JUNE 1993

THERAPEUTICS SECTION Bulletin

THERAPEUTICS SECTION, DEPARTMENT OF HEALTH, WELLINGTON, NEW ZEALAND

Next month the health reforms become a reality with the official start-up of Regional Health Authority and Crown Health Enterprise operations.

The Therapeutics Section will remain basically unchanged except for the addition of the medicines control functions currently carried out by the area health boards. It is important that those involved in the new structures clearly understand what we do, and for whom.

Although most of our work is not particularly visible to the public, the Therapeutics Section is essentially consumer-oriented.

With funding of personal health services moving away from the Department of Health to RHAs, we in the Health Regulation service area will need to place even greater emphasis on providing the sort of service which the public wants.

This section's basic task is to ensure the safe and effective use of medicines and medical devices for the public good.

That means constantly weighing up the balance between risks and benefits of medicines and medical treatments.

It may sometimes seem that we are stressing the negative - emphasising the risks. But we also recognise the enormous benefits that can flow from proper application of methods of treatment.

Although we must protect the public against dangerous products or practices, the overall emphasis of our work remains positive. We will continue to ensure that new information and technology about medicines can be safely used to improve health care for all New Zealanders.

Finally, it was a real boost to receive such positive feedback about our first Therapeutics Section Bulletin. That edition introduced staff members and outlined the work of the various teams. This time we focus more on specific areas of Therapeutics Section activity, particularly those where recent developments may be of wider interest.

I hope you find the Bulletin informative and helpful in carrying out your work.

Bob Boyd Manager

Signing of the memorandum of understanding. See page 9 for details

The Therapeutics Section

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

While the Therapeutics Section's prime responsibility is to the Minister of Health, we acknowledge that our services depend greatly upon the co-operation and the goodwill of our clients who range from local and multinational pharmaceutical companies, industry associations, consumer groups, the media and other government agencies, to individual pharmacists, prescribers and the general public. The section welcomes the chance to consult and to learn of concerns about its service.

New Staff

DR STEWART JESSAMINE

Stewart recently joined the Therapeutics Section as a Medical Advisor and the fifth member of the visiting team of the Prescriber Resource Service. Scottish-born Stewart graduated from Glasgow University in 1981. He worked for several years as a medical registrar and completed a Family Medicine Programme in Scotland before coming to New Zealand to work as a GP. He joins Margaret Ewen in visiting prescribers in the lower half of the North Island.

Stewart Jessamine

OBITUARY

Dr Canagaratmam Sri Ananda ("Sri")

We report with sadness the recent death of former Therapeutics Medical Advisor Dr Canagaratmam Sri Ananda (known to his workmates as Sri) from lung cancer. Originally from Sri Lanka, Sri spent his early years as a doctor with the British Colonial Service in West Africa before coming to New Zealand to work as a special area medical officer. He joined the Department in 1978 where he worked in the evaluation of medicines, first with the Clinical Services Division, then with Medicines and Benefits and finally with Therapeutics. Sri, who spent a great deal of his time looking after his intellectually handicapped son, retired from the Department last year.

Therapeutics Section Staff List

	Special Responsibilities	Direct Dial Telephone
Bob Boyd	Manager	496-2088
Rosemary Cooney	Executive Assistant	496-2262

Evaluation Team

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

Compliance Team

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

Utilisation Team

Margaret Ewen	Team leader	496-2107
Catherine Marnane	Support Officer	496-2179
Carol Smith	Support Officer and Secretary MCC	496-2096
Stewart Jessamine	Medical Advisor	496-2274
Kathlyn Ronaldson	Secretary MARC	496-2365
Myfanwy Fulford	Visiting Advisor, Auckland	PH (09)378-4030 FAX(09)378-4050
Alister Livsey	Visiting Advisor, Auckland	PH (09)378-4030 FAX(09)378-4050
Isobel Smith	Visiting Advisor, Christchurch	PH (03)366-7394 FAX(03)366-1156
Malene Hook	Secretary, Auckland	PH (09)378-4030 FAX(09)378-4050

Special Projects

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

Therapeutics Update

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

Aussie Rules on Blood Code....

New Zealand is adopting Aussie rules for manufacture of blood and blood products. The Therapeutics Section has just published the first New Zealand Code of Good Manufacturing Practice (GMP) for the manufacture of blood and blood products. It is based on the Australian Code, with minor modifications for New Zealand use. The Department of Health and the Blood Transfusion Service agree that the Australian Code is a suitable document for use in New Zealand.

