THERAPEUTICS SECTION
Bulletin
DECEMBER 1993
THERAPEUTICS SECTION, MINISTRY OF HEALTH, WELLINGTON, NEW ZEALAND

"Experience Teaches" *Tacitus*

This Bulletin would hardly be a credible publication if it only discussed the Section's outright successes.

Experiencing a battering about sunscreens from the media and others, some of whom should have known better, has been a salutary lesson for each individual staff member.

The message for us has been the same message as applies in any business:

'Keep the objectives clear and simple'.

After embarking upon a project to check the physical quality and the label claims of cosmetics as a contribution to Women's' Suffrage Year we ended up being described as botching a study on unsafe sunscreens.

Clearly, when publishing anything at all about sunscreen effectiveness we should have calculated what use the public would make of the information. After all, our mission is to protect the health of New Zealanders.

When the study was finished we knew that cosmetics overall seemed to be of a much higher quality than the last time they were sampled, but that an unknown proportion of sunscreens on sale last year which claimed to be "broad-spectrum" yet failed to meet the UVA blocking requirements set down in the Australian Standard for a broad-spectrum sunscreen.

That information is not sufficient to help anyone buy wisely. Therefore we erred in publicising it in the way we did. Once the media headlined "unsafe" and "defective" sunscreens (neither of which were our words) the situation was apparently irretrievable.

Did we err in publicising it at all? I don't believe so. We had an obligation to do so. Then, why not release product names from this limited sample of last year's products? We still believe that releasing the information would not help anyone to make an informed choice about what to purchase this year and it would not necessarily relate to the product they already had in their bathroom cupboard.

Has any good come out of all this? Thankfully yes. There is now a well-publicised New Zealand standard for sunscreens, many more people know to seek very high levels of protection from the sun's rays and the Ministry has published a list of recommended products.

We'll never know the long term effect on the incidence of melanoma, but we all hope it will be positive.

Bob Boyd, Manager

INDUSTRY LIAISON GROUP

Back – Left to Right
Mark Rowland, Hugh Baber (Deputy Director-General, Health Regulation and Protection), Bob Boyd, Jeff Douglas (Generic Companies), Michael Byrnes (Proprietary Medicines Federation and Nutritional Foods Association), Brian Ellis (New Zealand Hospital Pharmacists Association), Christopher Moore (Researched Medicines Industry Association), Catherine Marnane, Abdul Mutlib (Health Industry Suppliers Association of New Zealand), Simon Jones (Researched Medicines Industry Association).

Front – Left to Right
Joan Baas, Susan Martindale

(see article "Our People Talk to Your People")

New Therapeutics Staff

HEAD OFFICE, WELLINGTON

AILSA SURMAN

Ailsa joins the Evaluation Team as an advisor. She has a MSc in Pharmacology from Auckland University and her previous work experience has been in community pharmacy and pharmacological research. Ailsa is involved in the 'paper' evaluation of data submitted to the Ministry in support of applications to market new medicines or to make changes to existing medicines.

SHEREE WELLINGTON

Sheree is also joining the Evaluation Team as an advisor. She is a pharmacist and has been managing a pharmacy in Lower Hutt for the past four years. She has previously worked in hospital and community pharmacies both here and overseas. Sheree has a Diploma in Pharmacy and is currently completing a Master of Pharmacy through the Otago University distance learning programme. Sheree, like Ailsa, is involved in the "paper" evaluation of data submitted to the Ministry in support of applications to market new medicines or to make changes to existing medicines.

CONNIE JANES

Connie is an Assistant Support Officer and has recently joined the Compliance Team, where some of her first work has been to process import and export licences for Controlled Drugs, using the new licence forms. Her previous experience includes working in a support capacity at ACC, the Department of Social Welfare and Parliament.

PETER PRATT

Peter joins the Compliance Team as Senior Advisor, Medicine Control. Peter is a pharmacist with over 20 years experience. After working in the Auckland District Office of the Department of Health as a District Advisory Pharmacist, Peter returned to community pharmacy for some time before returning to medicine control activities, firstly with the Area Health Board, and since July 1993 in the Section's Head Office in Wellington. His major task is to co-ordinate the functions of the 16 Medicine Control staff working in the five Regional Licensing Offices around the country.

DEREK FITZGERALD

Derek's area of special interest is pharmaceutical manufacturing. A member of the Compliance Team, Derek works with Christine Deveson in auditing the manufacturing practices of pharmaceutical companies manufacturing within New Zealand. Another area of shared responsibility with Christine is the audit of Blood Transfusion Services. Both sets of audits are carried out using the appropriate Code of Good Manufacturing Practice as a reference. Derek is the officer handling medicine complaints and recalls for the Ministry.

