certain groups of drugs such as peptic ulcer treatments, thyroxine and anti-diabetic drugs and
(iii) the prescribing of drugs of limited clinical value such as cough suppressants and topical NSAID's.

The Committee is of the opinion that it is important to obtain the fullest possible value from the data that is presently available from the GMS Payments Board and would support on-going work in this area.

The Committee recommends that the Board should hold ongoing study days for GP's on quality and rational prescribing as part of ongoing CME programmes.

The Committee recommends that programmes to encourage quality prescribing should also be developed in hospitals, along the lines of the proposals of the Nation Therapeutics Advisory Committee (see Appendix F).

The Committee welcomes the initiatives that have been undertaken by the GP Unit whereby a GP Unit doctor is now a member of the Hospital Therapeutics Committee in their local areas. One result of this initiative has been the introduction of a combined formulary for hospital and GP use at St. James' Hospital.

"Public education programmes on the appropriate use of medicines"

The Committee is of the opinion that public education programmes on the appropriate use of medicines are an essential component of policies to encourage safer and more cost-effective use of therapeutic drugs. Research indicates that there is greater public demand for more information regarding prescription drugs. Public education programmes should address the following issues:

- provision of appropriate information to patients regarding therapy
- compliance
- safe storage and disposal of drugs
- patient demand for drugs
- public misinformation
- programmes should be carefully targeted at specific audiences.

The Committee recommends that public education programmes on the appropriate use of drugs should be developed as a priority, having regard to research and evaluation of similar programmes which has taken place elsewhere.

APPENDIX A

Summary of Recommendation for a National Surveillance Programme of Foodborne Diseases by the Food Safety Advisory Committee, April, 1994.

Foodborne disease is illness caused by food or drink contaminated by pathogenic micro-organisms or their toxins and by chemicals.

There has been an increase in recent years in the reported incidence of listeria, campylobacter and salmonella.

In considering each of these agents, it was evident to the Committee that there were difficulties in bringing together whatever information was available nationally. A considerable amount of knowledge and expertise is available in veterinary laboratories, microbiological units, public analyst laboratories, public health departments and within the food industry generally.

Article 4 of Council Directive (92/117EEC) demands that -

"1. Member States shall ensure that:

(d) The competent authority collects information on any zoonotic agents the presence of which has been confirmed in the course of tests or examinations carried out and on any clinical cases in humans or animals of the zoonoses listed in Annex 1, point 1.

2. In Accordance with the procedure laid down in Article 16, the provisions of this article may be extended to cover the zoonoses and zoonotic agents listed in Annex 1, points II and III".

Council Directive (91/497/EEC) Article II, paragraph 3 states that:

"Member States shall submit to the Commission information on certain diseases and particularly cases where diseases transmissible to man have been diagnosed".

There is clearly a need to gather and interpret surveillance information relating to the spread of disease-producing agents to humans from animal products and other foods. This task should be undertaken in a co-ordinated fashion using relevant data available in Ireland and abroad.

A food surveillance programme is required to bring together information both microbiological and toxicological on aspects of food safety. The programme would obtain information from sources such as public analyst laboratories, microbiological departments of hospitals, veterinary and university laboratories.

Some laboratories should specialise in different topics and become acceptable as recognised reference laboratories.

To ensure the success of the programme it is essential that there be adequate funding and inputs from all relevant Departments.

A National Surveillance Centre should be established which would develop and expertise in the area of food-borne illness. Such a Centre would promote better food safety practices and result in better laboratory and epidemiological controls.

The National Surveillance Centre would collaborate with centres in other countries and international agencies such as the World Health Organisation.

APPENDIX B

Scientific Co-operation by Member States in the examination of questions relating to food.

Council Directive 93/5 of the 25th February, 1993 provides for assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food. An inventory of tasks has been established and this is to be up-dated every six months.

Item 1 - in the inventory is concerned with flavouring substances - Ireland is taking no part in this

Item 2 - is concerned with microbiology, particularly the collation of scientific and methodological information with a view to the assessment of microbiological risks for certain foodstuffs and also a study on temperature control. Ireland is taking part in this. Dr. Marlene Proctor of the Dublin Institute of Technology attends the meetings.

Item 3 - is concerned with contaminants. Specific reports are to be prepared for the Scientific Committee for food - risk evaluation of specific contaminants with particular reference to dietary exposure in each Member State of the following:

1. Aflatoxins
2. Ochratoxin
3. Nitrate
4. Cadmium

The author is collecting data on these contaminants for transmission to Brussels.

