NOVEMBER 1992

THERAPEUTICS SECTION Bulletin

THERAPEUTICS SECTION, DEPARTMENT OF HEALTH, WELLINGTON, NEW ZEALAND

This is the first in a series of bulletins about the activities of the Therapeutics Section. The content is prepared by the staff of the Section and is intended to inform, explain and sometimes amuse. Topics covered will include the evaluation and control of medicines and related products, medical devices, cosmetics and therapeutic information.

In the past we have been criticised for a lack of communication and consultation. I believe that view is no longer sustainable. We endeavour to be prompt, courteous and absolutely impartial when answering your queries and we welcome visitors to our Wellington office. You may not always get the remedy you want, but we try to sugar the pill by taking an understanding and friendly approach to resolving any difference.

PHOTO COURTESY OF N.Z. DOCTOR

Although we already publish material in the form of the Prescribers' Notes and various technical guidelines, we have seen a need to communicate more directly with our clients which should be to our mutual benefit. Hence this new publication which I hope you will find informative.

If you require clarification of any issue raised in this bulletin or if you have any questions that you want discussed in the next issue then please let us know. Communication only works when it is two-way. Our address is listed on the back page.

BOB BOYD MANAGER

STOP PRESS

The Director-General of Health has announced changes to the structure of the Department of Health and an eventual name change to the "Ministry of Health" as part of the current health reforms.

The functions of the Therapeutics Section will remain with the proposed ministry. There are likely to be only minor changes in the structure and processes of the section as a result of the exercise. But, as noted elsewhere in this bulletin, major changes may arise within the next two years following a review of the medicines legislation.

The Therapeutics Section

The Therapeutics Section is part of the Health Regulation and Protection Group of the Department of Health and is funded partly by the Crown and partly from fees charged for its services, notably fees for applications to market new and changed medicines, to carry out clinical trials and to manufacture medicines.

Our mission

Our aim is to promote and protect the health of all New Zealanders by:

1. minimising the risks of unsafe, poor quality, or ineffective therapeutic goods;

2. improving acceptance of and compliance with safety and quality standards in the manufacture, distribution, promotion and prescription of medicines and other forms of therapy;

3. achieving greater prescriber and public awareness about the rational and safe use of medicines and other therapeutic options.

An Efficient Organisation

Under the Medicines Act 1981 and the Misuse of Drugs Act 1975 the Minister and the Department of Health are charged with setting and monitoring standards for the manufacture, promotion and distribution of medicines, medical devices and other forms of therapy.

The pharmaceutical industry is obliged to maintain standards and quality control procedures.

Therapeutics staff have to approve these standards and quality control procedures before products are marketed, and also periodically carry out checks. The Therapeutics Section's brief is to promote the safe, rational and cost-effective use of prescribed medicines through visits to prescribers, sponsorship of the National Preferred Medicines Centre (PreMeC) and the National Toxicology Group's Adverse Reactions Centre. This work is done by a small and efficient team of just over 20 people with a diverse range of skills including medical, pharmacy, sciences, law enforcement and administration. Most are based in Wellington, but visiting professional advisors also work out of Auckland and Christchurch. Day-to-day work is divided between three teams, Evaluation, Compliance and Utilisation. The functions of each group are described later.

Meeting International Obligations

New Zealand participates fully in the activities of the World Health Organisation and the Therapeutics Section ensures that local adverse reaction reporting data is fed into the World Health Organisation (WHO) co-ordinating centre at Uppsala. The section also regularly shares information with the WHO pharmaceutical programme in Geneva.

Hazard reports are exchanged with other regulatory agencies and especially close links are maintained with the Australian Therapeutics Goods Administration (TGA) concerning all facets of medicine and device control.

The section is also a corresponding member of the International Society of Drug Bulletins.

Client Focus

While the Therapeutics Section's prime responsibility is to the Minister of Health, we acknowledge that our services depend greatly upon the co-operation and the goodwill of our clients who range from local and multinational pharmaceutical companies, industry associations, consumer groups, the media and other government agencies, to individual pharmacists, prescribers and the general public. The section welcomes the chance to consult and to learn of concerns about its service. A liaison group, with members from the Therapeutics Section and the industry, is being established in 1992 to oversee the appropriate use of resources in carrying out the section's activities.

Therapeutics Section Staff

The Therapeutics Section is headed by manager Bob Boyd. Staff are divided into three teams - evaluation, compliance and utilisation. A small number of additional staff work on special projects.

WHO WE ARE AND WHAT WE DO

Manager

BOB BOYD

Bob is manager of the Therapeutics Section with overall responsibility for the quality and timeliness of the section's activities and for keeping within the allocated budget.

Bob is a medical practitioner and a member of both the College of Community Medicine and the Royal NZ College of General Practitioners. He has been associated with pharmaceutical controls and pharmaceutical pricing during all of his 12 years with the Department.