Scottish born, Derek is a pharmacist and has worked in community pharmacies in New Zealand and for hospitals in both Britain and Saudi Arabia. His most recent position before starting at the Ministry was as Production Manager at the Lower Hutt factory of pharmaceutical company Rhone-Poulenc Rorer.

Peter Pratt

Derek Fitzgerald, Ailsa Surman, Sheree Wellington and Connie Janes.

AUCKLAND REGIONAL LICENSING OFFICE

GARY SYME

Gary is a pharmacist with many years of medicine control experience. This has included attending Drugs Advisory Committee meetings at the Ministry. He worked for the Department of Health, then the Auckland Area Health Board, before joining the Ministry of Health in July.

GLENYS RIGGER

After qualifying as a pharmacist Glenys initially worked in a hospital pharmacy. She was then employed by the Department of Health, working in the area of medicine control, before joining the Auckland Area Health Board and more recently the Ministry of Health.

NIKKI ANDERSON

Nikki is also a pharmacist with wide experience. She worked for a number of years in Auckland community pharmacies before joining the Department of Health, the Auckland Area Health Board, and more recently the Ministry of Health, as an advisor in medicine control.

ANNA BRAY

Anna continues her interest in medicines control, having previously worked in the same team as the pharmacists for the Department of Health and the Auckland Area Health Board. Anna is an assistant advisor.

Back Row, Left to Right:
Cecilia Niumagumagu, Anna Bray, Nikki Anderson

Front Row, Left to Right:
Glenys Rigger, Gary Syme

CECILIA NIUMAGUMAGU

Cecilia has a clerical background, having previously worked for the Department of Social Welfare as a senior section clerk. She is now in the Auckland office and enjoying her new role as assistant advisor.

HAMILTON REGIONAL LICENSING OFFICE

TED LEIGH

Ted has many years experience as a community pharmacist. Before joining the Ministry he was a medicine control advisor in the Waikato Area Health Board. Ted, along with Philippa, works from the Hamilton Regional Licensing Office.

PHILIPPA DRIVER

Philippa brings a wealth of experience from working for the Waikato Area Health Board to her present position as assistant advisor in medicine control.

Philippa Driver and Ted Leigh

Therapeutics Section Staff List

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Rosemary Cooney	Executive Assistant	(04) 496-2262

Business Support Unit

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Tania Paull	Support Officer	(04) 496-2136

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Marilyn Anderson	Special Projects	(04) 496-2234
Rosemary Thompson	Database Project	(04) 496-2098

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HEAD OFFICE, WELLINGTON

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Carol Smith	Secretary MCC	(04) 496-2096
David Stevens	New Medicine Applications	(04) 496-2093
Gary Twinn	Changed Medicine Notifications, Clinical Trials	(04) 496-2038

AUCKLAND REGIONAL LICENSING OFFICE

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Malene Hook	Secretary	

CHRISTCHURCH REGIONAL LICENSING OFFICE

Isobel Smith	Visiting Advisor	Phone (03) 366-7394
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Compliance Team

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Nikki Anderson	Medicine Control Advisor	
Anna Bray	Assistant Advisor	
Cecilia Niumagumagu	Assistant Advisor	
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Melissa Young	Medicine Control Advisor	
Rachael Trudgeon	Assistant Advisor	
Anne Cherry	Assistant Advisor	
CHRISTCHURCH REGIONAL LICENSING OFFICE		
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Nicky Harris	Assistant Advisor	Fax (03) 366-1156
DUNEDIN REGIONAL LICENSING OFFICE		
Denise Martin	Medicine Control Advisor	Phone (03) 479-2561
Jeanine Benson	Assistant Advisor	Fax (03) 477-6368

WELLINGTON REGIONAL LICENSING OFFICE

DOUG LONGMIRE

Doug is a pharmacist with many years experience in community pharmacy and medicine control activities. He comes to the Ministry from the Wellington Area Health Board. Doug, along with Lawrence, Melissa, Rachael and Anne, works from the Wellington Regional Licensing Office.

LAWRENCE YOUNG

After graduating as a pharmacist, Lawrence worked in a number of community pharmacies in the Wellington region. He then joined the Wellington Area Health Board, and more recently the Ministry of Health, as a medicine control advisor.