Item 4 - Intake and exposure assessments. This involves a study of food consumption data-bases in the European Union and is being co-ordinated by Professor Michael Gibney of Trinity College

APPENDIX C

Proposal for upgrading of Public Health Laboratory, submitted by Dr. B. Dillon

Work done by Public Health Laboratory

Medical Microbiology

Microbiological specimens are sent to the Laboratory from Cherry Orchard Hospital, St. Mary's Hospital, Phoenix Park, Chesire Home, Phoenix Park, Clonskeagh Hospital, Bru Chaoimhin, Cork Street, Crooksling, Nursing Homes, Health Clinics and General Practitioners.

Medical Microbiology includes the following:

- **Faeces** - are examined for Salmonella, Campylobacter, E. Coli, Shigella, Dysentery, Staph Aureus, Yersinia, Rotavirus and Ova and Parasites, Swabs (throat, ear, eye, mouth, nasal, vaginal, rectal and urethral) are examined for pathogens and if found antibiograms are done to test their sensitivity to antibiotics. Nasal and throat swabs are cultured for Pertussis (Whopping Cough).

- **Urines** - analysed and if pathogens are found antibiograms are done.

- **Sputums** - are examined for pus cells and cultured for pathogens and if found antibiograms are done.

- **Serology** - bloods are examined for antibodies to typhoid, Para Typhi A,B,C, Brucellosis and Typhus.
  These specimens come from hospitals in Dublin, the rest of the county health clinics and General Practitioners.

- **Parasitology and Helminthology** - faeces are sent for examination of parasites and helminths - these specimens come from hospitals, General Practitioners, play schools, creches and returning holiday makers.

- **Environmental Microbiology** - swabs from the preparation area in catering premises, cooking utensils, fridges, workers' hands and throats are examined for gastro-enteric pathogens. Faeces are examined for Salmonella, nasal and throat swabs are examined for Staphlococci food poisoning organisms when workers are commencing work in catering.

- **Water examination** - (potable, recreational and environmental).

  Potable waters - samples are taken every month from the catchment areas that supply the resevoirs. These are examined from coliform organisms, faecal coliform organisms, main resevoirs are examined every day as are samples from ships, canteens, wells, planes, trains, fountains, pumps and bottled waters.

  Recreational waters - swimming pools (seawater and fresh) foot baths and examined for faecal organisms, as are jacuzzis which are also cultured for pseudomonas. Canals, rivers and lakes (anywhere there is swimming, boating, surfing or water skiing are monitored during the bathing season. On occasion some of these samples ar examined for ova and parasites also. Seawaters are monitored during the summer months for total coliform organisms, faecal coliforms, strep faecalis and Salmonella. These analysis have to comply with the EC guidelines for bathing water. Returns are sent to the EC. Samples are examined every week from beaches that wish to fly the blue flag

  Foods and Drinks - Foods (cooked and raw) and ice creams are brought by EHO's from EHB areas and any of the other health boards if they have difficulties with a food poisoning outbreak or portable water contamination. Routine examination of foods is done every day.

Samples are sent by EHO's, General Practitioners, Matrons and are also accepted from members of the general public when there is a food complaint. Foods are often sent for identification of foreign bodies found in them or crustaceans in portable water samples.

- **Serology** - serum samples are examined for antibodies to Typhoid, Paratyphi A, Paratyphi B, Paratyphi C, Salmonella, Brucellosis and Typhus. These are referred from hospital and General Practitioners from anywhere in the country.

- **Environmental swabs** - swabs from the environment are examined for pathogens- these are done on a routine basis and are usually taken from worktops where food is being prepared or baby's bottles are being filled. If there is an outbreak of food poisoning a large number of environmental swabs may be taken. Seawaters and swimming pools (seawater an fresh) and foot baths are examined regularly, as are jacuzzis, which are also examined for pseudomonas. The beaches are examined every two weeks during the tourist season. Tests are done in accordance with the guidelines laid down by EC for bathing beaches. The results ar forwarded to the EC and Environmental Department. Further tests ar done on beaches in Ireland that have good clean beaches and qualify to fly the blue flag.

  By far the heaviest amount of work is done during the warmer months. Food poisoning is more common then when people are returning from holidays abroad and many of them are infected with Salmonella, Dysentery, Campylobacter and/or parasites or helminths. EC guidelines for the frequency of monitoring foods for food poisoning organisms and the number of tests required to be done on each specimen will be carried out very shortly.

