THERAPEUTICS SECTION Bulletin

NOVEMBER 1996

THERAPEUTICS SECTION, MINISTRY OF HEALTH, WELLINGTON, NEW ZEALAND

Building Bridges

In a previous Therapeutics Section Bulletin a lead article looked at Transnational Dynamics and developments between New Zealand and Australia as well as Europe. As the Trans Tasman Mutual Recognition Agreement came into effect in July it is timely to provide an update.

New Zealand and Australia have always had close links both formally and informally and the therapeutic products area is no exception.

STOP PRESS

Therapeutics Section is Up, Up and Away

We've moved. The head office of the Therapeutics Section, and the Wellington Regional Medicine Control Advisors, is now located on the 18th and 19th floors of the Grand Plimmer Tower, 2-6 Gilmer Terrace, Wellington. The postal address remains as PO Box 5013, Wellington however freight should be sent to our street address. Email addresses and telephone numbers have not changed (phone 04 496 2000 or direct numbers). Our new fax number is 04 496 2229.

All visitors and meeting attendees must report to the reception desk on the 18th floor. The Manager, Business Development and Support Team and the Wellington Regional Medicine Control Advisors are on the 18th floor. Evaluation and Compliance Teams are on the 19th floor. Expect to see some fit Therapeutics Section staff in the future - there will be a lot more stair-climbing than in the Ministry building.

New Zealand has membership on several committees, observer status on others, as well as participation in joint committees developing standards through the Standards Australia / Standards New Zealand system. These links were further strengthened when a Memorandum of Understanding was signed between the Ministry of Health and the Australian Therapeutic Goods Administration (TGA) in 1993.

During 1995 industry views were sought on the Trans Tasman Mutual Recognition Agreement (TTMRA) and its applicability to the therapeutics sector. Industry told us that it did not support a harmonisation of regulation between New Zealand and Australia if it meant New Zealand had to pick up the Australian system.

What has changed since then?

The TTMRA came into effect in July 1996 and under its umbrella New Zealand and Australia are to operate under an 'Official Co-operation' programme. This recognises the complex nature of the regulatory requirements for therapeutic products in both countries. It is for this reason that therapeutic products have been given a special exemption from the Arrangement and are the subject of a co-operation programme. The programme is designed to permit officials to continue dialogue on how best to achieve the aims of the TTMRA and to decide whether the final outcome should be permanent exemption, mutual recognition or harmonisation for that sector.

As part of that process, discussions and sharing of information have occurred between New Zealand and Australia. It is pleasing and refreshing to note that Terry Slater, the new National Manager of TGA, has demonstrated a positive attitude to co-operation with New Zealand. Terry previously managed the Australian National Food Authority and was involved with negotiating the Treaty signed between the Governments of both countries to set up a joint food standards setting system. I was also involved from the New Zealand perspective.

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What has happened in the food area?

The food area is unique. For the first time one organisation will be responsible for recommending standards that have the force of law in two jurisdictions. This is unprecedented in New Zealand, Australia or the wider Pacific. In the food area the industry played an important role in seeing the benefits of a single system for food standards. Mind you, the value of Trans Tasman food exports is close to $1 billion! Although the new system will break down barriers and free up trade it will also make certain that the protection of public health is the highest priority - food safety is of utmost importance. Food is a forerunner in the harmonisation area and may show other sectors the benefits of a closer alignment with Australia.

What might the benefits be in the therapeutics area?

- reducing compliance costs for industry through efficiency gains, reduced fees and shorter approval times;
- lowering product prices through reduced compliance costs for industry;
- improving the quality of regulation through sharing technical knowledge and expertise across a range of specialist areas;
- demonstrating a leadership role in the region for the development of common standards for the South East Asia and APEC regions.

These are some of the more obvious potential benefits and there are likely to be others. What is clear though, is that there are strengths and weaknesses in **both** systems and co-operation and closer alignment should result in a unity of strengths and a minimisation of the weaknesses. What is also clear is that a change to legislation in both countries would be necessary to achieve the full benefits.

Closer alignments of regulatory requirements are occurring globally, the most obvious example being Europe. New Zealand is now a member of the Pharmaceutical Evaluation Reports (PER) Scheme which gives New Zealand access to a much wider pool of expertise and evaluation reports from other member countries once products have been approved. As we are in the business of risk management, access to information is of crucial importance. Sharing expertise as well as maintaining standards is likely to benefit the community as a whole.

Clare Van der Lem
Acting Manager

New Therapeutics Staff

CLARE VAN DER LEM

Clare comes to the Therapeutics Section as Acting Manager on secondment until the end of November from her position as Manager of Food and Nutrition in the Ministry of Health. She finds work in Therapeutics not unfamiliar having previously worked in the old Clinical Services Division and then Medicines and Benefits Section of the then Department of Health. She had previously worked on the first review of the Pharmacy Act. Clare holds a Batchelor of Arts from the University of Otago and a Diploma in Business Administration from Victoria University. Most of her career has been in Health with sojourns as Secretary of the Mt Cook National Park Board and a spell in the management services area of the State Services Commission.

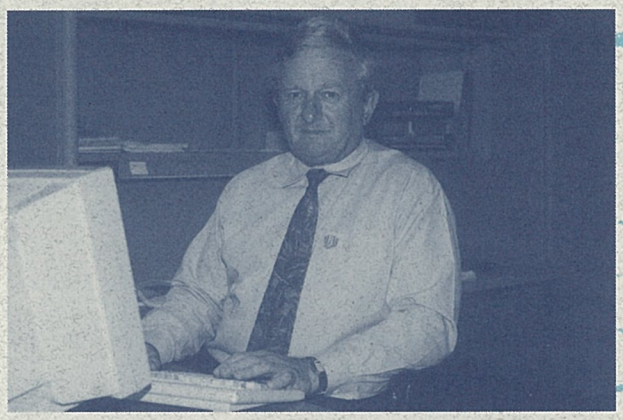
Last year Clare was awarded a World Health Organisation Fellowship and spent four weeks in Europe looking at comparable food systems in the Netherlands, Sweden and the United Kingdom. She returned with an appreciation for just how well a small country such as New Zealand does.

One achievement that Clare takes pride in was leading the team that successfully negotiated an international treaty (with Australia) to set up a joint food standards setting system for New Zealand. This is a first for New Zealand as it is the first such agreement that will have the force of law in both countries.