MELISSA YOUNG

Melissa has a B.Pharm (Hons) and a Masters in Clinical Pharmacy. She joined the Ministry in 1993 with a varied background in community, hospital and industrial pharmacy. Her experience will be valuable as a medicine control advisor in the Wellington office. Melissa and Lawrence, in answer to a frequent question, say that, "no they are not related".

RACHAEL TRUDGEON

Rachael has inside knowledge, having previously worked in the Compliance team at head office. She enjoys her new position as assistant advisor and the challenges of medicine control.

ANNE CHERRY

Anne joined the Ministry in 1993 after many years in community and hospital pharmacies in the Wellington region as a senior pharmacy technician. Anne likes her new position as assistant advisor and sees her role as an extension of her pharmacy background.

Left to Right:
Doug Longmire, Lawrence Young, Anne Cherry, Rachael Trudgeon, Melissa Young

CHRISTCHURCH REGIONAL LICENSING OFFICE

SHELDON RAMER

Many people will remember Sheldon working as a medicine control advisor in the Auckland region. He originally worked for the Department of Health, then the Auckland Area Health Board and now the Ministry of Health. He is a pharmacist with a Masters in Public Health. The move to Christchurch has been a fresh challenge.

NICKY HARRIS

Nicky comes to us from the Christchurch Area Health Board and is happy continuing her medicine control activities as an assistant advisor for the Ministry. Nicky, along with Sheldon, works from the Christchurch Regional Licensing Office.

Nicky Harris and Sheldon Ramer

DUNEDIN REGIONAL LICENSING OFFICE

DENISE MARTIN

Denise is a familiar face to the pharmaceutical industry in the South Island, having worked as a medicine control advisor for the Otago Area Health Board prior to joining the Ministry of Health. Denise is a pharmacist and has also worked in community pharmacy in the Otago region. Denise and Jeanine work from the Dunedin Regional Licensing Office.

JEANINE BENSON

Jeanine is an Otago University graduate new to the position of assistant advisor, medicine control, but enjoying the challenge. She is also a qualified dispensary technician.

Jeanine Benson and Denise Martin

Therapeutics Update

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

Data Sheets On the Move

Ever wondered what happens to the 30 approved copies of the data sheets that a manufacturer or distributor has to send to the Ministry? Do you picture them being neglected and mouldering interminably in dusty basements?

Not so! The Ministry undertakes to distribute all approved data sheets within 90 days of their receipt. Even our existing database is designed to track the approval process from the time a draft is first received. Beware those who fail to send in the 30 approved copies within a reasonable time! Defaulters will be likely to hear from Support Officer Carol Smith in one of her six monthly follow-ups.

Where there was once a backlog in the area of data sheet evaluation, this is becoming a thing of the past. The clearing process is picking up speed and with two new evaluators recently added to the Evaluation Team we hope to make even better progress. The evaluation of a data sheet can take up to a whole day of an individual evaluator's time. During the second part of this year we have been distributing about 30 approved data sheets a month.

At regular intervals piles of data sheets are laid out on every available surface and arranged in order ready to be put into ring binders for distribution. This explains the need for uniform size, margin width and, above all from the distributor's point of view, the need for them to be hole punched ready to insert into the binders.

The most important reason for having an approved data sheet is so that there is an agreed reference point for the information being used to promote medicines. Therefore the Ministry would like to think that all distributors maintained copies of their data sheets to hand out to prescribers as needed. Distribution of the Ministry's supply is really only a secondary, but important, function.

And what is their ultimate destination? The Ministry has tried to place copies of approved data sheets where they will be the most useful. With a more effective computer system we envisage holding an electronic copy of the most recent approved data sheet of every product, readily accessible to anyone. Meanwhile, here are some of the destinations for which your data sheets are bound:

- Visiting professional advisors in Auckland and Christchurch;
- Drug information centres;
- Pharmacy Guild and the Pharmaceutical Society;
- National Preferred Medicines Centre;
- Pharmac;
- Health Benefits Centre, Wanganui;
- Centre for Adverse Reactions Monitoring;
- Medical and Pharmacy School libraries;
- NZ Medical Journal and Adis International; and
- Pharmaceutical computing companies.

~~Letter of the Law~~ Law of the Letter

A new New Zealand standard for condoms superseding NZS/BS 3704:1979, has recently been given the rubber stamp. It is the ISO standard 4074 with some additional New Zealand specific requirements.

The Ministry has requested all manufacturers or distributors of condoms to have each batch entering the country tested against the Standard before they are put on the market. Testing is currently carried out by the Wellington Science Centre at Gracefield.