- **Mycobacterium examination** - specimens are examined for Mycobacterium, then identified as to type (human, bovine, avium etc.) and antibiograms done. These specimens are sent by hospitals and General Practitioners. Cultures of positive Mycobacterium are sent to this laboratory from hospitals in EHB areas and from many hospitals in the country for typing and antibiograms.

Staff Allocation

In 1972 there were nine Technicians, one of these was a Chief Technologist, three Seniors and five technicians. In addition, there were two medical personnel, a Consultant and an acting Microbiologist. At present we have one Chief, two Seniors, three Technicians and two basic grade locum Technicians and one Consultant Microbiologist. The two temporary locum Technicians have now been with us over two years and have been trained in water and food analysis. They are now anxiously looking for permanent positions. We would find it difficult to cope if they were to leave. It takes some time for Technicians to become proficient in food analysis and water biology. During the holiday season and in the winter months, when respiratory infections are prevalent, our numbers can be very depleted and were down to three on one occasion last year.

During food outbreaks or a breakdown in the water system very large numbers of specimens are sent to this Laboratory. In some of these big outbreaks we have received over one hundred samples for examination at the one time. A locum Technician employed at this time only compounds the situation. As someone has to try and train the locum Technician. If possible we would like to make our two temporary Technicians permanent and engage another Technician who has experience in food and water examination and identification of Mycobacteria.

This Laboratory has always been sanctioned as a food and water Laboratory and a reference Laboratory for Mycobacteria and Salmonellae. The building is very satisfactory and is only a few years old and very spacious. Some of our equipment is new but a large part of it is very old and faulty. The Health Board have employed a number of EHO's recently for food analysis. They will be bringing a large number of samples to comply with EC guidelines - more specific tests on food will need to be done.

Now that EC funds are available, it would be a good opportunity to get replacements for some of our old equipment. I am enclosing a list of the new equipment required and I hope to have quotations on costs very shortly and I will send that on.

Food examination and water biology is a rapidly growing science and, as new organisms emerge and/or old ones become more virulent and resistant to antibiotics, it is vital for us to be au fait with modern methods. It is sometimes necessary to attend workshops in the UK or to attend some of the public health laboratories there to ensure we have the necessary methods and techniques.

Ms. Cummins, the Chief Technologist has already been to Leeds Public Health Laboratory this year for this purpose. New text books on Microbiology, food and water analysis and virological organisms causing food poisoning are required, also journals and videos.

New personnel are required - three Technicians. There are two already working with us and are now trained in food and water analysis to be made permanent and one new Technician who has experience in Mycobacterium examination and antibiograms.

Office staff - this extra work will increase the work on the office staff. It is difficult to estimate how much they will be affected. The summer is the busiest time in the Laboratory. There is a big increase in the number of recreational waters submitted for examination. We already examine the popular beaches during the tourist season and submit results to Dublin Corporation, Dublin County Council and to the Environmental Department of the EC. Beaches with a very low microbial content qualify to fly the "blue flag" and these are examined every week. This would ensure that there was always one full-time Secretary available in the Laboratory and would avoid trying to train in a new Secretary during the holiday period or for sick leave.

Expenses for attending Seminars and Workshops.
Expenses for servicing, repairing and replacing equipment.
Expenses for new text books, journals and videos.

Requirements:

Staff requirement:	Annual Salary
One Senior Grade Technician	£19,454
Two Basic Grade Technicians (14,674)	£29,348
One Clerical Grade II Clerk Typist -	£ 9,530
Total	**£58,332**

Equipment Required:	
Three Microscopes	3,000
One flourescent fitting for Leitz Microscop	
Two large incubators	3,000
One medium incubator	500
Two small incubators	700
One Deep Freeze (small - low temperature: 70°C	5,500
One Gravimetric Diluter	6,000
Stomacher	1,300
One Spiral Plater	7,845
Three Balances	3,000
Two Centrifuges	11,050
Two inoculating safety cabinets	4,900
One Peristaltic pump	500
Autoclave	17,000
Total	**£64,295**

Other requirements:	
Journals - weekly	£ 300
- monthlys	£ 200
Text books	£1,000
Repair and servicing of instruments	£2,000
Office/Computer PC equipment	£11,000
Total	**£14,500**