Up until this year he has chaired the Pharmacology and Therapeutics Advisory Committee which recommends on the inclusion of medicines in the Drug

Tariff. This is associated with his special interest in how prescribers choose their therapies and what information they need to do this effectively. Now he feels that role can be better serviced through working with PreMeC and the visiting professional advisors.

Recently Bob spent six weeks as a rural GP to "keep his hand in" and to experience first hand the effects of the Department's policies. In July 1992 he was part of the faculty of the Summer School of the International Society of Drug Bulletins in Tokyo and attended the society's three yearly general meeting.

Evaluation Team

The Evaluation Team has three main tasks, all related to evaluating new and existing medicines. Evaluation staff do the "paper" evaluation of data submitted to the Department in support of applications to market new medicines, or to make changes to existing medicines. In this work they have a close relationship with the Medicines Assessment Advisory Committee (MAAC) which reviews new chemical entities. They also provide information about applications for clinical trials to the Health Research Council. A sub-committee of the council - the Standing Committee on Therapeutic Trials (SCOTT) makes the decisions on clinical trial applications which are then processed by the Evaluation Team. The Evaluation Team is also involved in monitoring adverse reactions to medicines. It feeds information to, and receives data from, the Medicines Adverse Reactions Committee (MARC) and the National Toxicology Group.

MARK ROWLAND

Mark is the leader of the Evaluation Team. A pharmacist, he spent many years working in hospital pharmacies, holding charge positions at the Tokanui and Hutt Hospital pharmacies. He has also served as a medic in a territorial army field hospital with the Royal New Zealand Army Medical Corps.

RICHARD GRIFFITH

In addition to his regular work as part of the Evaluation Team, Richard is secretary to the Medicines Assessment Advisory Committee (MAAC) and serves as one of two Department of Health members of the Medicines Classification Committee (MCC). He joined the Department 17 years ago after working in the pharmaceutical industry and in hospital and retail pharmacy in Australia and New Zealand.

KATHLYN RONALDSON

Kathlyn deals with all queries concerning adverse reactions and is secretary to MARC. She is also the person who issues labelling exemptions. And, if she has any spare time, she turns her hand to New Medicine Applications.

ABDUL MUTLIB

Abdul works with generic medicines. He is Secretary of the Generics sub-committee of the MAAC and assisted in compiling "Guidelines on Comparative Pharmacokinetics" and "Guidelines on Aerosols". He recently attended the International Conference on Bio-equivalence in Canada. He also evaluates medicine applications. Abdul has an M.Pharm and worked at the Government Pharmacy in Fiji and a retail pharmacy in Dunedin before joining the Department.

KHAY OOI

Khay is a plant and herbal medicine expert, with a masters degree in plant biochemistry. As well as handling matters relating to herbal medicines, he carries out more routine evaluations of orthodox new and changed medical applications. Before joining the Department, he worked at Christchurch Hospital and later at the Malaghan Institute of Medical Research.

JEREMY BRETT

Jeremy specialises in applications relating to vaccines and recombinant products. He is a chartered biologist and member of the Institute of Biology (UK). He has previously worked at diagnostic medical microbiology laboratories in the UK and New Zealand, and has done research into the treatment and immunology of tuberculosis with Medical Research Council units in the UK.

COLIN HUGHES

Colin came to the Department from a position as head of the School of Pharmacy at the Central Institute of Technology. British-born, he has a Ph.D in synthetic chemistry and spent seven years working on research and development in the UK for E.R. Squibb.

DAVID STEVENS

David is the Evaluation Team's executive officer and acts as secretary for the Departmental Evaluation Review Meetings. He handles inquiries about the current status of New Medicine Applications and deals with the paper work as applications progress through the evaluation process before approval to market is granted. David came to the Department four years ago after working in management with Telecom and the Post Office.

GARY TWINN

Gary's job is to keep track of Changed Medicine Notifications and Clinical Trial Applications and to make sure these are acknowledged. He also provides clerical assistance to other team members.