Consumers can expect that the condoms they purchase in New Zealand - provided they are not novelty items - have been tested. The Customs Department provides the Ministry of Health with lists of condom imports which allows ready identification of new untested batches.

"The new Standard does not require any statement to be printed on the containers to the effect that the product meets the NZ standard," explains Trevor Nisbet of the Compliance Team. "This is in line with international practice and eliminates the need for importers to re-package especially for the New Zealand market." However, compliance with the Standard is mandatory under the Contraception, Sterilisation and Abortion Act, so no condoms should be on sale unless they fully comply.

SWEDIS - Sektionen Utvärderar Mjukvara

We know about Swedish Volvos and Saabs, Swedish massage and even Swedish Bitters, now it's Swedis software...

Susan Martindale and Dean Martin (Manager of the Ministry's Database & Systems Management) travelled to Sweden in October to evaluate the Swedis information system, a software programme which is being considered for use by Therapeutics Section.

Therapeutics Manager Bob Boyd, who was in Europe attending a conference, joined the Ministry team to see the system running in the Swedish Medical Products Agency, the Ministry of Welfare, Health and Cultural Affairs in the Netherlands and the World Health Organisation Collaborative Reporting Centre for Adverse Reactions (WHO ADR).

Swedis was originally developed in the 1970's by the Swedish Medical Products Agency in collaboration with the local University Computer Centre. It is now available through a private company (Pharmasoft Swedis AB) and has been installed by a number of regulatory agencies, e.g. Canada, Sweden, Norway, Netherlands, Switzerland, Ireland, and also by a number of developing countries. The company is also working with pharmaceutical manufacturers to develop computer applications which make use of its technology.

Susan Martindale, project leader, says that "the Swedis system is suitable for New Zealand use as it is compatible with the Ministry's Windows system, has a relational database, and uses international standards such as SQL and Edifact."

Therapeutics Section has identified that it needs a system that will:

- capture information about medicines and medical devices;
- record the Section's administrative processes and provide a tracking system for the processing of applications;
- generate business reports;
- produce up to date product information from the Section's files;
- create efficiency.

We expect the system to be accessible to the Section's clients so that they can check what stage of evaluation their products have reached, and view a bulletin board containing news of Therapeutics happenings and Therapeutics services.

"Individual company confidentiality will be built-in," says Susan. "We have consulted widely and are certain that we can control the access so that, for instance, the system can provide an approved updated data sheet for any enquiries, while keeping applications for a new formulation totally protected."

Full evaluation of the Swedis system, including a cost-benefit analysis, will be completed by the end of January 1994.

Dean Martin (Manager of the Ministry's Database & Systems Management), Susan Martindale and Bob Boyd arriving at Pharmasoft Swedis AB in Uppsala, Sweden, October 1993.

Avoiding International Isolation - The New Zealand Approach

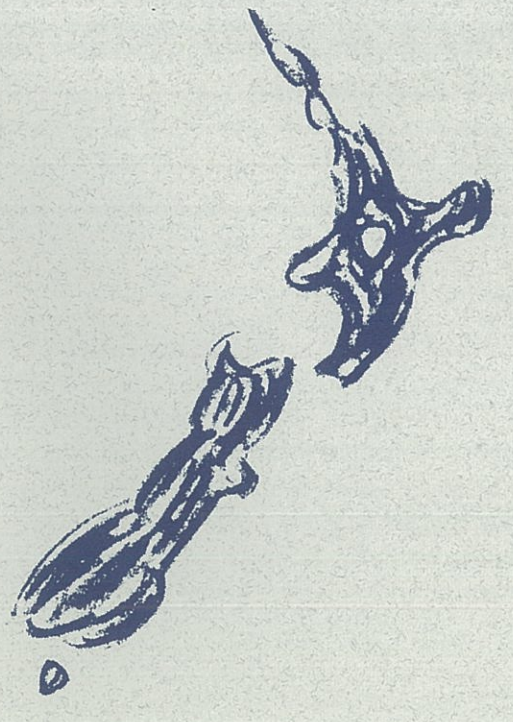
This was the title of a presentation Section Manager Bob Boyd gave at the Drug Information Association's (DIA) EuroMeeting '93 held in London during October. The DIA provides a world-wide forum for exchanging knowledge and information on the discovery, development, evaluation and utilisation of medicines and related healthcare technologies.