APPENDIX D

Public Analyst Laboratory Costs

Staff Costings **Laboratory services including Library costs**	
1 Librarian	£ 25,000
1 Clerical Officer	£ 9,156
2 Grade II Clerk Typists (£9,530)	£ 19,060
1 Grade II Receptionist	£ 8,474
Sub-Total	**£ 61,690**
Other Costs	
Laboratory information systems	£ 80,000 (approx.)
Public Analyst Laboratory equipment	£150,000 per annum for 3 years
Office furniture/computer PC equipment	£ 12,000
Total	**£303,690**

APPENDIX E

EHO Service Staff requirements	
7 Environmental Health Officers (£14,000)	**£98,000**
7 Clerk Typists (£9,530)	**£66,710**
Sub Total	**£164,710**
Other Requirements	
Office/Computer PC equipment	£18,000
Total	**£182,710**

APPENDIX F

Recommendations of the Food Safety Advisory Committee

This report addresses the question of an appropriate policy for control of products which are on the borderline between foods and medicines. It considers them under three broad category headings, viz.,

1. concentrated sources of nutrients such as vitamins and minerals
2. natural materials whose compositions and status have not been established, and
3. fortified foodstuffs (conventional foodstuffs which have been fortified by the addition of nutrients).

Regulation

The new Food Safety Advisory Board recently announced would be an appropriate body to provide advice on official control of products dealt with in this Report.

The main recommendation of the Committee for the three categories are as follows;

A. Concentrated Sources of Nutrients such as Vitamins and Minerals (Food Supplements)

A positive list of food supplements should be established by the regulatory authority.

A product may be deemed a food supplement if;

(i) its nutritional benefits have been established on the basis of scientific evidence
(ii) it is not liable to cause toxicity under normal conditions of use, and
(iii) its maximum daily intake recommended by the manufacturer does not include quantities of ingredient(s) which, subject to any individual's special health indications, contain more than one tenth of the daily safe upper level of the particular ingredient(s) or other criteria which may be established by an appropriate authority for the purpose.

Food supplements should be subject to certain labelling and packaging requirements. A file containing technical details should be retained by the manufacturer for each product. This file should be available to the regulatory authority.

B. Natural Materials whose Composition and Status have not been established.

This category includes herbal extracts, herbal teas, essential oils, ginseng, royal jelly, pollen and ethnic supplements. These products should be subject to approval by the regulatory authority, prior to importation and prior to marketing.

The regulatory authority should draw up a list of prohibited plants (e.g. comfrey, sassafras, calamus, pokeroot), primarily based on the listing by the EU of herbs and herbal derivatives withdrawn for safety reasons in one or more Member States. This prohibited list should eventually be substituted by a positive list of herbal materials for use in foodstuffs.

C. Fortified Foodstuffs

Developments in the field of food fortification should be carefully monitored.

APPENDIX G

Poisons Legislation

The parent Act governing this area is the Poisons Act 1961 which was enacted out of a concern about misuse of poisons and which as an enabling Act allowed the Ministers for Agriculture and Health to make regulations to prevent any abuses. The first set of regulations were made in 1982 and to date there have been four sets of amendment regulations. For the purposes of the final draft report these regulations may be correctly cited as the Poisons Regulations 1982 and 1991 (see Table 1). The regulations are very detailed and abound with many exemptions and exceptions. In short, poisons (which include antibiotics and other medicines) are arranged in different schedules and different controls are imposed depending on whether or not the poisons can be sold from chemists shops or from premises licensed by health boards. In all cases however, the sale of poisons are strictly prohibited from a travelling shop, vehicle or vending machine. Of all the regulations the 1984 and 1986 amendments are the most extensive, but the complex manner in which different poisons are dealt with has led to most of the difficulties and anomalies that I now hope to touch on.

1. Sale to Strangers

Any poison in Schedule 11 must be recorded and the purchasers signature received. For strangers, a householder must certify that person and in addition the vendor must be satisfied that the householder is of good character and a responsible person. There is confusion about certification and with broad exceptions relating to urgent circumstances and signed ordering of poisons the view is that the seemingly strict records procedure is easily neutralised.

2. Sale by Wholesale

Is prohibited if the wholesale vendor is satisfied that the purchaser is not entitled to sell the poison by retail sale. Its not surprising that this prohibition seems to have little effect as travelling salesmen always have adequate stocks.

3. Sale by Retail

It would be more effective if Schedule 11 poisons could not be sold except on request. The act of having to ask for a particular poison would help both the vendor and purchaser appreciate that poisons can be dangerous.