Meanwhile, Compliance Team staff are beginning a round of inspections of all New Zealand blood transfusion centres. "Blood audits" of all centres should be completed by the end of June.

NZ adopts PIC Code

Still on Codes of Practice - in the last Bulletin we reported that New Zealand was to adopt the international Pharmaceutical Inspection Convention (PIC) Code for medicines. The PIC is a multinational agreement among government authorities to exchange information on the state of good manufacturing practice compliance by pharmaceutical manufactures. The "Guide to GMP for Pharmaceutical Products" is a single code issued by the PIC for use by its member countries. It allows for mutual recognition of inspection standards between various countries and lays emphasis on quality management to achieve safety and efficacy of products. A new Code of Practice based on the PIC Code has now been published and is available from the Department.

Joan Baas, who heads the Compliance Team, says it is sensible for New Zealand to adopt a code with international standing. "Whilst New Zealand is not a member of the PIC, we nevertheless recognise the need to align with a well-established international code of practice. This new code now becomes the standard against which the manufacturing audit programme of the Department is conducted."

..And still more on Codes

Two activities not covered in the PIC Code will shortly have their own special codes. A code covering compounding and dispensing within pharmacy should be published by the end of June. This code will be used to clarify what hospital and retail pharmacies can do in the way of compounding of medicines - an issue which came under the spotlight as part of a critical Audit Office report.

A code covering wholesale distribution of medicines and procedures for medicine recall should be published by the end of the year.

Former cop helps Compliance team get tough

Recruiting a former police officer has had big pay-offs for the Compliance Section of the Therapeutics Division. Ex- policewoman Marie Scott was hired last year to help prepare prosecutions against medicines importers who break the rules. Since then the Department has brought four successful prosecutions and handed out 10 official warnings.

One high-profile investigation involved the import of "Stop Drops". This product was labelled as a homoeopathic formulation and advertised as an easy, safe and effective way to lose weight, but analysis showed it contained phenylpropanolamine, a prescription medicine which is dangerous when misused. Phenylpropanolamine can cause severe

hypertension and possibly death. The company which imported "Stop Drops", Eden Joy (NZ) Ltd, was convicted on 37 charges of breaching the Medicines Act 1981, fined a total of $32,700 and ordered to pay analysis fees of $4050. It was also disqualified from obtaining a new licence to sell medicines and had to forfeit those it still held.

Compliance Team leader Joan Baas is delighted with results so far. "We're making it clear that we will get tough on major, potentially dangerous breaches of the law."

And she's pleased that the industry is backing the new, tougher stance. "In some cases, the industry has informed the Department of breaches. The message we've got is that they want a tougher line too."

CARM new-look for adverse reactions centre

The medicines adverse reaction monitoring centre in Dunedin has a new name (Centre for Adverse Reactions Monitoring), a new acronym (CARM), and a new Medical Assessor, Peter Pillans. Dr Pillans was previously director of the national adverse reactions reporting programme in South Africa.

The new-look centre is keen to raise its profile. It's aiming to have more communication with health professionals, and hopes this will encourage an increase in reporting of adverse reactions.

Kathlyn Ronaldson, Secretary of the Medicines Adverse Reactions Committee (MARC), says MARC believes there is significant under-reporting of adverse reactions in New Zealand.

She says both MARC and the Dunedin centre would like to see companies taking an active role in increasing the rate of reporting by encouraging doctors to report adverse reactions to their products, or by passing the details on to the centre themselves.

"With a higher rate of reporting, it would be possible to give prescribers, pharmacists and companies more feedback on reactions to different products," she says.

The guidelines set down by MARC request reporting of all unexpected serious adverse reactions to medicines and vaccines. "Serious reactions" include all reactions which significantly affect a patient's management and are suspected of causing death, danger to life, hospitalisation, prolonged hospitalisation, interruption of productive activity, increased investigation or treatment costs, or birth defects.

The Dunedin centre analyses all adverse reaction reports received and presents a report to MARC three times a year. MARC receives information from other sources as well - international literature, companies and overseas regulatory authorities.

MARC uses all this data to ensure appropriate action is taken over adverse reactions. It makes recommendations to the Minister of Health, which can range from suggesting a change in data sheet, to proposing (via a recommendation to the Medicines Assessment Advisory Committee) that the medicine is removed from the market.

MARC is also responsible for advising health professionals about adverse reactions, generally through articles in the Prescriber Update.