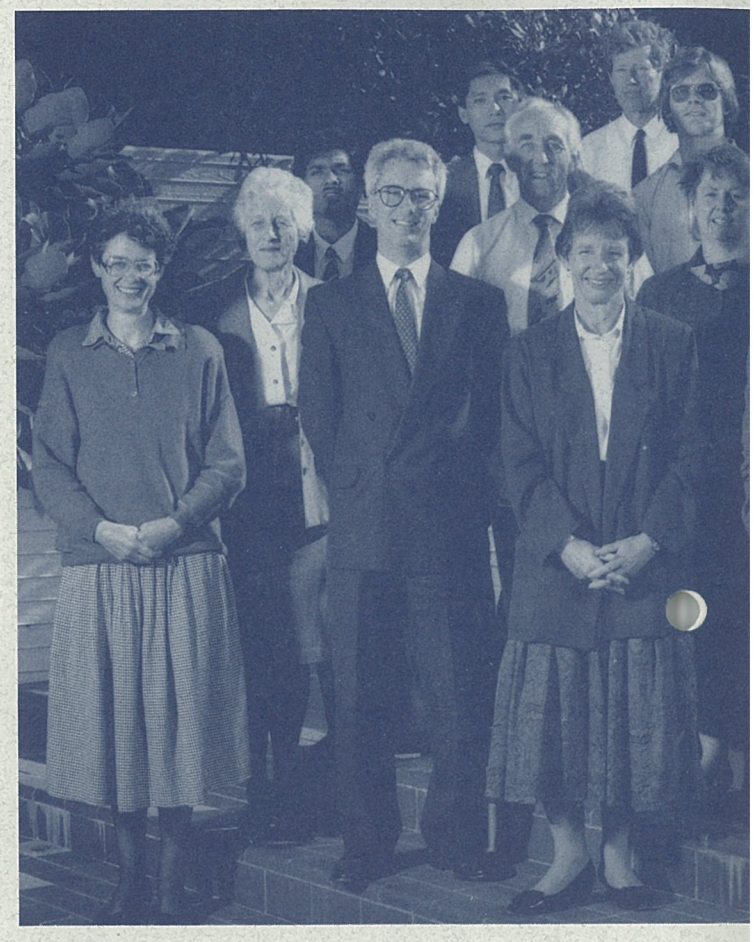
Compliance Team

The Compliance Team is responsible for surveillance of all therapeutic goods on the market, and for keeping an oversight of medical advertising. The Compliance workload is divided into two categories - medical devices (items like prostheses, catheters, breast implants and diagnostic kits for glucose testing) and cosmetics; and medicines and related products. They aim to ensure that the products are safe and have been manufactured, stored and distributed according to acceptable standards.

Compliance staff investigate complaints about defective products and, where necessary, may request a recall of items.

They carry out their own testing programmes for devices and cosmetics. And this year, after a gap of some years, the Compliance Team has also been inspecting device manufacturing operations, to ensure that they are in line with Good Manufacturing Practice (GMP). (Unlike requirements for medicines, which have to be manufactured under licence, no special permit is required to make medical devices. This may change, however, with the review of the Medicines Act which is likely to recommend stricter regulatory control of medical devices.) Compliance staff are in charge of licensing for controlled drugs. They administer the requirements for import and export of narcotic and psychotropic substances and also prepare statistics on imports and exports of these substances for the International Narcotics Control Board.

In the wake of a critical report by the Audit Office, Compliance staff have been inspecting hospital pharmacies, which, however, now manufacture very few medicines and are working with representatives of pharmacy to develop a Code of Practice for Compounding and Dispensing.



JOAN BAAS

Joan is leader of the Compliance Team. She is a scientist with a D.Phil in biochemistry from Waikato University. She has taught biochemistry at university level, worked in hospital laboratories and done research into animal biochemistry.

TREVOR NISBET

Trevor's specialist area is health and safety issues involving medical devices and cosmetics. He monitors overseas recalls and supervises the testing programmes for devices and cosmetics. At present he is working on developing improvements in the control of importation and distribution of medical devices. Trevor joined the Department 13 years ago, after working in pharmaceutical companies both in New Zealand and overseas. He has a D.Phil in physical chemistry, and last year was awarded a WHO Fellowship to study regulatory controls and safety concerns relating to medical devices in other countries.

CHRISTINE DEVESON-SHEPPARD

Christine's areas of special interest are GMP, and hospital pharmacy manufacturing issues. She is also responsible for surveillance of medicine advertising and distribution (including exemptions under Section 29) and licensing under the Misuse of Drugs Act. She has a masters degree in pharmacy from Sweden, and worked for the National Corporation of Swedish Pharmacies before coming to New Zealand and managing a health centre.

BARBARA CAVANAGH

Barbara is an Executive Officer and secretary to the Medicines Review Committee (MRC). She has been with the Department for nine years, working in administration and advisory positions.

RACHAEL TRUDGEON

Rachael uses her computer skills to input Section 29 applications into a data base, and licensing under the Misuse of Drugs Act.

Front Row:
Kathlyn Ronaldson, Helen Harvey, Jeremy Brett, Joan Baas, Bob Boyd, Margaret Ewen, Christine Deveson-Sheppard, Canagaratnam Sri-Ananda (now retired), Trevor Nisbet.

Middle Row:
Abdul Mutlib, David Stevens, Susan Martindale, Carol Smith, Colin Hughes.

Back Row:
Khay Ooi, Richard Griffith, Gary Twinn, Barbara Cavanagh, Mark Rowland.