Clare Van der Lem

DAVID BUCKLE

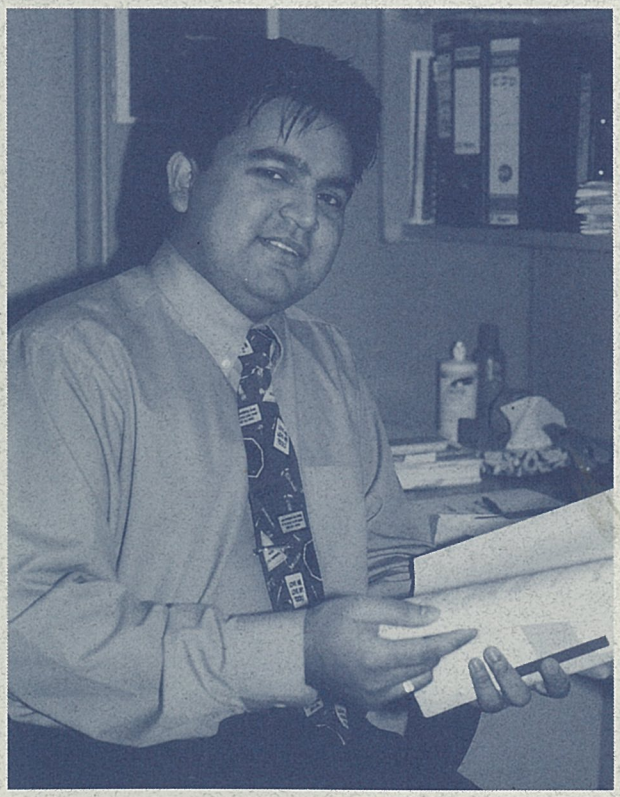
David began work as an Analyst for the Special Projects Team in January 1996. He was initially employed to work with the legislation project team to draft Regulations and Rules for the Therapeutic Products Bill. He is currently working on other projects. David comes to the Ministry with a vast knowledge of the pharmacy sector having been the Chief Executive Officer of the Pharmaceutical Society of New Zealand for six years. Prior to working at the Society David owned a community pharmacy for 30 years in Auckland.



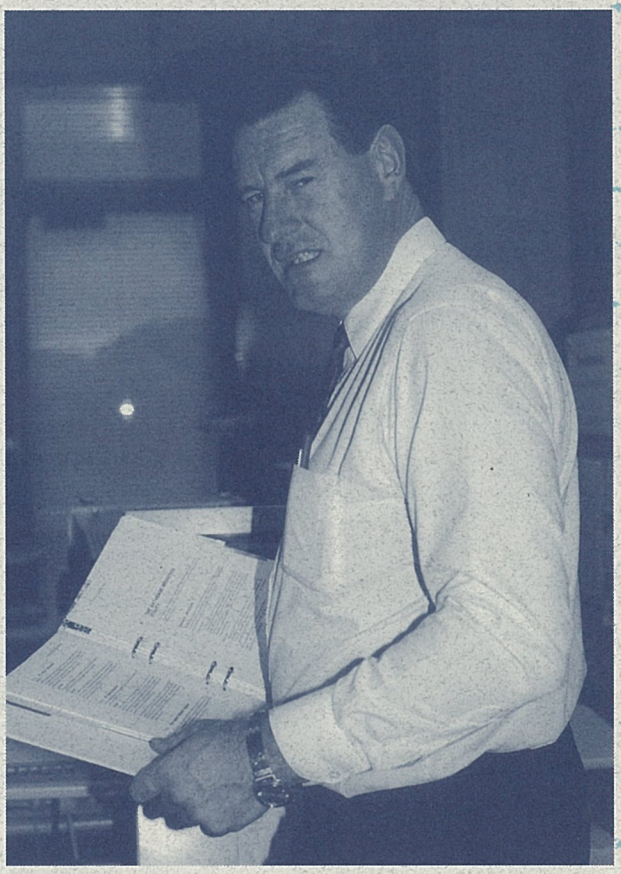
David Buckle

FELIX RAM

Felix joined the Therapeutics Section's Evaluation Team earlier this year as an Advisor. He holds the degree of Master of Pharmacology and a post-graduate Diploma in Public Health from the University of Otago. While in Dunedin Felix worked part time as a community asthma field educator, a poisons information officer for the National Poisons Information Centre and as a clinical research associate involved in bioavailability trials. At the University of Otago he lectured in pharmacology for a number of years and in 1994 also became a senior tutor in pharmaceutical analysis at the School of Pharmacy. Felix's bioavailability knowledge will be advantageous in his role as secretary to the Generics Sub-Committee of the Medicines Assessment Advisory Committee (MAAC).



Felix Ram



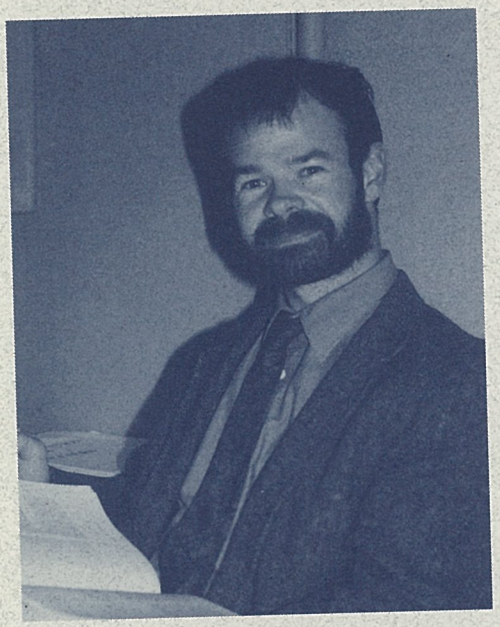
Paul Richards

PAUL RICHARDS

Paul has moved from the Database and Systems Management Section of the Ministry to work as the Therapeutics Section systems administrator. As a member of the Business Development and Support Team he is responsible for the administration and management of REGULATOR, the Section's new computerised information system. Paul has an extensive computing background that started with work as a programmer on Taranaki's first computer and has included being the data processing/information systems manager for several organisations. He has run his own computer bureau and was involved in setting up computer systems for a number of small businesses.

KEITH HOLMES

After three years of living in the United States, Keith returned to New Zealand and in January joined the Evaluation Team as an Advisor assessing medicines. He hails from the deep south where he attended the University of Otago. He gained a PhD specialising in pharmacology and neurophysiology before undertaking a post-doctorate fellowship at the Medical Branch of the University of Texas in Galveston. As well as conducting research, he lectured post-graduate medical and pharmacy students in pharmacology. Keith became secretary of the MAAC at the beginning of August.



Keith Holmes

SHEREE WELLINGTON

Sheree has returned to the Ministry of Health after seven months of travelling. She has joined the Business Development and Support Team as an Analyst. In her new position she will be able to utilise the research skills she developed while completing her Master of Clinical Pharmacy from the University of Otago last year.

Juliet Herrick (left) and Cheryl Palmer

ANDROULLA KOTROTOS

Androulla has joined the Therapeutics Section as an Advisor, Medicine Control based in the Wellington Regional Licensing Office. She graduated with a Diploma of Pharmacy from the Central Institute of Technology in 1991. Since then she has been working in community pharmacy. The pharmacy she worked in had a special interest in contract dispensing and rest home care. Androulla is currently undertaking the New Zealand Nutritional Foundation's Nutrition Course for Pharmacists.

Androulla Kotrotos

CHERYL PALMER

Cheryl is an Assistant Advisor, Medicine Control at the Auckland Regional Licensing Office. She comes to this position with experience in a variety of roles in the public and private health sectors. She started her career with the Department of Health in Auckland, where she did a variety of clerical tasks. More recently, Cheryl has been a support clerk for the North Harbour Public Health Office and then an administration clerk for the North Shore Office of Auckland Healthcare Public Health Protection. Amongst other things, Cheryl has also worked as a nurse aid in two Auckland rest homes.

JULIET HERRICK

Juliet has been appointed as an Assistant Advisor, Medicines Control in the Hamilton Regional Licensing Office, for twelve months while Michelle Bishop is on parental leave. Juliet completed her MSc (hons) in Botany in 1992 and has previously worked as a technician at the Auckland Museum. Last year she moved to Hamilton and, seeking a change in career, undertook a Diploma in Management Studies. She says she has not experienced a dull day since she started in September.