Any companies not currently receiving Prescriber Update or CARM annual reports can contact the Department and ask to be included on the mailing list. Companies can also request, for a fee, print-outs of adverse reactions to their products.

The IMMP programme - reporting on some new medicines

For some "innovative" new medicines, the adverse reaction reporting requirements are much more stringent. As part of the Intensive Medicines Monitoring Programme (IMMP), doctors are asked to report all adverse effects, pharmacists to supply a record of every prescription and companies to supply sales figures. Companies are also asked to indicate on promotional material that the medicine is subject to the IMMP.

The IMMP is internationally recognised as an exceptionally effective programme for post-marketing surveillance of adverse reactions. Its continuing effectiveness, however, depends on the co-operation of everyone involved.

A helping "hand-out"

Pharmaceutical companies will have received, with their circular letter in early March, guidelines for making submissions for reclassification to the Medicines Classification Committee (MCC).

MCC secretary Carol Smith says the committee would like companies to use the suggested format when applying for re-classification.

"That makes it easier for the committee to make speedier recommendations."

Information required falls into two broad categories. Part A covers basic product information.

Part B looks at the reasons for reclassification and covers issues like safety, comparison with other similar medicines, the ease with which the condition in question may be diagnosed and treated and any problems which could arise.

Copies of the requirements are available from the Secretary, Carol Smith, Therapeutics Section, Department of Health, Box 5013, Wellington.

What is the MCC and what does it do?

The MCC is a ministerial advisory committee which makes recommendations to the Minister of Health on matters relating to classification or reclassification of medicines.

Most submissions to the MCC are for reclassification to a less restrictive category. Generally, new chemical entities are given a prescription classification and aren't considered for over-the-counter sale until they have been widely used for three years, allowing time for any adverse reactions to be observed.

The six-member committee (two members from the Department, two from the Medical Association and two from the Pharmaceutical Society) holds two meetings a year, generally in May and November, to consider submissions for reclassification.

The submission process

Eight copies of each submission are required. Submissions should be concise and only key papers should be sent. Where appropriate, references should be provided to other material.

Submissions should be sent two months before an MCC meeting, where possible, to allow the Department to prepare its own submissions and to allow time for MCC members to receive papers in advance. Companies are informed of the cut-off date for accepting submissions prior to a meeting.

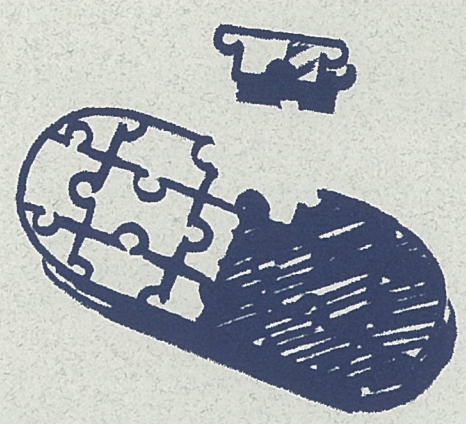
The MCC considers submissions then makes recommendations to the Minister of Health which are kept confidential till the Minister has made a decision. (MCC recommendations are generally accepted.)

Companies are informed of all proposed classification changes by circular letter. Four weeks later these changes are published in the *NZ Gazette*. This gives companies time to prepare new labelling and pharmacists time to prepare for selling a medicine with a different classification category. Companies can also use this four week period to appeal against a classification change.

When a medicine is reclassified, manufacturers have three months to change labelling and packaging. After this period, all stock supplied to warehouses should carry the new labelling, and within six months all stock in retail outlets should reflect the classification change.

Classification changes take effect from the date of publication in the *NZ Gazette*. If you want to check the classification of a medicine, first look up the most recent accumulative *Gazette* notice. Changes in the *Gazette* override the Medicines Regulations. If it's not in the accumulative *Gazette* notice, then the Regs still stand. Take heart, a new schedule of classified medicines is on the way.

What's new!!!!!



A new interpretation of what constitutes a "new" medicine seems to have confused some pharmaceutical companies. Over the last few months, the Therapeutics Section has received a number of changed medicine notifications (CMNs) which should, in fact, be new medicine applications (NMAs). Evaluation Team leader Mark Rowland says getting the category correct is crucial because incorrect applications result in delays for the company and extra work for the Department. (It's also crucial in dollar terms. The fee for a CMN is $1600 as opposed to $7800 for an NMA! And, while the Department is required to process CMNs in 45 days, there is no set time-limit for NMAs which generally take nine to 12 months.)