Absent:
Rachael Trudgeon, Catherine Marnane, Tania Paull, Graham Leslie.

Utilisation Team

The Utilisation Team is responsible for three main areas - prescriber education, the MCC and the generic substitution project. Utilisation staff provide advice to prescribers both through face-to-face visits and via publications like the Clinical Services Letters and Therapeutic Notes. These are sent out regularly to doctors, retail pharmacists, dentists and midwives and cover issues such new legislation, changes in medicines classifications and adverse medicine reactions of clinical importance.

The Utilisation Team services the MCC which is responsible for advising where and how medicines can be sold. It aims to ensure that people have access to medication with the least barriers consistent with safe use of the product. In the last couple of years, many more medications have become available, without prescription, in pharmacies, supermarkets and other outlets, as a result of reclassification.

A Special Project Group with the Utilisation Team is working on the Generic Substitution Project. This involves a review of most generic products approved before July last year, in order to develop a list of generic medicines considered safely substitutable at pharmacy level. The project is also examining legislative requirements, and developing a practical scheme for implementing generic substitution.

Other special projects include the publication of a New Zealand Formulary which will give detailed medicines information and therapeutic guidelines for New Zealand prescribers, and a safety packaging project. The latter is a pilot project aimed at measuring the degree of public interest in child-resistant closures for medicine containers. It will get underway shortly.

MARGARET EWEN

Margaret is leader of the Utilisation Team. She has a Dip.Pharm., and worked for many years as Charge Pharmacist at Thames Hospital and then in a retail pharmacy in Auckland before joining the Department. Margaret visits prescribers in the lower North Island as well as preparing the prescriber series of publications, liaising with PreMeC and carrying out projects involving medicine utilisation.

CATHERINE MARNANE

Catherine is the Support Officer for Utilisation, in charge of administration and publications. Catherine has been with the Department for four years. She spent two of those years on secondment to the Minister of Health's office, coming back to manage the Ministerials unit which handles correspondence to the Minister. Earlier, Catherine worked as a GST auditor for the Inland Revenue Department and spent five years as a Customs officer.

CAROL SMITH

Carol is an Advisory Officer and secretary to the MCC, and is in charge of distribution of data sheets. Carol worked as a secondary school teacher before joining the Department four years ago.

TANIA PAULL

Tania is an Assistant Support Officer. She joined the Department in 1990, working first for Human

Myfanwy Fulford and Alister Livsey

Resources Management and then for Primary Services Contracts. She shifted to the Therapeutics Section recently.

MYFANWY FULFORD

Myfanwy is an Auckland-based Visiting Professional Advisor. She visits prescribers in the top two-thirds of the North Island. She is a registered pharmacist with extensive managerial experience in retail and urgent pharmacies. She has also done a stint in Hospital pharmacy. She joined the Department in 1982, and has worked as a District Advisory Pharmacist dealing with medicine control and as a Senior Advisory Pharmacist dealing with the interpretation and implementation of the Drug Tariff.

ALISTER LIVSEY

Alister is also an Auckland-based Visiting Professional Advisor, visiting prescribers in the top two-thirds of the North Island. He worked in various areas of pharmacy before joining the Department, and has been visiting GPs and specialists for 10 years. He has a Dip Health Admin. and is a member of both the New Zealand and the Royal Pharmaceutical Societies.

ISOBEL SMITH

Isobel is a newly-appointed Christchurch-based Professional Advisor, visiting prescribers throughout the South Island. A registered pharmacist, she worked most recently as Chief Pharmacist to the Taranaki Area Health Board.

MALENE HOOK

Malene is a part-time assistant to the Professional Advisors in Auckland. She joined the Department in 1990 from Adis International Ltd.

Special Projects

SUSAN MARTINDALE - Therapeutic Goods legislation project

Susan chairs the MCC and is project manager for the Therapeutic Goods Legislation Project which started this year. The projects aims to amend the legislation which controls medicines, medical devices, related products and cosmetics (therapeutic goods). The aim is to harmonise the new legislation with that of major trading partners, particularly Australia. Susan has a Ph.D in biochemistry and worked as a registered patent attorney before joining the Department. Susan has previously worked in the Evaluation Team and until taking on this project was the Team Leader of the Compliance Team.

GRAHAM LESLIE - Generic Substitution programme

Graham is employed on contract to manage the Generic Substitution Project which will introduce generic substitution at a pharmacy level. Graham is a pharmacist and has worked with pharmaceutical companies. Most recently he worked with a generic company in New Zealand where his job was to find and introduce generic products onto the New Zealand market. He has lived and worked in England travelling extensively in Europe and North America on business. He has now set up his own business in New Zealand providing contract management services in regulatory affairs and business and product development to the pharmaceutical industry.