New Look Therapeutics Section

As well as new premises, the structure of the Therapeutics Section has changed.

The Ministry is currently advertising for a Business Manager for the Section. This has resulted from Dr Bob Boyd accepting a position as Chief Advisor, Regulation and Safety. Bob will be providing medical and technical advice to the Therapeutics Section as well as to the Implementation Group within the Ministry.

A new team has been formed entitled *Business Development and Support Team*. The team is lead by Susan Martindale and combines a logical array of skills and strengths under one umbrella. Members of both the previous Special Projects and Business Support teams are included, along with staff previously from other teams.

The functions of the team are:

strategic business planning and development;
provision of information;
resource management;
corporate requirements; and
internal audit.

Projects and work already planned for this financial year will proceed as normal.

Following the resignation of Mark Rowland, Michael Thompson has been appointed as the Evaluation Team Leader.

Left to right. Susan Martindale (Team Leader, Business Development and Support), Peter Pratt (Team Leader Compliance), Clare Van der Lem (Acting Manager, Therapeutics) and Mike Thompson (Team Leader, Evaluation).

Therapeutics Staff on the Move

Mark Rowland	Has jumped the ditch to CSL Limited's Regulatory Affairs department in Melbourne.
Peter Abernethy	Was tempted back to the Ministry's Communication Section as a Senior Media Advisor.
Myfanwy Fulford	Is a Pharmaceutical Society Field Educator in the Auckland region as well as locuming in pharmacies on Auckland's North Shore.
Isobel Smith	Now monitoring clinical trials for Eli Lilly and Company (NZ) Ltd.
Merle Turner	After 20 years of working in the health sector is now selling Auckland real estate.
Michelle Bishop	On parental leave looking after baby Colin.
Melissa Young	Working for PHARMAC as a Therapeutic Group Manager responsible for hormonal, oncology and immunosuppressant agents.
Kim Willcox	Working in the Ministry's Human Resource Management Section.

Therapeutics Section Staff List

	Special Responsibilities	Direct Dial Telephone
Clare Van der Lem	Acting Manager	(04) 496-2081
Rosemary Cooney	Executive Assistant	(04) 496-2262

Business Development and Support Team

Susan Martindale	Team Leader	(04) 496-2092
Marilyn Anderson	Analyst	(04) 496-2234
Paul Richards	Information Technology	(04) 496-2012
David Buckle	Analyst	(04) 496-2140
Stewart Jessamine	Senior Medical Advisor	(04) 496-2274
Margaret Ewen	Therapeutic Information	(04) 496-2107
Kathlyn Ronaldson	Secretary MARC	(04) 496-2365
Sheree Wellington	Analyst	(04) 496-2412
Catherine Marnane	Senior Support Officer	(04) 496-2179
Rachael Trudgeon	Support Officer	(04) 496-2155
Carol Smith	Secretary MCC	(04) 496-2096
Rose Joe	Assistant Support Officer	(04) 496-2090

Evaluation Team

HEAD OFFICE, WELLINGTON

Mike Thompson	Team Leader	(04) 496-2094
Jeremy Brett	Secretary Vaccines Sub-committee, Biological Products	(04) 496-2097
Raymond Wilson	Medicine Evaluation, MAAC	(04) 496-2040
Richard Griffith	Medicine Evaluation, MCC	(04) 496-2363
Khay Ooi	Medicine Evaluation	(04) 496-2339
Alison Cossar	Medicine Evaluation	(04) 496-2460
Alexander Bolotovski	Medical Advisor	(04) 496-2078
Brian O'Sullivan	Medicine Evaluation	(04) 496-2331
Felix Ram	Secretary Generics Sub-committee	(04) 496-2114
	Medicine Evaluation	
Arman Farjam	Medicine Evaluation	(04) 496-2098
Keith Holmes	Secretary MAAC	(04) 496-2338
David Stevens	Support Officer, NMAs	(04) 496-2093
Gary Twinn	Support Officer, CMNs & Clinical Trials	(04) 496-2038
Leonardo Va'a	Support Officer (commencing Dec. 96)	

Head Office and Wellington Regional Medicine Control Office
Fax Number: (04) 496-2229. Postal Address: PO Box 5013, Wellington.
Visitors and Freight: 18th Floor, Grand Plimmer Tower, 2-6 Gilmer Terrace, Wellington.

Compliance Team

	Special Responsibilities	Direct Dial Telephone
HEAD OFFICE, WELLINGTON		
Peter Pratt	Team Leader	(04) 496-2362
Trevor Nisbet	Medical Devices and Cosmetics	(04) 496-2364
Christine Deveson	GMP, Section 29 Meds, CD's	(04) 496-2378
Derek Fitzgerald	GMP and Medicine Recalls	(04) 496-2176
Lawrence Young	Medicine Control Co-ordinator	(04) 496-2136
Barbara Cavanagh	Support Officer	(04) 496-2191
AUCKLAND REGIONAL LICENSING OFFICE		
Glenys Riggir	Medicine Control Advisor	Phone (09) 309-3035
Gary Syme	Medicine Control Advisor	Fax (09) 302-5061
Nicola Anderson	Medicine Control Advisor	
Cecilia Niumagumagu	Assistant Advisor	
Cheryl Palmer	Assistant Advisor	
HAMILTON REGIONAL LICENSING OFFICE		
Tony Gerred	Medicine Control Advisor	Phone (07) 834-0013
Juliet Herrick	Assistant Advisor	Fax (07) 834-0015
WELLINGTON REGIONAL LICENSING OFFICE		
Doug Longmire	Medicine Control Advisor	(04) 496-2439
Cristine Della Barca	Medicine Control Advisor	(04) 496-2018
Androulla Kotrotos	Medicine Control Advisor	(04) 496-2436
Anne Cherry	Assistant Advisor	(04) 496-2437
Mark Fulcher	Assistant Advisor (commencing Dec. 96)	Fax (04) 496-2229
CHRISTCHURCH REGIONAL LICENSING OFFICE		
Sheldon Ramer	Medicine Control Advisor	Phone (03) 366-7394
Nicky Harris	Assistant Advisor	Fax (03) 366-1156
DUNEDIN REGIONAL LICENSING OFFICE		
Denise Martin	Medicine Control Advisor	Phone (03) 479-2561
Lisa Pearson	Assistant Advisor	Fax (03) 477-6368

Head Office Therapeutics Section staff and Wellington Regional Medicine Control Advisors can be contacted by e-mail using the following Internet address: first name.surname@mohwn.synet.net.nz

Managing the Evaluation Workload

At the Industry Liaison Group meeting held in Wellington recently, participants were presented with figures on the Evaluation Team workload and how this was being managed.

The numbers of both New Medicine Applications (NMAs) and Changed Medicine Notifications (CMNs) received by the section have been steadily increasing since 1993. The biggest increase has been seen with the CMNs, with a 40% increase in numbers in the 1995/6 year compared to 1994/5, and over twice the number that were received in the 1993/4 year. This increased workload has been managed by recruiting extra medicine assessors and has resulted in a significant reduction in the time to first response for NMAs. As well, a review of some medicine assessment procedures is underway. Recommendations will follow on how target assessment times will be maintained or further reduced.