Although it was a European meeting, the proceedings were overshadowed by predictions about the impact on the pharmaceutical industry of price-reduction measures promoted in the US by Hilary Rodhan Clinton, and in Japan. Together, those two countries represent 70% of the world pharmaceutical market which explains the air of gloom when analysts were predicting a halving in US drug spending.

Therefore it was no surprise to find that the emphasis of so many speakers was on doing things smarter; reducing drug development times; and making the same data work for you in several different ways.

Other speakers made the same points about regulatory agencies also. Faced with having to do more with the same resources, there are numerous attempts being made to harmonise regulations amongst countries and make one marketing submission suit many markets.

Trade blocs are having an increasing influence on pharmaceutical supplies and Bob used his talk to put forward the case for the smaller countries, which are excluded from many of the harmonisation agreements, and consequently become less able to influence the quality of the products they are being offered.



It was heartening to receive, from an audience comprised mainly of pharmaceutical company executives, overwhelming support for maintaining a local New Zealand regulatory capability with trans-national links, rather than depending solely upon overseas decision makers.

The Ministry appreciates the opportunity provided by the DIA to have one of its senior officers attend the EuroMeeting.

New Code for Pharmacists

The new code of practice for Dispensing and Compounding has now been published and distributed. Officially it is Part 3 of the New Zealand Code of Good Manufacturing Practice (GMP) for Manufacture and Distribution of Therapeutic Goods.

The Code was developed in close consultation with the pharmacists' professional and commercial bodies. As well as applying to the preparation of a medicine for an individual patient, the Code also covers preparation or repacking of medicines in small scale batches, as would occur in a pharmacy. The actual sizes of the batches are specified in the Code's introductory chapter. They are designed to allow continuation of the traditional pharmacy function of compounding, where a pharmacist uses his or her professional knowledge and skills to meet the needs of the local prescribers.

The contents of the Code follow the outline of the Code of GMP for commercial size manufacture but have been adapted to the circumstances of a dispensary without compromising the quality of the end product.

Although most pharmacists will be familiar with what is required to achieve good compounding and dispensing practices, the Ministry's Medicine Control Advisors will be visiting community and hospital pharmacies around the country to introduce the concepts behind the Code and clarify any issues if necessary.

Audits to the Code are planned to take place over the next financial year and the Ministry will continue to liaise with the Pharmaceutical Society and Pharmacy Guild as work progresses.

Spreading The Word

The Therapeutics Section is continually working at raising its profile amongst its client groups. This year the Section joined many companies from the pharmaceutical industry in staffing a display stand at the annual conferences of the New Zealand Hospital Pharmacists Association and the Royal New Zealand College of GPs.

Margaret Ewen, who co-ordinates the Section's promotional activities, says their presence was appreciated by both the doctors and the pharmacists. She says the other exhibitors also took an interest in the 'new kids on the block' and offered much useful advice on how to snare the passing conference attendee.

Interestingly, one of the more popular attention-catchers on the Therapeutics Section stand proved to be silicone breast implants. Margaret says the implants proved a real hit. Many doctors had never seen them unimplanted before and along with everyone else they were fascinated by them. She says it is a bit like the claims made about the Listener; once picked up they are very hard to put down.

Another useful activity has been the involvement of Therapeutics Section staff in the education of pharmacy and medical students. Staff from the Section have given presentations to medical and pharmacy students at Otago and Auckland universities, meeting the challenge of explaining the role of the Section in only an hour or so.

We look forward to including the Clinical Schools of Medicine at both Christchurch and Wellington in the programme next year.

Stewart Jessamine, Margaret Ewen and Isobel Smith promoting the Therapeutics Section at the Annual Conference of the Royal New Zealand College of GPs, Dunedin, June 1993.

Medicine Control - New Focus, New Offices, But Familiar Faces

From July the Ministry became responsible for medicine control activities. Peter Pratt, Senior Advisor and co-ordinator of medicine control activities, says the shift of regulation of medicines from the Area Health Boards to the Ministry has gone smoothly. Nine advisors and seven assistant advisors have been appointed and are located in the newly formed Regional Licensing Offices in Auckland, Hamilton, Wellington, Christchurch and Dunedin (see new staff profiles and photographs).

The main focus will be surveillance, safety and breaches of the Medicines Act and Misuse of Drugs Act. The areas covered are:

- Monitoring for compliance with the requirements of the Medicines Act and the Misuse of Drugs Act and assisting in implementing disciplinary procedures and prosecutions for breaches.
- Inspecting, interviewing and reporting on the suitability of applicants for licences under the Medicines Act (wholesalers, packers and hawkers of medicines) and the Misuse of Drugs Act (dealers in controlled drugs).
- Auditing community and hospital pharmacies for compliance with standards of practice for compounding and dispensing.
- Assisting when requested in licensing of hospitals and old people's homes in relation to their medicines acquisition, storage and administration.
- Surveillance of controlled drug and abusable medicine prescribing and preparing Restriction Orders.
- Issuing and recording controlled drug prescription pads and supply orders.