HELEN HARVEY - Generic Substitution programme

Helen is responsible for liaising between pharmaceutical companies and the Generic Substitution Review Committee in the updating of files and the presentation of summaries of prescribed generic medicines. The generic medicines being reviewed are already approved for use in New Zealand and are generic equivalents of the top-selling 200 medicines on the Drug Tariff. Helen has an honours masters degree in science, and is a member of the New Zealand Institute of Chemistry. She worked for many years as an analytical scientist at DSIR specialising in analysis of pharmaceutical products before joining the Department in 1987.

Therapeutics Section Stafflist

	Special Responsibilities	Direct Dial Telephone
Bob Boyd	Manager	496-2088

Evaluation Team

Mark Rowland	Team leader	496-2091
Richard Griffith	MAAC	496-2363
Kathlyn Ronaldson	Secretary MARC	496-2365
Abdul Mutlib	Secretary Genetics sub-committee	496-2098
Khay Ooi	Traditional and Herbal Medicine	496-2339
Jeremy Brett	Biological Products	496-2097
Colin Hughes	Secretary MAAC	496-2331
David Stevens	New Medicine Applications	496-2093
Gary Twinn	Changed Medicine Notifications Clinical Trials	496-2038

Compliance Team

Joan Baas	Team leader	496-2362
Trevor Nisbet	Medical Devices and Cosmetics	496-2364
Christine Deveson-Sheppard	Section 29 Medicines and Hospitals, GMP	496-2378
Barbara Cavanagh	Support Officer	496-2191
Rachael Trudgeon	Asst Support Officer	496-2338

Utilisation Team

Margaret Ewen	Team leader	496-2107
Catherine Marnane	Support Officer	496-2179
Carol Smith	Advisory Officer and Secretary MCC	496-2096
Myfanwy Fulford	Visiting Advisor, Auckland	PH (09)480-2154 FAX(09)480-2156
Alister Livsey	Visiting Advisor, Auckland	PH (09)480-2152 FAX(09)480-2156
Isobel Smith	Visiting Advisor, Christchurch	PH (03)379-0187 FAX(03)377-1587
Malene Hook	Secretary, Auckland	PH (09)480-2151 FAX(09)480-2156

Special Projects

Susan Martindale	Therapeutic Goods Legisation	496-2092
Graham Leslie	Generic Substitution Project	496-2040
Helen Harvey	Generic Substitution Project	496-2094

Therapeutics Update

Each issue of the bulletin will include several short items of topical interest, reflecting the varied activities of the Therapeutics Section.

Evaluation of Medicines

The process for evaluating medicines has undergone significant change in the last couple of years. In the past, applicants frequently had little idea whether their applications contained the information required, in the format required. Evaluation Team leader Mark Rowland says: "A company might have put in a marketing application and then hear nothing until it got a letter declining its application." The revamped evaluation process aims to give applicants a clear idea of the information needed before they put in their application. As well as providing greater transparency for applicants, the changes bring New Zealand into line with the formats used within the European Community (EC). Mark says this is a sensible move. The majority of medicines used in New Zealand come from Europe, so companies applying to market products here have generally made initial application in Europe, using the EC format. "The Australian TGA has recently also announced that it will accept the EC format. This certainly makes sense for so many of our companies have trans-Tasman connections," he says. A revised Medicines Distribution Guide reflecting the changes is to be published by the end of this year.

Evaluation of generics

New and up-dated guidelines for the evaluation of generic medicines have been recommended by the generic sub-committee of the MAAC and published by the Therapeutics Section following consultation with professional and industry groups. The guidelines reflect the optimum international standards for the evaluation of generic medicines. The Evaluation Team sent scientist Abdul Mutlib to the international conference on bio-equivalence in Canada in June this year to make sure it had first-hand information on latest developments.

Harmonisation touches MAAC

Harmonisation is everywhere it seems. Even the MAAC is not immune. Members are now asked to report on each medicine they evaluate according to the format used in the international Pharmaceutical Evaluation Review (PER) scheme. This opens the way for future exchanges of evaluation reports with other regulatory agencies.

Electronic applications

The Evaluation Team is interested in the efforts of some pharmaceutical companies and regulatory agencies to develop a process of electronic applications. To date, it hasn't received any "real-life" electronic applications, though staff have participated in demonstrations of the process. In future, as the technology improves, an electronic format may become the norm and a new medicine application may arrive as two CD-ROM discs instead of a pallet-load of over 200 volumes.