NMAs submitted for Medicine Assessment Advisory Committee (MAAC) review have been increasing in number, size and complexity. A survey of major New Zealand pharmaceutical companies was carried out in May to gauge the likely number of applications to be submitted up to the end of 1997. The data predicted that the overall number of applications will double compared to the previous year. Recommendations on how to manage this increase have been presented to MAAC.

Across the Ditch and Over the Counter

Recommendations to streamline the evaluation of non-Prescription Medicines (nPMs) will soon be promulgated to pharmaceutical companies for comment and consultation.

Evaluation Team Advisor Alison Cossar recently visited the Therapeutic Goods Administration (TGA) in Canberra and the Therapeutic Goods Unit in Melbourne to compare the Australian and New Zealand way of evaluating nPMs, with a view to recommending whether we should adopt some, or even all, of the Australian procedure.

She says the need for the review arose out of a realisation that the time we take to evaluate these medicines was longer than necessary considering the relative risk associated with the use of these medicines.

"It therefore seems unreasonable to evaluate non-Prescription Medicines to the same degree as Prescription Medicines," she said. "My trip was to look at the mechanisms the TGA had in place for assessing these medicines and to evaluate the success or otherwise of these mechanisms."

Alison identified the following:

- in Australia medicines are evaluated in streams according to their relative risk while in New Zealand they are evaluated according to the date of receipt;
- an independent Medicine Evaluation Committee recommends approval for nPMs in Australia while an Evaluation Review Meeting, comprising evaluators and medical advisors, recommends approval here. The value and disadvantages of both are recognised;
- criteria for the dossier are set out in guidelines issued by the TGA while in New Zealand EU criteria (common to Prescription and non-Prescription Medicines) are required in most cases;
- Australia uses a standard application form which is advantageous in terms of ensuring all required information is included in an application. New Zealand currently does not have a standard application form for nPMs;
- Drug Master Files are not usually required in Australia, unlike here where they are;
- starting material specifications for Australia must be BP or better. New Zealand accepts BP, EP, USP or better;

- Australia has an average turnaround time of 70 working days from receipt of the application to final decision, exclusive of company response time. New Zealand's current performance measure is for the first response to be made within nine months of receiving the application.

Alison is currently preparing a report on her findings and will be making several key recommendations including that:

- the New Zealand system of evaluation for non-Prescription Medicines is excessive in relation to the relative risk of the products;
- the Australian philosophy on non-Prescription Medicine evaluations should be adopted, but the Australian implementation system is unsuitable in New Zealand;
- specific guidelines should be generated for non-Prescription Medicine evaluation covering areas such as legislation, stability requirements, labelling requirements etc.;
- a new application form should be developed;
- second evaluations should be replaced by a forum of internal assessors such as a medical advisor and several evaluators. This forum would also act to recommend a product for approval or deferral;
- the time taken from receipt of an application to the final decision should be within an initial time frame of 20 weeks, with an aim to reduce this time as the process becomes familiar to both Therapeutics Section and the industry;
- New Zealand should retain most of the standards that it currently has. There is no perceived need for New Zealand to be more restrictive;
- 'line extensions' as a concept should be removed, and as in Australia, all new non-Prescription Medicine applications considered New Medicine Applications;
- a separate non-Prescription Medicine evaluation process should be instigated with specialist staff to assess non-Prescription Medicine New Medicine Applications and Changed Medicine Notifications; and
- Therapeutics Section should conduct training sessions on the proposed changes.

Consultation with industry will commence in the new year on the recommendations contained in the report. New guidelines and application forms will, in turn, be developed and sent to companies for comment before final adoption. Alison also envisages that training of Therapeutic Section evaluators and pharmaceutical company regulatory affairs staff will be necessary before final implementation occurs.

Exchange Rate Up

The Therapeutics Section is trialing an information exchange with its Australian counterpart.

With the consent of those companies involved, Therapeutics Section and the Australian Therapeutic Goods Administration (TGA) are exchanging evaluation reports on the chemical, pharmaceutical and bioavailability data for new medicines considered by the Medicines Assessment Advisory Committee. Over the last six months, 14 Part II reports (that is, chemistry and pharmaceutical data) have been exchanged.

Although the Ministry and the TGA are swapping information, each is following its own evaluation standards and procedures.

Evaluation Team Advisor Raymond Wilson says that such an exchange encourages sharing of experience and skills and is a useful form of peer review. He says it also reduces duplication and can speed up the assessment and approval process for new medicines because we are able to process more new medicines each year.

MAAC News

A workshop was held last November to review the structure and function of the Medicines Assessment Advisory Committee (MAAC). Some of the changes that have been instigated since January 1996 are -

Committee Structure

The Committee now comprises "core" and "pool" members. The introduction of "pool" members has expanded the expertise available for the assessment of New Medicine Applications. The total number of committee members has increased. There are currently 9 core and five pool members of MAAC.

MAAC Brief Summary

The requirement for companies to produce and submit this document has been removed. The PER format includes summaries therefore the MAAC Brief Summary is superfluous.

Committee Secretaries

- Keith Holmes replaces Mike Thompson as secretary of the MAAC.
- Jeremy Brett is the secretary of the VSC.
- Felix Ram replaces Jeremy Brett as secretary of the Generic Sub-Committee (GSC).

MAAC Assessors Reports

A company whose medicine application or notification is discussed at a meeting will routinely be sent the assessors' reports and the minute relating to their medicine following the meeting. It is no longer necessary for the company to request these under the Official Information Act.

Vaccine Sub-Committee (VSC)

A sub-committee has been formed to review applications for new vaccine products. At present this committee is made up of five members, two of whom are core MAAC members. Applications will be assessed by the sub-committee members and a report will be presented at a MAAC meeting for ratification. A recommendation for approval, deferral or decline will be made by the MAAC. The VSC met for the first time in August and defined its terms of reference and processes.

Scotsman Reclassified

After six years of chairing the Medicines Classification Committee Susan Martindale has decided to make way for new blood. Susan says "The last few years have been exciting times with changes occurring with reclassification of several Prescription Medicines to Restricted Medicine or Pharmacy-Only status. This has included the recommendation that emergency contraceptive tablets are safe to be sold by pharmacists".

Stewart Jessamine, Senior Medical Advisor to the Section, will be appointed as the new Chair. Stewart has been involved in reclassification issues and prepared many assessment papers considered by the Committee. The date for Stewart's first meeting as Chair is expected to be in April next year.

Committee Meeting Dates

Medicines Assessment Advisory Committee
3 December 1996
18 March 1997
24 June 1997
2 December 1997

Medicines Adverse Reactions Committee
4 December 1996

Medicines Classification Committee
April 1997 - date yet to be announced

Black And White Is OK With Us

The Evaluation Team medicine assessors will now advise on the acceptability of draft labels submitted in black and white which accompany New Medicine Applications and Changed Medicine Notifications. A coloured specimen label will not necessarily be a pre-requisite for approval.

The sponsor is responsible for ensuring that the colour contrast in the final label does not impair readability. As well, the sponsor will be asked to submit a colour copy of the label, when printed, for the file.

Fast Tracking Anti-HIV Medicines

Up until June 1996 it has been the Ministry's policy to fast track all applications for new anti-HIV medicines. As there are now a number of therapeutic alternatives for the treatment of AIDS patients, the decision has been taken by the Minister not to routinely fast track the assessment of applications for anti-HIV medicines.