4. Licensing

A health board may grant either an A licence or a B licence. The A licence is in respect of poisons set out in Part 2 of Schedule 1 and does not include intermammeries, while a B licence includes everything covered by an A licence and in addition the sale of intermanneries. However, it should be noted that the vast majority of herbicides, fungicides and insecticides do not require an A licence. The licence is in respect of both the applicant and the premises and is valid for two years. The licence may also state the names of not more than two people who may act as responsible deputies on behalf of the licensee. However, an anomaly here is that there is not provision for altering the poisons register in the event that one of the deputies is replaced, a situation which occurs on a regular basis. Also, there is no obligation on the health board to transfer a licence to another person. A health board may refuse a licence on four grounds, one of which is that the applicant or one of his deputies is "not a fit and proper person". One of the difficulties here is that no definition or guidance is given in the regulations for this phrase. Also, while reference is made to the premises in Article 14(8)(B) the reference is unclear as it seems to suggest that an unsatisfactory premises may make an applicant "not a fit and proper person". Another contentious ground for refusal relates to the level of "direction and control" y the authorised person, i.e. the Vet or Pharmacist. The difficulty here is that it is extremely difficult for the Environmental Health Officer to know whether or not the level of direction and control is satisfactory as the only evidence of a Vet or Pharmacists visit to a licensed premises is his/her dated signature on the antibiotics register which incidentally he/she is not obliged to sign.

Other anomalies exist in relation to revoking, suspending or restoring licences as the regulations do not state on what grounds all these measures can be taken.

5. Powers of Entry

An Environmental Health Officer can enter any premises or vehicle and can inspect substances, take substances for analysis and study or copy any documentation found therein. However, he/she cannot enter the premises of a manufacturer or wholesaler, a chemist shop or a private dwelling house. One of the anomalies here is that if an officer is refused entry there is no redress as it is not an offence to refuse entry.

6. Other Anomalies

(a) Environmental Health Officers have no power of immediate seizure of contraband, unlike the more extensive powers of the Department of Agriculture officers under the Animal Remedies legislation. In general, Department of Agriculture regulations made under the Poisons Act 1961 and the Animal Remedies Act are much more effective and in need of practically no amendment, although they cover virtually the same area as ourselves. The view nationally among Environmental Health Officers is that this entire area is one that should be dealt with the Department of Agriculture because of their day to day involvement with farmers and Co-ops and their extensive knowledge of the preparations in use in the market. Licensing by health boards and the use of inferior enforcement legislation is seen as an unnecessary duplication. Furthermore, all new EC directives controlling this broad area are going to the Department of Agriculture.

(b) Schedules in the regulations refer only to the scientific names of poisons while in retail outlets all the poisons have brand names which do not readily identify their contents. Where contents are disclosed it is an extremely laborious exercise to match contents with the difference scheduled poisons as there are vast numbers of poisons in the market. Enforcement could be simplified if the Department of Health circulated a list of brand names which are poisons and ensured that the list was up-dated regularly. However, there is widespread recognition that manufacturers are staying well ahead of the legislators as they can easily produce new brands or simply alter concentrations or substitute certain ingredients with other equally effectively through dangerous and unlisted poisons in order to keep outside the regulations and frustrate controls in this area.

Table 1

Poisons Act 1961	S.I. No. 12 of 1961
Poisons Regulations 1982	S.I. No. 188 of 1982
Poisons Amendment Regulations 1983	S.I. No. 51 of 1983
Poisons Amendment Regulations 1984	S.I. No. 349 of 1984
Poisons Amendment Regulations 1986	S.I. No. 424 of 1986
Poisons Amendment Regulations 1991	S.I. No. 353 of 1991

APPENDIX H

Prescribing Issues: Summary of Research Carried Out by the Department of Pharmacology and Therapeutics, University of Dublin.

The influence of pharmacoeconomic factors on prescribing in Ireland were reviewed by Feely in 1992.[4] Drug costs were particularly high in Ireland, almost one-third higher than the EC norm, even though Ireland was one of the poorer countries in Europe. However, the high cost of drugs was balanced by relatively low prescribing rates in Ireland. It was postulated that the high cost of drugs in this country was largely attributable to our long-standing involvement in the EC and linkage of prices to our more affluent neighbour, Britain.