Internal assessments standardised

Peer review systems for internal assessment of new medicine applications are being strengthened and standardised. Some new medicine applications, for instance for non-prescription items and generics, don't have to go before the MAAC and are instead reviewed internally. Two appropriately qualified evaluators, one from the Institute of Environmental Health and Forensic Sciences (formerly DSIR) and one from the Department's Therapeutic Section separately review each application, working to check-lists and producing reports which are presented to a monthly Evaluation Review Meeting. The meetings are attended by staff from both units and there is often lively debate about various aspects of an application before the meeting is satisfied that safety, efficacy and quality of the product is assured. Standard operating procedures are being established to ensure that decisions on issues like "fast-tracking" an application, or referral to expert consultants, are made in a consistent and systematic way. Generic approvals face a further review by the Generic sub-committee of the MAAC as a final check on the evaluation standards.

"Quid pro quo"

It is now just over a year since a fee structure was introduced for New and Changed Medicine Applications and for Clinical Trial Applications. This has been an extremely busy time for evaluators in the section. In the four days before the new fees came into force, the section received four months worth of medicine applications. This put enormous pressure on the evaluators. The law requires that Changed

Medicine Applications must be assessed and applicants informed of any resulting queries, within 45 days. The evaluators managed to meet these deadlines, but, as a result, work on some New Medicine Applications was delayed.

The backlog of New Medicine Applications has now been substantially reduced. The Evaluation Team has undertaken to send a full evaluation review letter to each applicant within nine months of receipt of the application. This is being achieved, with the exception of a handful of applications still affected by delays resulting from the pre-fee flood of paper work.

Since the fee system came into force, there has been a settling down period where applicants and the Department have worked together to apply the somewhat complicated fee structure and waiver system in a practical fashion. It is now time to consider how well the system is operating and whether there is any need for adjustment of the fees policy. A liaison group with representatives of various sections of the industry meets in November for the first time and will be asked to help the Therapeutics Section audit its own performance. Subsequent issues of Therapeutics Section Bulletin will include the findings of the liaison group.

Therapeutics Section Database (TSD)

The Therapeutics Section has developed its own database - TSD - to help standardise operating procedures. The major benefit of TSD is that it can be used to "track" the progress of each medicine application and to record significant dates like the due date for replying to a Changed Medicine Notification.

TSD - based in the Paradox operating system - replaces the 8"x 5" cardboard cards which, until now, were the major reference source about medicines available in this country. Once fully operational, TSD will be a valuable resource, containing a complete set of information on each product and a cross reference to all raw material and finished goods manufacturers. Currently two pharmacists have been contracted to work full-time transferring information from the files onto TSD.

TSD is already contributing to a more effective and speedier turnaround of applications. The benefits should be more evident as the transfer of information gets further advanced.

Labelling not yet licked

Ever since the Medicines Act came into force in 1984 the Department has given labelling exemptions for products which are manufactured overseas and imported in small quantities only to fulfil a need in this country. The process has become more formalised in recent years, but it is still difficult to administer fairly, so that one manufacturer does not get a financial advantage from being exempted from having New Zealand-specific labelling.

Already we have identified those regulations which could be modified slightly to allow importation of products labelled appropriately for markets such as Australia, the United States, Britain and Canada.

The emphasis this year is on harmonising with Australia's labelling and packaging requirements, to see if it is possible to have more products using the same packaging on both sides of the Tasman.

Recognising that compatible scheduling of medicines would be an important step toward this goal, Susan Martindale recently went with an officer from the Ministry of Agriculture and Fisheries (MAF) to a meeting in Canberra about overcoming these barriers and has joined a working party on scheduling issues.

Tinkering with devices

The recent publicity about the safety of silicone gel breast prostheses highlighted the relative shortcomings of current legislation in New Zealand controlling medical devices.

Medical devices do not need to go through a pre-marketing approval process. Removing suspect devices from the market is correspondingly more difficult than it would be for a medicine.

Commentators were quick to point out that consumers were not really being adequately safeguarded.

Trevor Nisbet, of the Compliance Team, returned earlier this year from a World Health Organisation Fellowship with several major recommendations on how devices should be controlled and safety assured.

After spending time meeting with the regulators and people in the industry from Stockholm to Singapore, Trevor would like to see us implement a pre-marketing notification system as soon as possible for

all devices distributed in New Zealand and to have the register on-line for hospitals and other purchasers.

For special categories of devices, such as those to be implanted for more than 30 days, he proposes an approval system, based initially on evidence of approval for marketing in the United States, Canada and the European Community or special device approval in Australia.

Parallel with the product registration system, Trevor would like to see the New Zealand agents taking more responsibility for their products, including recalls and notification of hazard alerts from overseas.

A booklet for women contemplating silicone gel breast implants has been prepared by the Compliance Team, working with surgeons' organisations, companies who manufacture and distribute implants, and consumer groups. All plastic and general surgeons will be sent copies of the booklet and urged to use it. Patients should be given the booklet to read before they decide to go ahead with an operation. There is a space for women to sign the booklet, indicating that they have read and discussed the contents with their surgeon.