The new criteria for fast-tracking applications for anti-HIV medicines are -

- The product is of a novel class of compound or has a different pharmacological activity to existing approved products; or
- Full clinical end-point data demonstrating the effect of the product on clinical outcomes and/or patient survival (as opposed to "surrogate" markers for disease progression) are submitted with the application; or
- A significant advantage of the product is indicated, either through an advance in therapy or through providing savings in expenditure.

Applications which are fast-tracked will be reviewed at the earliest available Medicines Assessment Advisory Committee (MAAC). Applications which are not fast tracked will be assessed by the MAAC in the normal time-frame (the current time to consideration at a meeting is approximately 9 months from receipt date).

What's New Doc

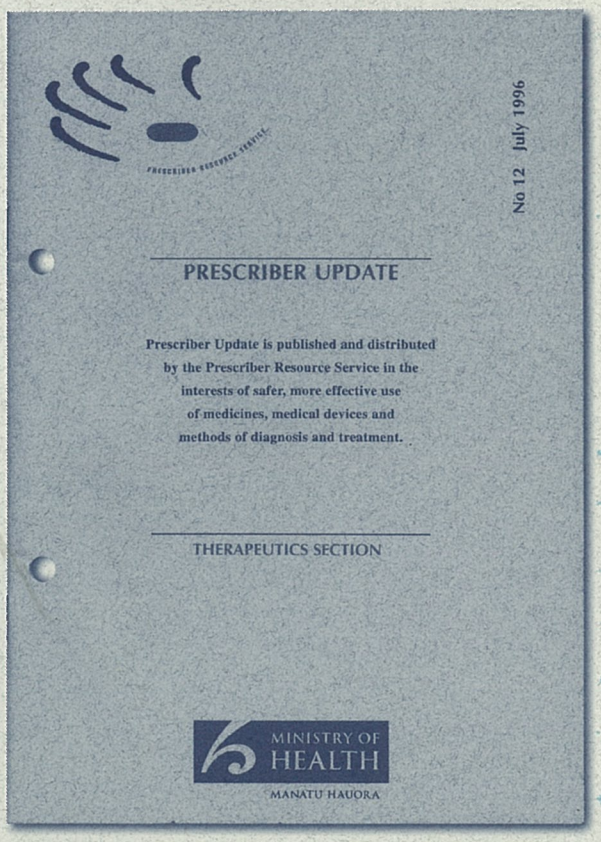
The first step in broadening the information disseminated to the outside world from the evaluation of medicines has been taken. After consultation with the pharmaceutical industry, a process has been developed where approved changes to existing medicines are considered for publication in *Prescriber Update*.

Only changes which are considered clinically significant, and therefore valuable information to prescribers, dispensers and/or consumers, will make it to print. Changes that would not be published include changes to the active ingredient manufacturer, finished product manufacturer or the packer. Changes to the method of manufacture, specifications and methods of testing would also not usually be clinically significant.

The Editorial Team of *Prescriber Update* will be responsible for reviewing all approved Changed Medicine Notifications, highlighting those that they consider are clinically significant and discussing their inclusion in *Prescriber Update*. When consent has been granted for changes in Indications, Contra-indications and/or Dosage and Administration, these changes will, if considered appropriate by the Editorial Team, be published in the next edition of *Prescriber Update*.

Other clinically significant changes will only be published once the sponsor company has notified the editor in writing. These changes are ones that will only be relevant once the changed medicine is on the New Zealand market, for example a new strength, new pack size or change in storage conditions. A letter will be sent to the company, with the draft article for publication, asking the company to notify the editor when it is appropriate for the change to be published. Obviously, we don't want to publish the approval of a new dose form or strength if it isn't going to be marketed for some time. Conversely, *Prescriber Update* is only published quarterly therefore exact timeliness can never be assured.

The second step in this process is to consider publishing information that the Ministry obtains during its evaluation of new medicines.



Do Unto Others...

The World Health Organisation (WHO) has developed guidelines to improve the quality of drug donations around the world.

WHO says many donated medicines are often not relevant for the situation, the disease or level of care available. They are often unknown by local health professionals and may not comply with locally agreed medicine policies - some may even be dangerous.

Citing examples of problems with medicine donations, WHO referred to a case in Lithuania in 1993 where 11 women temporarily lost their eyesight after using a donated medicine which was mistakenly used to treat endometritis. The medicine had been received without product information or package insert.

After the earthquake in Armenia in 1988, 5000 tons of medicines and medical supplies were donated. It took 50 people six months to gain a clear picture of what had been received and less than half the medicines were usable. The remainder were destroyed.

WHO has developed 12 guidelines on donating medicines which are based on four core principles:

1. Donations should benefit the recipient to the maximum extent possible.
2. Donations should be given with full respect for the wishes and authority of the recipient and should support existing government health policies.
3. If the quality of an item is unacceptable in a donor country, it is also unacceptable as a donation.
4. There should be effective communications between the donor and recipient - the donation should be based on expressed need and not be sent unannounced.

The WHO guidelines suggest:

- all medicine donations should be based on expressed need and be relevant to the disease pattern in the recipient country and not sent without prior consent;
- all donated medicines should be approved for use in the recipient country and appear on the national list of essential drugs;
- the presentation, strength and formulation of donated medicines should, as much as possible, be similar to those used in the recipient country;
- all donated medicines should be obtained from a reliable source and comply with quality standards in both donor and recipient country;
- no medicines should be donated that have been issued to patients and then returned to a pharmacy, or elsewhere, or given as free samples;
- after arrival all donated medicines should have a remaining shelf-life of at least one year;
- all donated medicines should be labelled in a language that is easily understood by health professionals in the recipient country and contain information including generic name, batch number, dosage form, strength, name of manufacturer, quantity in container, storage conditions and expiry date;
- as much as possible, donated medicines should be represented in larger quantity units and hospital packs;
- all medicine donations should be packed in accordance with international shipping regulations and be accompanied by a detailed packing list. The weight per carton should not exceed 50kg and medicines should not be mixed with other supplies in the same carton;
- recipients should be informed of all medicine donations being considered, prepared or actually underway;
- in the recipient country the declared value of a medicine donation should be based upon wholesale price of its generic equivalent in the recipient country or the wholesale world-wide market price;
- costs of international and local transport, warehousing, port clearance, and storage and handling should be paid by the donor agency unless otherwise agreed.

WHO says that the guidelines are not an international regulation but should be adapted, implemented and reviewed by countries and organisations dealing with donations.

To obtain a copy of these guidelines contact a Medicine Control Advisor at your local Regional Licensing Office.

High on Drugs

On occasion this year the Ministry has had to request an increase in the allocation of some controlled drugs from the International Narcotic Control Board (INCB).

Although this is not unusual, there have been a few hiccups when the Ministry is asked by the INCB to provide a full explanation for its request for an increase.

Compliance Team Advisor Christine Deveson says that pharmaceutical companies should provide the Ministry with details of any production change or new medicine development that may impact on New Zealand's allocation of controlled drugs.

"A full explanation initially can save the need to go back to the INCB several times, and subsequent delays can be avoided."

Hawk-Eye MOH

The Ministry of Health has introduced a new system for assessing applicants for licences to hawk medicines.