In contrast to the UK, there was no restriction on pharmaceutical promotion in Ireland, and **there appears to be a positive relationship between expenditure on pharmaceutical promotion and national consumption of pharmaceuticals in European countries.**

Sources of Drug Information

A postal survey of GP's was carried out to determine the important sources of drug information for drugs prescribed by them.[2] **Information from pharmaceutical representatives and recommendations from consultants/hospital prescriptions were the most important source of information about new drugs prescribed.** A random survey of Irish GP's were asked to prospectively record prescription details.[3] Of 3,400 prescriptions analysed, hospital initiated prescriptions accounted for 37.9% of GMS prescriptions and 41.2% of the total cost. The researchers concluded that a **significant proportion of GMS prescriptions are initiated by hospital doctors. Any effort to influence GP prescribing should also address hospital prescribing.**

Formularies and Restricted Drugs Policies

Formularies and restricted drug policies aim to improve prescribing practice by encouraging prescription of drugs on the grounds of efficacy, safety and economy. However, continuous intervention, review and feedback are required if a formulary is to continue to achieve its objectives[4].

A limited list of prescription items for the GMS was introduced in 1982. GMS savings achieved as a result of this may have been somewhat reduced as evidence suggested that **prescribers substituted more expensive prescription items** (which were free or re-imbursable) for the cheaper items which patients now had to buy over the counter.[1] Although the limited list produced a short-lived reduction in the rate of increase in medical expenditure, total costs have continued to rise.

The effects of introducing a hospital formulary alone, and with active intervention in a Dublin hospital are reported in a paper published in 1990.[5] Intervention comprised feedback on prescribing habits, peer comparison and information on drugs. **In the year in which intervention occurred, generic prescribing rose by 50% and inappropriate prescribing of third generation cephalosporins fell.** During the next year, when no form of intervention took place previous gains were eroded.

Feely noted that the introduction of a National Formulary for the GMS scheme in 1991 had little impact on prescribers.[1] He considered that this was not unexpected as users were not involved in its construction, received no encouragement or feedback on its use, and there was no peer review.

Surveillance of drugs in clinical practice through the reporting of adverse drug reactions is an important aspect of safe prescribing of drugs. A study in a Dublin hospital showed that the introduction of a fee to junior doctors for reporting of adverse drug reactions greatly enhanced the level of such reactions reported, m any of which were serious reactions, including those associated with newer treatments.[6] **The researchers concluded that further evaluation of the use of a reporting fee is warranted.**

Generic Prescribing

The level of generic prescribing was compared in the Republic of Ireland, Northern Ireland and England.[7] **The level of generic prescribing in Ireland was low.** In 1993, generic drugs (pure generics and branded generics together) comprised 17.4% of total dispensing in the General Medical Services (GMS), significantly less than Northern Ireland or England where pure generics alone comprised 25% and 38% respectively of total dispensing in the National Health Service (NHS). In addition, a questionnaire was circulated to 10% of the membership of the Irish College of General Practitioners seeking information on their attendance in the past year at meetings on generic or economic prescribing and their concerns about economic prescribing. Some 57% of respondents had attended a meeting on economic or generic prescribing in the preceding year. **Issues of concern** were the **reliability** and **quality** of generic products on the market, possible **legal liabilities** associated with their use and fact that **pharmacists may legally dispense more expensive proprietary preparations** in the case of private prescriptions written generically. **The researchers concluded that prescribers need reassurance regarding legal and quality assurance aspects of generic prescribing in the level of generic prescribing is to increase.**

A survey of hospital doctors showed that they had a good knowledge of the generic names of drugs and this was not the reason for a low level of generic prescribing.[8] **However, they had a poor awareness of the cost of drugs,** overestimating the cost of cheaper drugs and under-estimating the cost of the most expensive drug in the study.

For the past 16 years, a system of biennial visits to GP's in Northern Ireland by a prescribing visitor has been in place.[4] The basis for discussion in the doctor's own prescribing records and the visitor indicates areas where prescribing might become more efficacious, safe and cost-effective. Four forms of intervention are used: a "best-buy" list, the range of drugs prescribed, specificity of prescribing and dissemination of drug information by seminars and mail-shots. Significant savings have been achieved by the implementation of this system.