Standards of practice

At present there is no requirement for inspection of clinical trials in New Zealand (though all trials have to be approved before they can go-ahead). This lack of a formal system for auditing good clinical practice in New Zealand has been recognised as a gap in our regulatory control. As a first step to bridge this gap, a member of MAAC and SCOTT is drafting guidelines, based largely on existing Australian guidelines for Good Clinical Practice (GCP). There will need to be consultation with interested parties before the guidelines are adopted. A progress report will be included in a future bulletin.

Readers will be aware that the Department has sought comment on a proposal to update the 1978 New Zealand Code of Good Manufacturing Practice for Medicines. A working party representing the interests of the research-based industry, generics industry, hospital sector and licensing authorities has met and recommended that New Zealand adopt the international Pharmaceutical Inspection Convention (PIC) Code. The Department was keen to see that a code with international standing was adopted in New Zealand and recognised that it would not be sensible for a New Zealand specific code to be drafted. The new agreed Code of Practice, based on the PIC Code will be available from the Therapeutics Section from December.

Three further Codes of Practice are planned. These will cover standard procedures for medicine recall, wholesale distribution of medicines, and dispensing and compounding of medicines within pharmacy. Each of these activities was referred to in the 1978 Code, but they are not specifically covered in the PIC Code and therefore need to be dealt with as separate documents. In the meantime, the 1978 code and the new PIC code will run in tandem - that is, the 1978 code will apply for areas not covered in the PIC code.

Consultation with interested parties over the compounding and dispensing code is already underway, and that document should be published early next year.

Medicines Act Review

The long-awaited review of the Medicines Act has begun.

A letter inviting comment on the review was sent out to about 500 organisations and individuals including government departments, medical and health professional associations, industry groups, consumer organisations, complementary medicine associations and practitioners, area health boards and health reforms associations and representatives of Maori and womens' issues. More than 600 submissions have been received, the majority from people interested in, or involved with, complementary therapies. All submissions are being analysed and a report outlining the main issues will be available in early December. A policy paper outlining proposals for the new legislation will be sent to the Minister in mid-December.

The new legislation aims to remove unnecessary requirements for therapeutic goods and to harmonise, where practicable, with the requirements of our major trading partners.

It is likely to include the introduction of a product licensing system for therapeutic goods. Under such a system, a company would receive the right to market a

product for a certain renewable period. A mechanism for a more equitable fee structure, to cover the cost of regulations, would then be possible.

This should bring greater transparency into the marketing of products, particularly those at the food/ medicine interface, an area which has always been blurred. There needs to be a clearer indication of whether an item is being marketed as a medicine or a food.

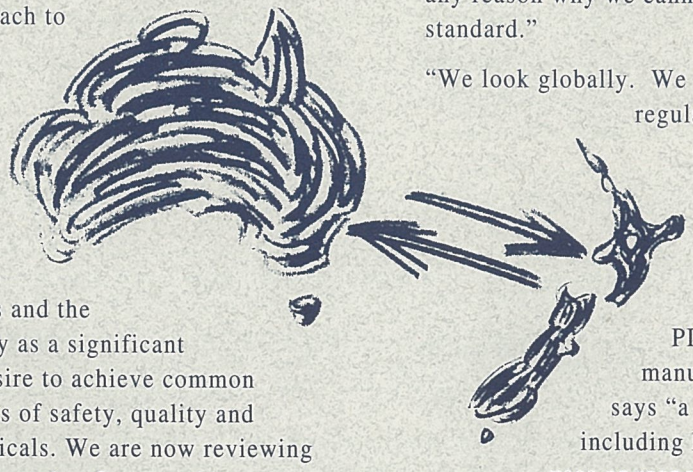
The new legislation is also likely to include strengthened controls for medical devices. At present devices do not have to go through a pre-marketing approval process. Problems that result have been outlined earlier. (See Tinkering with Devices).

Another aim of the review is to remove unnecessary legislative controls which increase costs for the consumer and the Government. The review will, for instance, look at whether prescribing rights for certain items should be extended to groups other than medical practitioners. Midwives are already allowed to prescribe certain drugs for use in childbirth, following the Nurses Amendment Act 1990.

Harmonisation - a marriage of convenience

Harmonisation is the buzz word in pharmaceuticals at present. What it means is that countries should not develop therapeutic regulations in isolation, but should attempt to work in harmony with other countries.

Harmonisations with Australia is particularly important for New Zealand. In recognition of this, New Zealand now has observer status at the National Co-ordinating Committee on Therapeutic Goods. This is a meeting of administrators from the Commonwealth, State and now New Zealand Departments of Health. This committee aims to see that there is an informed, safe and co-ordinated approach to the regulation of therapeutic goods.