The need for the revised system was due, in part, to changes made to the New Zealand Institute of Medical Representatives Inc. (NZIMR) training course which dropped Stage 1 in favour of the Introduction to the New Zealand Health Industry Certificate.

All pharmaceutical company representatives who intend supplying samples of Prescription, Restricted or Pharmacy-Only Medicines must have a hawker's licence. Before issuing these licences, the Ministry must be satisfied the applicant meets the requirements of section 51(1) of the Medicines Act 1981, that is, have *sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines in which it is proposed to deal.*

New applicants who have a pass in the old NZIMR Stage 1 course or who have completed the new Introduction to the New Zealand Health Industry Certificate course do not have to sit a test. Other new applicants are required to sit one of the written tests and should contact Medicine Control staff to arrange a time to do so.

Passing the test requires applicants to have sufficient knowledge of the:

- medicines legislation and how it relates to the sale and distribution of medicines;
- terms used in the Pharmaceutical Schedule relating to the availability of medicines; and
- sections of the RMI Code of Practice relating to medical representatives.

Licensees applying for renewal of their licence are not affected by the new procedure.

Cutting Through The Red Tape

The Therapeutics Section continues to take a proactive approach to help pharmaceutical companies understand and comply with the medicines legislation.

The Evaluation Team is currently compiling the 'New Zealand Regulatory Guidelines for Medicines, Vol.1 - Prescription Medicines' so companies know how best to assemble their applications for new and changed Prescription Medicines. This will replace the current Medicines Distribution Guide and other guidelines, and consolidate the information on Prescription Medicines into one document.

Raymond Wilson, Evaluation Team Advisor says the Therapeutics Section receives many medicine applications, however a number arrive incomplete and lack some of the information required.

"These guidelines set out the type of information we need and the format in which we like to receive it," he said.

"We believe this will make the application process smoother and easier for everyone. The guidelines will also give companies an insight into the procedures and processes we use when assessing their applications."

The 200-page document has undergone a year-long process of compilation, revision and editing. Raymond says that it is important to make sure that the guidelines are user-friendly, self explanatory and easily understood.

The draft guidelines have been sent to a range of pharmaceutical companies and others, for example regulatory affairs consultants and the Australian Therapeutic Goods Administration, for consultation and pretesting. It is anticipated the guidelines will be published and distributed by mid-1997.

Off the Road

Therapeutics Section's Prescriber Resource Service has ended its visiting service to concentrate its resources on generating and delivering health information to general practitioners through *Prescriber Update* and other more targeted information delivery options.

The visiting service originally consisted of four regionally based staff members who visited general practitioners to discuss appropriate prescribing and information about medicines. In recent times the visiting service has been operating at half its strength and in January this year it was decided to end the service completely.

Effective communication with general practitioners and other prescribers remains of crucial importance to help ensure that therapeutic products are used as safely and effectively as possible. To this end, the range of information provided in *Prescriber Update* is being broadened to include clinically significant information generated from the medicine evaluation process (see article *What's New Doc*).

IT Promises Positive Gains

Information technology is promising some positive gains in the Therapeutics Section.

The Section is moving closer to implementing a new computer software system, purchased from Pharmasoft AB and known as REGULATOR (previously referred to as SWEDIS), which will assist in carrying out our broad range of risk management functions more effectively.

The first parts of the modular system have been delivered and tested. These modules include *medicines* which will capture a range of information about medicine products; *contacts* which records contact details of all organisations and individuals the Section deals with; and *substances* which provides details of the ingredients of medicines.

Another set of modules will be delivered and tested over the next year and gradually added to the new system.

A competition to find a suitable name for the new system, run in the last edition of the *Therapeutics Section Bulletin*, failed to attract any entries - something project team member Marilyn Anderson attributes to a lack of interest in the prizes on offer!

"Now we have to decide whether or not we should continue to encourage entries or else settle for TRIM (Therapeutics Risk and Information Management) - an acronym we came up with which reflects the broad range of functions the system covers," she said.

If you think you can come up with something sharper than this, there is time to send your ideas to Marilyn Anderson, Therapeutics Section, Ministry of Health, PO Box 5013, Wellington.

Bengt Dahlberg, Vice President of Pharmasoft AB, and Dr Karen Poutasi, Director-General of Health, signing the contract to purchase REGULATOR.

A celebratory drink after the signing of the contract. From left to right – Marilyn Anderson, Bob Boyd and Susan Martindale (Therapeutics Section), Bengt Dahlberg (Pharmasoft AB) and Swee Loon Loke (Database and Systems Management Section, MoH).

Human Albumin in Medicines

Concerns about medicines containing human blood products, such as albumin, have recently been raised.

Because of the need to inform patients, the Ministry now requires pharmaceutical companies to state when a medicine contains a blood product. This information must be included in the data sheet, labelling and information written for consumers.

All pharmaceutical companies are asked to comply with this requirement by 1 June 1997. Changed Medicine Notifications are not required as this requirement is not considered a material change. However, companies should submit the revised data sheet, labelling and consumer information.

Fax Attack

The Therapeutics Section has joined forces with crown health enterprises (CHEs) to share information on medical device alerts and recalls.

Annually the Compliance Team investigates approximately 180 medical device recalls and alert notices received primarily from overseas. Currently there is no register of medical devices in New Zealand so, on occasion, it has been difficult to determine if a device is being used here. When the device is marketed in New Zealand the distributor, in consultation with the Ministry, takes the appropriate action such as recalling or modifying the device.

In addition, the Therapeutics Section now has a facsimile programmed to automatically transmit information to the 23 CHEs. Whenever the Ministry transmits a recall or alert notice, each CHE circulates this information to the appropriate person in their organisation.

"If we are unable to determine that a device is in New Zealand, the network allows us to share information rapidly with CHEs to ascertain if the device is here and alerts the users of the problem," said Trevor Nisbet, Medical Device Advisor. "Likewise a CHE can advise the Ministry of a problem with a device and we can investigate the issue, with the distributor, and inform other CHEs if necessary."

Trevor adds "Device's are not always at fault. The problem can be caused by the way a device is being used. Here again, the network is extremely useful for passing on this concern."

Generic Substitution - Are Changes Ahead?

The Therapeutics Section has been instructed to prepare advice about the advisability of introducing wider generic substitution by pharmacists. It has been suggested that the legislation be amended to permit substitution at pharmacy level without the authority of the prescriber.

A letter was distributed in June seeking opinions from interested parties about the advantages or disadvantages of amending the Medicines Legislation.

Seventy-seven submissions were received from health professional organisations, consumer organisations, regional health authorities, independent practitioner associations, crown health enterprises and the pharmaceutical industry.

Two proposals for change were suggested in the letter. The first asked whether pharmacists should be able to substitute one brand of a medicine for another brand of the same medicine without prior authorisation. The letter asked for the reasons supporting or opposing the change and suggestions for safeguards to be put in place if there was a change.

The second proposal would require pharmacists to tell their customers whenever a less expensive generic equivalent medicine is available and could be substituted for the prescribed brand.

An analysis of the submissions is being undertaken. Forty-six percent of the submissions are in favour of the proposal to allow wider substitution, thirty-five percent oppose and nineteen percent either state no comment or no preference.

Once analysis is complete, the project team will decide what further work will be undertaken before a briefing paper is presented to the Minister.