If you're not sure whether you need a CMN or an NMA, read the following examples:

Example 1: Company A manufactures a standard product containing aspirin and codeine. It decides to add ephedrine (to produce a medication which will attack the sniffles as well as relieving pain). A new active ingredient has been added to an existing medicine. A new product has been manufactured. Company A needs to lodge an NMA.

Example 2: Company B makes an aspirin/codeine/ephedrine compound. It decides to replace the codeine with pholcodine. The resulting compound is a new medicine with a different efficacy/safety profile which needs to be evaluated from scratch. Company B needs to lodge an NMA.

Example 3: Company C also manufactures an aspirin/codeine/ephedrine compound. It decides to simply remove the codeine. Subtraction of an active ingredient doesn't require re-evaluation of safety and efficacy. Company C can lodge a CMN.

Mark says the Department changed its interpretation of what constitutes a "new" medicine largely to keep its procedures in line with international criteria. Cost was also a factor. Under the old rules, evaluation of some CMNs which involved major change, was as time-consuming as evaluation of a new medicine. Under the new rules, such applications would generally fall within the NMA category.

Medicine Control Functions

From 1 July 1993 the Therapeutics Section will have staff in five regional offices. These staff include medicines control officers whose functions have been transferred from area health boards to the Ministry of Health.

The regional offices in Auckland and Christchurch will also house the Section's visiting professional advisors.

District Office Therapeutics Section Staff List

Auckland

Medicines Control Officers: Niki Anderson, Glenys Riggir, Gary Syme. Visiting Professional Advisors: Myfanwy Fulford, Alister Livsey

Address: Ground Floor, Te Puni Kokiri Building 114-116 Ponsonby Road, Ponsonby, Auckland
PO Box 47511, Ponsonby. Telephone 09 378 4030 Fax 09 378 4050

Hamilton

Medicines Control Officer: Ted Leigh
Address: First Floor, Hochstetter House 18 Rostrevor Street, Hamilton. PO Box 1123, Waikato Mail Centre Telephone 07 834 0013, Fax 07 834 0015

Wellington

Medicines Control Officers: Peter Pratt, Doug Longmire, Lawrence Young

Address: 3rd Floor, General Building, 38-42 Waring Taylor Street, Wellington

PO Box 10327, The Terrace. Telephone 04 499 5159 Fax 04 499 6169

Christchurch

Medicines Control Officer: Sheldon Ramer. Visiting Professional Advisor: Isobel Smith

Address: Ground and First floors, National Radiation Laboratory , 108 Victoria Street, Christchurch
PO Box 25177. Telephone 03 366 7394
Fax 03 366 1156

Dunedin

Medicines Contol Officer: Denise Martin
Address: 9th Floor, John Wickliffe House, Princess Street, Dunedin. PO Box 384. Telephone 03 479 2561 Fax 03 477 6368

Safety alerts on medical devices

International safety alerts are rapidly passed to New Zealand authorities. The Department of Health gets safety alerts from the Australian Therapeutic Goods Administration, the United States Food and Drug Administration, Health and Welfare Canada, and the United Kingdom Medical Device Directorate.

Each alert is reviewed and, if the device is in New Zealand, the problem is discussed with the local agent. The agent may be asked to recall the device or the device may have to be modified. In some cases, the Department may alert hospitals or users to a particular problem.

Any concerns about the safety of a medical device should be reported to the Compliance Section who will, if necessary, raise the issue with overseas health authorities.

Talking high tech

The Therapeutics Section is heading down the "high-tech" track. A consultant has been hired to identify the section's current and future information technology needs, and project manager Susan Martindale says the result is likely to be a much greater capacity for electronic data input in future. Susan says the Department recognises that efficient, rapid and resource-sparing transfer of information will be vital in the new health environment. "Increasingly, our clients - pharmaceutical companies and others - will be sending us information electronically. We need systems which are geared up to handle increasing volumes of information, both from outside, and within the Department." Decisions on new technology will be made once the consultant's work is completed.

Trans-Tasman language barriers

When it comes to medicines, New Zealanders and Australians haven't been talking the same language. Differences in drug labelling terminology have been holding up trans-Tasman harmonisation.

Susan Martindale of the Therapeutics Section, says there are "huge variations" in terminology at present.

"For instance, what we call a "restricted medicine", the Australians would call an S3."

She's optimistic though that the problems will soon be sorted out largely as a result of closer liaison between the two countries through the Drugs and Poisons Schedules Standing Committee (DPSSC).