"The medicine control staff are certainly kept busy," says Peter. "Nearly half of the community pharmacies in New Zealand have had a pre-audit visit to explain the new Code for Compounding and Dispensing. Also, nearly 200 licenses have been issued under the Medicines Act since July."

Peter also explained that it has been a mammoth task collating the licensing information previously held by Area Health Boards. Each Regional Licensing Office spans several Area Health Board territories and in some cases this has involved collating information from three different filing systems from separate districts within one Board. "Thankfully," says Peter, "the databases are now all near completion and we can now be more efficient and more helpful when we receive an enquiry about licenses."

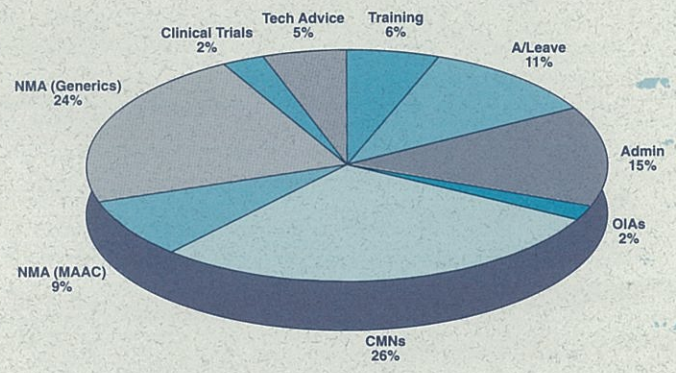
Our People Talk to Your People

The Industry Liaison Group meetings are continuing to prove valuable. The Therapeutics Section has just hosted its third Industry Liaison Group meeting. The all day meetings are held every six months and include representatives from most of the Therapeutics Section's clients. Manager Bob Boyd says the meetings act as a valuable forum for 'testing the water' on various issues the Section is dealing with that have implications for clients. "They give the industry a chance to provide feedback on our performance, while also giving us the opportunity to show the industry how we spend the revenue collected from fees," says Bob.

At the last meeting the Liaison Group was given an update on Swedis, the information system the Ministry is currently evaluating and which will eventually give industry access to information about products regulated by the Ministry (see separate article).

One of the items of information presented to the meeting which may have wider interest was a breakdown of the salaried hours of the Evaluation Team.

EVALUATION TEAM TIME ON ACTIVITIES



Key

A/Leave:	Annual leave
OIA:	Official Information Act requests
CMN:	Changed medicine notifications
NMA (MAAC):	New medicine applications (Medicines Assessment Advisory Committee)
NMA (Generic):	New medicine applications for generic medicines.

Informing the Public

Empowering consumers to make informed decisions about their health care - that's what 'CPI' is all about, and no, it's nothing to do with the price index. It's about Consumer Product Information - providing simple, concise information to the consumer which will improve patient understanding about the proper use of their medicine.

Australia has already moved down this path and the results of several studies and trials on CPI are expected by March, 1994. The New Zealand project will shadow the Australian experience for the most part, with one significant exception: industry, pharmacy and consumer consultation will be sought before seeking legislative changes.

Although still at the information collection stage, consultation has already started with the Industry Liaison Group, the Researched Medicines Industry and the Proprietary Medicines Federation. It has been reassuring to find that the industry is already carrying out its own preparatory work on CPIs in New Zealand. The project team is consulting offshore as well. Margaret Ewen recently attended a meeting hosted by the Proprietary Medicines Association of Australia, where various CPI issues were discussed. Stewart Jessamine is focusing on the European pharmaceutical industry response to the 92/27 EEC Directive on labels and package inserts.

Once the information has been collated, a draft Code for preparing and providing Consumer Information on Medicines will be drawn up and distributed for comment by May of next year.

Industry and pharmacy input will be vital in developing the final version of the Code. The Industry Liaison Group has been asked to assist in identifying members for a working party which will be looking at not only the content, but also such things as language, ownership, format, updating, assessment and delivery of CPI.

Although the consultation process parallels discussions on the proposed changes to the Medicines Act, CPI is clearly an independent project which addresses the need to allow patients a more informed role in their own medical management.