New Legislation Update

There is little progress to report on the introduction of the Therapeutic Products Bill, but the Section is optimistic it will be introduced early next year.

Watch this space!

An Inspector Calls

Audits of hospital pharmacies are due to commence this month.

The purpose of the audits is to ensure that manufacturing, compounding and dispensing by hospital pharmacies is within the scope of the hospitals 'deemed' licence. They are also to ensure that the pharmacies operations are being undertaken in accordance with the appropriate parts of the Codes of Good Manufacturing Practice and the medicines legislation.

Senior Medicine Control Advisor Lawrence Young says the audits will provide useful feedback to hospital pharmacies on their manufacturing and dispensing operations in addition to highlighting areas which could be improved. The audits will be undertaken in a structured manner which will create minimal disruption to the pharmacies day-to-day activities.

Because of the geographic spread of hospital pharmacies, and the preparation time needed to conduct each audit, it is expected that completion of a full round of audits may take up to two years. Both hospital pharmacists and CHE management will be notified of their pharmacy audit well in advance of the date on which it is proposed to be undertaken.

Lawrence says the Ministry will keep the New Zealand Hospital Pharmacists' Association informed throughout the programme of any common issues or areas of concern identified from the audits.

Any queries should be directed to Tony Gerred or Cristine Della Barca (see page 7 for contact details) who will be conducting the audits.

Rescheduling Benzodiazepines

The Ministry is looking at rescheduling benzodiazepines as controlled drugs in order to comply with the International Convention on Psychotropic Drugs. The convention requires control over the export, import and use of all controlled drugs, including benzodiazepines.

New Zealand was a signatory to the convention in 1988 and has been requested by the International Narcotic Control Board (INCB) to reschedule benzodiazepines in line with international treaties to ensure greater control over the movement and use of these medicines. The INCB approves the rescheduling of these medicines in New Zealand as controlled drugs.

The Ministry is preparing a discussion document suggesting that compliance with the INCB request could be achieved by adding benzodiazepines to the Third Schedule (Class C) of the Misuse of Drugs Act (1975). As well, the discussion paper will examine the merits of the different subclasses of the Class C schedule.

Peter Pratt, Compliance Team Leader says the Ministry hopes to achieve compliance with the rescheduling request with minimal disruption to patients, prescribers, pharmacists and the pharmaceutical industry. "The requirement for import and export controls is paramount. It is not envisaged that prescriptions will need to be on the triplicate controlled drug prescription form" says Peter.

The discussion paper is expected to be distributed by Christmas. If you would like to receive a copy contact Peter.

Certificate of a Pharmaceutical Product Revised

The revised World Health Organisation (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce has been adopted by the Ministry.

The WHO certification scheme gives an importing country a guarantee that a medicine from an exporting country has been approved. The scheme conforms to international standards governing the manufacture and quality of medicines. The new format replaces the existing Certificate of a Pharmaceutical Product, commonly known as a Free Sale Certificate.

David Stevens, Evaluation Team Support Officer, says in line with WHO recommendations these certificates don't have to be notarised.

The fee has been reduced to $100 plus GST (that is, $112.50) for the first hour taken to produce the certificate and $60 plus GST for each additional hour. It is anticipated that the fee for most certificates will be $112.50. It would be appreciated if a cheque for $112.50 was enclosed with the request.

No Longer Sitting on the Fence

Guidelines for standing orders for the administration of Prescription Medicines are nearing completion.

Standing orders allow an authorised person to administer a medicine in certain situations, usually an emergency, when a doctor is not present. Standing orders may be prepared to allow nurses to adjust morphine doses to postoperative patients or ambulance officers to administer a bronchodilator.

The guidelines recommend that a documented system be in place showing the administration of the Prescription Medicine is in accordance with the predetermined written instruction of a doctor.

The guidelines will specify:

- who can administer the medicine (particular staff or groups of staff);
- situations where standing order will be used (particular ward, ambulance service etc);
- limitations of the standing order;
- to whom the medicine may be administered and for what indication(s);
- accountability of each participant;
- reason for the standing order;
- medicine(s) the standing order applies to, contra-indications, dose or dose range, route of administration etc;
- requirements for review (who will review the standing order, how often etc);
- competency of the staff involved (the agreed level of training required); and
- time limits for written confirmation and actions required if the time limit is exceeded.

A working party of representatives of the pharmaceutical industry, crown health enterprises, hospital pharmacists, nurses and representatives of nurses' professional organisations met to discuss the guidelines in May.

A final draft is currently being prepared and is expected to be distributed for wider consultation within the next two months.

Blood Guidelines Near Completion

Establishing uniform minimum standards to improve the safety and quality of New Zealand's blood supply is the aim of a new publication produced by the Ministry of Health.

Minimum Standards for the Collection, Processing, and Quality Assurance of Blood and Medicines Derived from Human Blood and Plasma was prepared from a World Health Organisation document and adapted to suit New Zealand circumstances using *A Guide to Operating Procedures for Transfusion Medicine Services in New Zealand* by Dr Jim Faed.

A working party of experts from the blood sector met three times to review the standards, with input also from the National Blood Transfusion Service Advisory Committee.

Advisor Brian O'Sullivan says the unique nature of blood requires high standards in all steps of its collection, processing and quality assurance procedures.

"The guidelines aim to establish uniform minimum standards at all Blood Centres around New Zealand," he said. "The document introduces new criteria and standards incorporating advances in transfusion medicine. Overall it seeks to improve the safety and quality of our blood supply."

Brian says some operators may choose alternative systems to those outlined in the Ministry's guidelines. "That is acceptable provided those operators can show they meet the minimum standards." He said any systems that go beyond these and increase blood safety are to be encouraged.

The guidelines are expected to be published in December 1996. They will be reviewed annually and will incorporate information on any technological advances.

Update on CMI

The project to develop a Code of Practice for Consumer Medicine Information has been outlined in recent editions of the *Therapeutics Section Bulletin*. Initially, a draft Code was distributed to a large number of organisations and individuals for consultation. A working party reviewed the submissions and has made recommendations on additions, deletions and alterations to the draft Code. Sections cover which medicines require CMI, language, presentation and style, content of CMI, delivery to prescribers and pharmacies, delivery to consumers, regulatory and complaints procedures etc.

Consumer Field-test

Earlier this year a consumer field-test was undertaken to evaluate New Zealanders' expectations of CMI and

their views of 'model' CMIs produced in accordance with the draft Code. The research involved a consumer survey and four focus group discussions. Focus groups were held with 5-6 representatives of people from Pacific Island nations, the elderly (65+ years of age), chronic medicine users (people with asthma and diabetes) and Maori.

CMIs were written for Augmentin tablets, Amoxil capsules and Ceclor syrup. The appropriate CMI was given to the patient, along with a questionnaire, when these medicines were dispensed from twenty pharmacies participating in the survey. A further twenty pharmacies acted as a control group, distributing a second questionnaire but no CMI.

The focus group participants reviewed all three CMIs and in all but one case, had not had the medicines dispensed.

Survey Results

An overall response rate of 37% was achieved - 41% for the control group (325 out of 791 questionnaires returned) and 33% for the experimental group (253 out of 757 questionnaires returned). The researchers considered this a satisfactory response rate for a postal self-administration questionnaire survey with no follow-up. The control and experimental respondents had similar demographic profiles.