The DPSSC is an Australian committee charged with deciding on the level of availability and public access, in Australia, for medicines and a wide range of other agents, from veterinary preparations through to household poisons and agricultural chemicals.

Susan and Ministry of Agriculture and Fisheries toxicologist John Reeve were recently asked to represent New Zealand on the committee, to ensure there is a consistent approach in decisions about scheduling.

"This means that when products come up for scheduling, we will have some influence on decisions," Susan says.

So far, the New Zealanders have only attended one DPSSC meeting. But, in a related initiative aimed at harmonisation, Susan and John were also asked to be members of a working party set up by the DPSSC to look specifically at harmonising packaging and labelling of medicines.

Susan says the working party is making good progress.

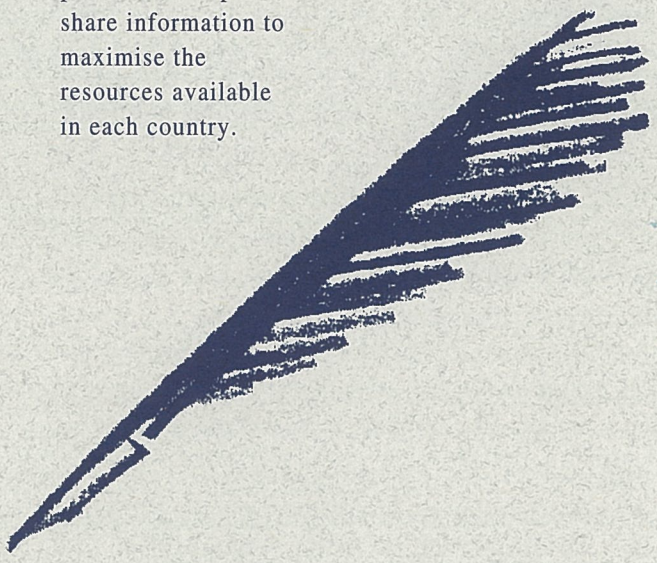
"I'm optimistic that the gaps will soon be closed so that medicines can be labelled to meet both countries' requirements."

And, though it's early days yet, she says moves by the DPSSC towards harmonisation in scheduling will clearly flow down and be reflected in labelling and packaging.

Memo signing a milestone for harmonisation in therapeutic goods administration

The signing of a memorandum of understanding with Australia in Rotorua last month marked an important milestone in harmonisation initiatives. The memorandum was signed during a meeting of the National Co-ordinating Committee on Therapeutic Goods (NCCTG) hosted by the Therapeutics Section. The meeting brought together State and Commonwealth representatives to discuss a uniform approach to the regulation of therapeutic goods in Australia. New Zealand has had observer status at these meetings since 1992 to foster harmonisation between the two countries.

The memorandum of understanding is a formal indication of the desire of both parties to co-operate and share information to maximise the resources available in each country.



Generic Substitution Project

The Generic Substitution Review Committee has presented recommendations to the Department on products proposed by generic manufacturers for substitution at pharmacy level. The Department is now developing a list of generic medicines considered to be interchangeable with corresponding innovator brands.

The next phase of the project is the development of policy for a generic substitution scheme in the reformed health sector, in consultation with interested parties, including the pharmaceutical industry. As part of this process, the Department is having discussions with Regional Health Authorities.

Legislation allowing generic substitution at pharmacy level is scheduled to go before Parliament this year, with opportunities for further wide consultation when the Bill is introduced into the House.

Incorrect applications cause delays for importers

Incorrect applications for licences to import and export controlled drugs are causing delays for all applicants - including those whose applications are correctly filled in.

"Sometimes the information asked for is not given, or is incorrect. Frequently the address for consignment is wrong. This is important as it is not always the same as the address of the applicant," says Christine Deveson-Sheppard, of the Compliance Team.

She says the maximum "turn-around time" from date of receipt to date of despatch should be three weeks. "We try and shorten the turn-around, and in general licences are issued within 12 days. But delays caused by incorrect applications are affecting the time taken to process correctly completed applications."

Christine acknowledges that the form is complex. "Someone in the applicant organisation with specialist knowledge needs to have a hand in filling in the form - particularly parts relating to drug content, and other technical issues. It's a good idea to look at the information on previously-issued licences."

She says problems also arise if the applicant's licence to deal in or possess controlled drugs has expired. Applications for renewal of a licence should be made between one and three months before the old licence expires. The old licence then remains in force until the new one has been processed.