"Top Security"

Child resistant closures have now got a higher profile following a recent campaign run by the Therapeutics Section to promote their use.

The project had two areas of focus. The first was to promote the use of child resistant closures (CRCs) amongst care givers of young children. The second was to establish that a suitable range of closures is available for care givers to purchase.

A magazine campaign began in August and continued for two months. The campaign consisted of full page colour advertisements alternating with factual articles. We received many congratulatory comments on the ad - the look of frustration on the face of the child reflected well the difficulty they have in opening bottles fitted with CRCs!

To complement the advertising campaign, GPs, pharmacies and Plunket clinics were sent posters and pamphlets. The Ministry asked these groups to get behind the campaign by displaying the material and promoting the use of CRCs.

To help the process along, pharmacies were given a 'starter kit' containing an assortment of different sized containers and CRCs, and information about how stocks could be re-ordered. The Plunket Society was also given samples so nurses, too, could demonstrate their use. Margaret Ewen says these demonstrations have gone a long way towards debunking the myth that CRCs are difficult to use.

Herbal Medicines

The use, wherever possible, of traditional or herbal remedies has the support of the World Health Organisation. In light of this, Khay Ooi, Advisor in the Evaluation Team, has been working on draft guidelines on preparing an application for marketing consent for a herbal medicine under the Medicines Act.

Now Khay's first draft is completed, it has been sent to Australia's Therapeutic Goods Administration (TGA) for comment, before being released for consultation in New Zealand. The Guidelines will then join the other documents in the "Therapeutic Guidelines" series which are explanatory notes referenced to the Section's Medicines Distribution Guide.

As part of the promotion of common trans-Tasman standards for therapeutic products, the TGA and Therapeutics Section regularly share their draft rules and guidelines for comment before they are finally published.

"It is important to realise that these draft guidelines cannot take precedence over the legislation," says Khay. "The Medicines Act remains the definitive document, but guidelines are useful for indicating to importers and agents what they should be doing to meet the requirements of the Act."

"I hope we can help the industry to meet an adequate standard which will protect the consumer and provide a degree of assurance for the companies involved," says Khay.

In August 1993, Khay took a couple of days out of his holiday trip back to see his family to visit the Ministries of Health in Singapore and Malaysia. Malaysia, he found, has embarked on a project to license all herbal medicines by the end of 1995. There is a staggering number of herbal products marketed in that country and Khay intends to keep in contact and follow the project with interest.

Goodbye Abdul

Abdul Mutlib's strong level of technical expertise and professionalism will be missed in Therapeutics. Abdul recently resigned from his position as Advisor (Science) to take up an appointment with Abbott Laboratories as Manager, Regulatory Affairs. Abdul worked in Therapeutics for almost two years, and during this time worked extremely hard in the areas of bioequivalence and generic medicines. We wish him every success in his new role and were pleased to be able to welcome him back in the Ministry building when he attended our Liaison Group meeting, representing the Health Industry Supply Association.

Recycling

Several schools in and around Wellington were delighted to receive a welcome donation of hard cover ring-bind folders from the Therapeutics Section recently.

Pharmaceutical companies who make applications for a new or changed medicine can use up to thirty of these folders per application. These were being emptied of their contents and then stored in the Ministry's basement ready for dumping.

Khay Ooi saw the stockpile growing to literally thousands over the past year, so he voluntarily organised the distribution to various local schools, after firstly ensuring that there was nothing of a confidential nature accompanying the folders.

Blood Manufacturing Under the Microscope

Audits of the 23 blood transfusion centres around the country were completed on schedule by the end of June. The audit was to the Code of Good Manufacturing Practice (GMP) for Therapeutic Goods, Part 2, which specifically relates to blood and blood products. All centres are now licensed under the Medicines Act to manufacture blood and blood products* - quite a new experience for the blood transfusion service.

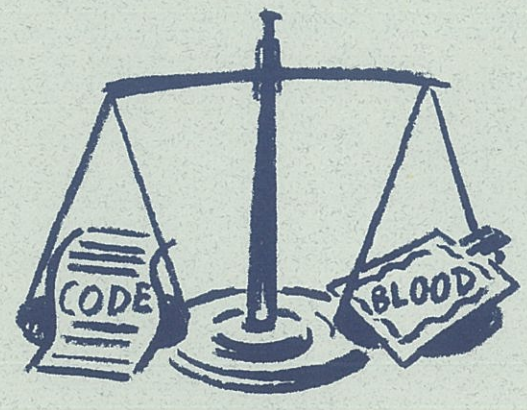
Compliance Team Advisor Christine Deveson, who was part of the audit team, says the response was positive and believes the half-day seminar held with the blood transfusion service prior to the audit was very effective in establishing the groundwork and easing the way for a successful audit.