- What respondents said about medicine information in general – Results indicated that most consumers approach medicine information on a 'need to know' basis. They will initially only read what they need to know to take the medicine. Dispensing labels, therefore, are well read (87% of respondents always read labels). Fewer consumers (62%) always read other information on the container and less always read a package insert when supplied (53%). 78% of respondents stated that at some time, there was information they wanted to know about a medicine that was not supplied with the medicine.

- Key points of what respondents said after reading the CMI leaflet – The results indicated that the design of the CMI, in terms of print size, amount of information and length (2 A4 pages), had "hit the mark" for most respondents. The style and presentation was also considered appropriate: 95% of respondents easily understood the information and 96% could find certain specific information in the 2 page leaflet. The majority of respondents (87%) stated they would like to receive similar leaflets with other medicines.

Results to a question assessing the impact of the leaflet showed that over half of the respondents (55%) found the information reassuring. Six percent found it worrying and the remainder of respondents found it made little difference to how they felt about taking the medicine.

Many respondents felt that CMIs should be provided by pharmacists and doctors and accompany all medicines, whether prescribed or purchased.

55% of respondents indicated they would keep the CMI. 59% of respondents taking long-term medication for a chronic condition indicated they only wanted to receive the CMI the first time the medicine was dispensed.

Consumers were asked whether they would be prepared to pay for CMI if it could not be provided free of charge. Numbers were approximately equally divided between those who indicated they would be prepared to pay and those who would not. When asked how much they would be prepared to pay, 76% of respondents said one dollar or less.

Focus Group Discussions

Almost all focus group participants held views similar to those found in the consumer survey. Similar questions about CMI content, readability, ease of use, preferred source etc were asked, with similar patterns of responses expressed.

The Maori and Pacific Island groups felt, however, that the CMI needed to be more visually appealing, for example by including pictures depicting how to take and store the medicine. The 2-page length was considered too long for some Maori and Pacific Island people to read. Additionally, the Pacific Island group felt some of the information was too technical. The Maori group felt that CMI written in Maori should be available.

Conclusion

The CMIs that were produced for this study received widespread endorsement and support from a cross section of consumers. Consumers were very enthusiastic about the CMIs and considered they provided the information they were seeking about medicine use. Further investigation, with a larger representation, is needed for some of the issues raised by the Maori and Pacific Island focus group participants.

Harmonisation with Australian CPI requirements

Australians' Jude Tasker (Merck, Sharp & Dohme) and Susan Parker (Astra Pharmaceuticals) travelled to Auckland in late August to discuss harmonisation of Consumer Medicine Information/Consumer Product Information requirements. New Zealand attendees were Margaret Ewen, Sheree Wellington and Stewart Jessamine (CMI Project Team, Therapeutics Section),

Dr David Woolner and Tony Miller (CMI Working Party members), and Kim Miles (RMI).

The meeting was beneficial for participants from both sides of the Tasman. "We were especially pleased to be able to explain the content of the draft Code and allay fears that we were producing New Zealand specific requirements" says Margaret. Jude and Susan also commented on the usefulness of the discussions.

Interim Requirements

A number of pharmaceutical companies have submitted, as part of the New Zealand regulatory process, Australian Consumer Product Information (CPI) leaflets intended as medicine package inserts. A letter was distributed to all pharmaceutical companies recently clarifying the Ministry's current position regarding medicine information for consumers.

New Zealand currently has no legislation regarding CMI. Until such time as the Code of Practice is published, the Ministry is happy for pharmaceutical companies to include Australian-produced CPI as package inserts for medicines marketed in New Zealand provided:

- the information is consistent with the New Zealand approved product information (usually the data sheet); and
- a copy is sent to the Therapeutics Section, Ministry of Health with a declaration that the information is consistent with the New Zealand approved product information.

This information will not be evaluated or approved by the Ministry of Health. This is in line with the proposal in the draft Code of Practice that CMI is not evaluated or approved. A self-monitoring process is proposed in the draft Code with a percentage of CMI audited against the requirements of legislation and the Code.

Where to from here

The CMI Working Party is currently finalising its recommendations on the draft Code of Practice for CMI. This should be completed by Christmas. The Ministry will, in turn, make final proposals on CMI and the Code of Practice.

In the meantime, any pharmaceutical companies wishing to start producing CMI are welcome to discuss with Margaret the best way of doing this in line with the draft Code of Practice.

Backing A Winner

Following a long gestation, and a difficult delivery, the Ministry of Health has great pleasure in announcing the birth of the "Interim New Zealand Guideline for Good Clinical Research Practice".

"Interim Guideline" is out of "Therapeutics Section" and sired by the Health Research Council's "Standing Committee on Therapeutic Trials". "Interim Guideline" establishes the bloodline of "Good Clinical Research Practice" in New Zealand.

During gestation "Interim Guideline" was subject to intense examination and genetic manipulation by private and commercial experts in the field to ensure maximum performance in New Zealand conditions.

The principles encoded in "Interim Guideline" provide the means for ensuring that clinical studies conducted in human participants are designed and conducted to the highest scientific and ethical standards.

Backing "Interim Guideline" is mandatory only for research conducted by the pharmaceutical industry. It is hoped that researchers outside of the industry stable will follow the form and back this spirited horse in future events.

As "Interim Guideline" is the first progeny of "Good Clinical Research Practice" in New Zealand, suggestions on further improving raceworthiness are encouraged. Copies of "Interim Guideline's" form and specifications can be obtained from "Interim Guideline's" jockey Stewart Jessamine at the Therapeutics Sections stable of the Ministry of Health.

Therapeutics Section Publications

The following publications can be ordered from:

David Stevens 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

   (a) Part 1 – Manufacture of Pharmaceutical Products (1993). Cost $16 including GST.

   (b) Part 2 – Manufacture of Blood and Blood Products (1993). Cost $16 including GST.

   (c) Part 3 – Compounding and Dispensing and Annex 1: Compounding of Sterile Pharmaceutical Products (1995). No charge.

   (d) Part 4 and 5 – Wholesaling of Medicines and Medical Devices and Uniform Recall Procedure for Medicines and Medical Devices (1995). No charge.

2. Information on Silicone Gel Breast Implants (1994).
3. Safe Management of Medicines – A Guide for Managers of Old People's Homes (1994).
4. Medicines Distribution Guide (1993).
5. Guidelines for Classification of Products - as either Medicines, Related Products, Dietary Supplements, or Cosmetics (1990).
6. Fees for Service: Supplementary Information (1991).
7. Guidelines for Preparing Data Sheets (1989).
8. Administrative Guidelines for Protecting Confidential Supporting Information (1994).
9. Interchangeable Multi-source Medicines (1996).
10. Minimum Standards for the Collection, Processing and Quality Assurance of Blood and Medicines Derived from Human Blood and Plasma (1996).
11. Interim New Zealand Guideline for Good Clinical Research Practice (1996).

Installing TRIM (see article 'IT Promises Positive Gains' on page 14) are Marilyn Anderson, Mark Handley and Paul Richards (all standing) with Ulf and Torbjorn, computer specialists from Pharmasoft AB.

In Our Next Issue

- **Sunscreen Standard – has 15+ increased to 30+ ?**
- **How TRIM is shaping up**

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