Patient Information

It is held that increasing patient knowledge of drug therapy improves compliance. patient knowledge of prescribed drugs was assessed in a Dublin hospital.[9] **The study indicated that both in and out-patients had a poor knowledge of medications.** In addition their main source of knowledge, i.e. the prescriber had poor ability to tell tablets apart. *It was suggested that both patients and prescribers knowledge needs to be improved.* In another study it was shown that patients on long term therapy for Epilepsy were unaware of important aspects of their medication, such as possible problems were driving, drinking alcohol or pregnancy and **it was recommended that additional education including written information and reminders concerning therapy could be useful.**

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APPENDIX I

Summary of Reports of the National Therapeutics Advisory Committee to the Minister for Health, April 1993.

Summary of Initial Recommendations

1. Develop a comprehensive Drug Prescribing Information System which can then be used to help modify prescribing in both hospital and general practice.

2. Set up a Pilot Study to computerise three hospitals prescribing practices as well as a cohort of associated general practices.

3. Provide hospitals with their own GMS prescription pads and establish guidelines for division of responsibility between hospitals and general practice.

4. Establish the proper structures and supporting data for the effective operation of Indicative Prescribing Targets.

5. Appoint a National Director and Practice Support Doctors to facilitate quality and cost-effective prescribing.

6. Consider the appointment of a Prescribing Fellow.

7. Drugs and Therapeutics Committees should be established immediately in all hospitals and hospital groups.

Summary of Second Report

Generic Drugs

The NTAC, having considered the detailed procedures of the NDAB, is wholly satisfied that all authorised generic products for human consumption on the Irish market are of equal standard with their proprietary counterparts.

Any promotion activities which tend to undermine the safety and efficacy of generic products on the Irish market are, according to the evidence currently available to this committee, totally unfounded.

Approval to the Code of Marketing Practice for the pharmaceutical companies should not be given unless the issues of concern in relation to marketing activity are properly addressed (frequency of visits by medical representatives, the large volume of literature forwarded to doctors and the conduct of medical representatives during visits).

Provision should be made for realistic sanctions to be applied to companies found to be in breach of the Code.

Local fora should be established where community pharmacists and GP's can discuss and agree broad principles and practice concerning prescribing and dispensing.

Product Authorisation for the introduction of new generic drugs to the Irish market should be granted only in respect of drugs which are consistent in shape, colour and size with the comparator products on the market.

The Group recommends that:

- it should be obligatory to prescribe by generic name and to dispense the least expensive product available, except in exceptional circumstances
- regulations should be drafted to facilitiate substitution of generic equivalents by the pharmacist where appropriate.

Any reappraisal of the GMS and non-GMS end point drug costs should include a review of the current disbribution network and control of medicines, dispensing fees and retail mark-up with a view to removing eh anomalies which currently prevail.

Hospital/GP Interface

Therapeutics Committees should be established at sub-Health Board level to provide a mechanism through which doctors and pharmacists from hospital and community settings can communicate.

The linkage of hospital prescribing data, hospital diagnostic data and GP prescribing data would have enormous benefits for service delivery. The Group recommends the establisment of a pilot project to evaluate the collection and sharing of data as above.

Consideration should be given to the provision of incentives to hospitals to actively seek savings in drug budgeting.

The success of hospital formulary is dependent on the ability of the hospital to implement the formulary, educate staff in relation to its usage and to monitor and review its contents on an ongoing basis.

The Group recommends the establishment of an independently funded central Drugs Information Unit.

Hospitals should be provided with their own GMS prescription pads with consultant numbers and a seven-day limit on the prescription.

Therapeutics Committees should be established and appropriately supported in every hospital.

Prescribing Information and Education

Concise monthly reports on information on prescribing that focus on one or two therapeutic groups are more likely to be of use to General Practitioners.

Provision of prescribing information to GP's should commence as a matter of urgency.

A group involving the National Drug Formulary Committee and a sub-group from the NTAC should be established to formulate Drug Informatio Bulletins on the treatment of certain conditions.

The Clinical Standards Committee of the Irish College of General Practitioners should be invited to draw up clinical guidelines.

Local multidisciplinary meetings should be established to develop agreed approaches to the management of common chronic conditions including prescribing and dispensing policies and indications for referral.

GP Units should provide information and education for GP's and are more likely to succeed if they work with GP's on an individual basis.

Education of the Public

There is a need to:

- identify specific issues which need to be addressed such as safety, patient demand, public misinformation
- identify the specific audience which needs to be targeted
- propose a range of strategies in consultation with the Health Promotion Unit

The NTAC should set up a working group in association with the Health Promotion Unit to devise priorities for public information campaigns.