Although blood auditing is a new area for the Section, Christine says the quality systems already in place for the manufacture of medicines are also applicable to the manufacture of blood and blood products. She was also very appreciative of the work put in by directors and staff of blood transfusion services during the consultation process which led up to the publication of the Code.

Additional information on some of the more unique technical aspects was gained from a visit to Australia and the blood audit programme there. "The Therapeutic Goods Administration (TGA) Blood Auditor was extremely helpful," says Christine. "That experience was vital in establishing procedures for our own programme."

Because it is a new programme, follow-up audits will be carried out in January/February 1994 to ensure that the quality systems implemented are effective.

* Under the Medicines Act (1981), blood and blood products are considered medicines.



Specification & Test Method Update to British Pharmacopoeia 1993

The new (1993) edition of the British Pharmacopoeia has been published and is available in this country. The Medicines Act refers to the British Pharmacopoeia as one of the 'Specified Publications'.

Where the data about medicines or related products refers to British Pharmacopoeia specifications and test methods, these are regarded as the specifications and test methods of the current edition of British Pharmacopoeia.

The Ministry proposes that 1 June 1994 shall be the date by which all British Pharmacopoeia product specifications and test methods must comply with the 1993 edition of the British Pharmacopoeia.

All notifications of changes to product specifications and/or test methods which are being introduced purely to comply with compendial updates will be automatically granted a full waiver of the Ministry's application fee. Any additional changes included in the same notification which are not directly consequential to the Pharmacopoeial update will attract the usual fee.

A Good Read

Short of something good to read over Christmas? Look no further. The Ministry has updated the Medicines Distribution Guide so that it now reflects current practices. This booklet provides a plain English guide to medicine control legislation in New Zealand. It is essential reading for anyone applying to market or manufacture medicines in New Zealand, and also for those conducting clinical trials of pharmaceuticals. To optimise the value of the guide it should be read in conjunction with the relevant legislation. Copies of the Medicines Distribution Guide are now available from the Ministry of Health (see page 15 for ordering details).

Therapeutics Section Publications

The following publications can be ordered from:

The Executive Officer (Evaluation)
Therapeutics Section, Ministry of Health,
PO Box 5013, Wellington, New Zealand.

1. New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods – Part 1 – Manufacture of Pharmaceutical Products ($16 including GST).
2. New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods – Part 2 – Manufacture of Blood and Blood Products ($16 including GST).
3. New Zealand Code of Good Manufacturing Practice for Manufacture and distribution of Therapeutics Goods – Part 3 – Compounding and Dispensing.
4. Code of Good Manufacturing Practice for Cosmetics (1982).
5. Guidelines for Preparing Data Sheets (Jul 1987, Sept 1987, Oct 1987, Feb 1989).
6. Guidelines for Compiling Applications for Contact Lens Solutions (Oct 1988).
7. Guidelines for Labelling Cosmetic Products (1990).
8. Guidelines as to Acceptable Levels for Micro-organisms in Cosmetic Products (1989).
9. Guide to Requirements for Labelling Medicines and Related Products (1989).
10. Comparative Pharmacokinetic Guidelines.
11. Draft Guidelines on Aerosol Preparations.
12. Generic Topical Medicines Guidelines.
13. Paracetamol Dosage for OTC Sale, Dispensing Packs, and General Use (1992).
14. Fees for Service: Supplementary Information.
15. Notice to Applicants: EC Guide on New Medicine Applications ($20 including GST).
16. Guidelines for Classification of Products - as either Medicines, Related Products, Dietary Supplements, or Cosmetics.
17. Guidelines for Submission of Proposals to Change the Classification of a Product.
18. Guidelines for GMP Certification Requirements.
19. Medicine Distribution Guide (Dec 1993).
20. Guidance Notes for Evaluation ($50 +GST)

In Our Next Issue

- **Consumer Product Information: its time has come.**
- **Medicines Legislation Review: will it be all the better for the delay?**

Bob McBoyd models latest fashion in corporate uniforms – Therapeutics tartan with wombat sporran (in the interests of harmonisation)?

As seen at a recent Scottish theme happy hour

Therapeutics Section Bulletin is published by the Therapeutics Section of the Ministry of Health, PO Box 5013, Wellington, New Zealand.

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