The International Conference on Harmonisation (ICH) held in Brussels last November was seen by both drug regulators and the pharmaceutical industry as a significant breakthrough in the desire to achieve common approaches to the issues of safety, quality and efficacy of pharmaceuticals. We are now reviewing the material which is emerging from working groups formed at the first ICH. This will alert us to future initiatives which we should consider as we develop our legislation standards and guidelines.

The WHO is also backing harmonisation and international co-operation in drug regulation. Every two years WHO sponsors an International Conference of Drug Regulatory Authorities. Two main aims of ICDRA are to promote collaboration between medicine control authorities and to reach consensus on matters of mutual interest. New Zealand has been a participant at these meetings since the beginning.

Susan Martindale, who attended the last meeting in Ottawa last year, says: "When you attend conferences like this, you realise that all regulators are basically working towards the same ends - to have safe products available for people. But they are all working by different methods, and often in isolation. So there are a whole lot of different sets of rules."

"Now at last, there is a willingness to say that this should change. Countries shouldn't all be trying to reinvent the wheel, there should be dialogue to try and develop a common approach."

"Now, when we decide we need a particular standard, guideline or code of practice, we see who else has done it, and what they have done. We ask if there is any reason why we cannot simply adopt their standard."

"We look globally. We ask ourselves which of the regulators seem to be most enlightened, and who has produced a document which is most widely accepted."

A recent example is New Zealand's adoption of the PIC code for good manufacturing practice. Susan says "a large chunk of the world", including Britain, Europe and Australia, uses or recognises that code so it is sensible for New Zealand to adopt it as well.

The benefits of harmonisation are obvious. It becomes easier to export products, if our regulations are in line with the importing company, and it is also easier for New Zealand authorities to satisfy themselves about imported products if the same standards have applied to their manufacture.

"Adopting international standards is sensible, it saves money and you are adopting something which has international respect," Susan says.

Removal of medicines from the market

The Therapeutics Section want to hear industry views on a proposal to set up a voluntary notification system for use when a company decides to remove a medicine from the market. There is no requirement for companies to notify the Department if they intend to stop marketing a particular product. But, if a medicine is suddenly unobtainable, this can cause problems for prescribers and panic among consumers. Margaret Ewen, Utilisation Team Leader has put forward the following proposal:

When a company decides to stop marketing a medicine, it notifies the Therapeutics Section. Both sides agree that the removal will not be publicised till a certain agreed date, thus ensuring that prescribers do not suddenly stop using the medicine while it is still available. The Therapeutics Section uses the period up until the agreed date to gather information - either on how to get new supplies of the same medicine, or on satisfactory alternative medicines. Once the deadline is reached, the Department can tell prescribers that the drug is coming off the market, and at the same time, give them comprehensive information about alternatives.

Generic Substitution Project

Graham Leslie is overseeing this project which has three basic parts. First he has to come up with a list of generic products which would be considered safe to substitute for brand-name products. This involves reviewing longer-established generic products on the market, in collaboration with the manufacturers of those products. Second, he has to recommend legislation to introduce generic substitution. (The legislation will allow pharmacists to dispense a generic instead of a brand-name drug prescribed by a doctor, unless the doctor specifically prohibits generic substitution.) Third, Graham has to develop a practical programme, including relevant publicity and educational material, for implementing generic substitution. This will coincide with the introduction of the legislation which is scheduled to go before Parliament next year.

Therapeutics Section Publications

The following publications can be ordered from:

The Executive Officer (Evaluation)
Therapeutics Section, Department of Health,
PO Box 5013, Wellington

1. Code of Good Manufacturing Practice for Manufacture and Distribution of Medicines (includes Related Products).
2. Code of Good Manufacturing Practice for Cosmetics (1982).
3. Guidelines for preparing Data Sheets (1988).
4. Guidelines for compiling applications for contact lens solutions (August 1984, December 1984, March 1985).
5. Guidelines for labelling cosmetic products (1989).
6. Guidelines as to acceptable levels for micro-organisms in cosmetic products (1989).
7. Requirements for labelling medicines and related products (1989).
8. Comparative Pharmacokinetic Guidelines.
9. Draft Guidelines on Aerosol Preparations.
10. Generic Topical Medicines Guidelines.
11. Paracetamol Dosage for OTC Sale, Dispensing Packs, and general use.
12. Fees for Service: Supplementary Information.
13. Notice to Applicants: EC Guide on New Medicine Applications.
14. Draft Guidelines for Herbal Medicines.
15. Guidelines for Categorisation of Products - as either medicines, related products, dietary supplements, or cosmetics.
16. Guidelines for Submission of Proposals to Change the Classification of a Product.
17. Guidelines for GMP Certification Requirements.

In Our Next Issue

- **"Who dunnit?" – inquiries under the Official Information Act**
- **The Utilisation Team – all is revealed**

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