(Anyone having difficulty understanding application forms for import or export of controlled drugs should ring Christine for assistance. See phone contact list on page3.

The Public Face of Therapeutics

Most Therapeutics Section staff are hidden away from the public, involved in "back-room" work like evaluating medicines. The Visiting Professional Advisors (VPAs) whose work forms part of the Prescriber Resource Service are, however, on permanent public display.

"That has advantages - and disadvantages," says Auckland-based VPA Alister Livsey.

"We're the visible face of the Department. Some prescribers see the visits as a good chance to dump all their "gripes" about the Department onto you and that can be tough. You just have to hear them out, though."

He's not complaining. The "gripes" are just part of a job which offers enormous variety and challenge. Understanding and dealing with prescribers' frustrations - talking through the issues - is part of the challenge.

Alister is one of a five-strong team which also includes Team Leader Margaret Ewen, and Stewart Jessamine (in Wellington), Myfanwy Fulford (also in Auckland), and Isobel Smith (in Christchurch).

The VPAs come from a variety of backgrounds. They bring to the job a wealth of medical and pharmaceutical knowledge and experience.

PRESCRIBER RESOURCE SERVICE

Their main task is to visit prescribers in their region. They provide them with the latest independently-researched information on medicines and talk through any problems with prescribing.

Each visit focuses on an area of topical interest - for instance, hormone replacement therapy, or hypertension treatment. The aim is to promote quality and safety in medicine use.

The VPAs often come into contact with pharmaceutical company reps in doctors' waiting rooms.

"We actually welcome contact from the companies to talk through issues relating to their products," Myfanwy says.

Though the focus of the service is on medicine use, the VPAs say their job ranges much more widely.

Isobel Smith, South Island Visiting Professional Advisor

Alister says a doctor may ask for advice on managing patients who refuse to take their medication.

Another area for discussion is new Departmental policy. Prescribers need to understand changes if they are to participate enthusiastically.

"For instance," says Isabel, "they need to understand why it's important to report all adverse reactions occurring in patients taking medicines on the Intensive Medicines Monitoring Programme (IMMP)."

Margaret describes the visiting services as "very much a two-way process".

"We tell the prescribers what's new and they tell us areas in which they want more information."

Feedback from prescribers is used as a basis for deciding what topics should be covered in upcoming issues of *Prescriber Update*, *Therapeutic Notes* and *Prescriber Wise Therapies*.

Discussions with prescribers also enhance input into the Department's policy-generation process.

Myfanwy says part of the pleasure of the job is that every visit is different - in length, style and sometimes, content.

"A visit to a prescriber can last anywhere between 15 minutes and two hours - or more. It's never the same from one visit to another," she says.

New face for our publications

The Therapeutics Section has given two of its regular publications a face lift.

The *Clinical Services Letter* and *Therapeutic Notes* have been regular publications of the Therapeutics Section for many years. These publications are distributed to doctors, dentists, pharmacies, pharmaceutical companies and a varied assortment of other organisations. "It was time for a change," says Margaret Ewen, who along with other members of the Utilisation Team, designed the new look.

The *Clinical Services Letter* has been renamed *Prescriber Update*. This name better reflects the purpose of the publication, which is to provide prescribers with topical information on the effective use of medicines, medical devices, methods of diagnosis and treatment. Readers will note a larger number of articles on medicine adverse reactions, the inclusion of medicine profiles, information on medical devices etc.

Visually there are quite a few changes too. The publication goes out under the Prescriber Resource Service logo. "There was a need to establish an identity for all the services the section provides in informing prescribers about the effective use of therapies. The logo provides this identity," Margaret says. The text is desk top published and printed in colours to complement the logo. Reading the document is now a lot easier on the eye.

Another publication to receive a make over is the *Therapeutic Notes*. *Therapeutic Notes* has a long history. It was first published in 1957. According to Andrew Herxheimer, Chairman of the International Society of Drug Bulletins, *Therapeutic Notes* is the second oldest publication of its kind. Only the Medical Letter from theUnited States is longer-established amongst the world's drug bulletins.

A *Therapeutic Note* is a detailed look at a particular issue, for instance cot death, asthma management, medicine and aviation, benzodiazepines, and is written by specialists in the field. "The regard in which this publication is held can be seen by the many requests we receive from overseas organisations for reprints of particular issues," says Margaret. "We don't mind being a bit controversial in this particular publication, for instance Dr Ross Bailey's new update on the treatment of urinary infections disputes the currently accepted dosage regimens and even the laboratory indicators of what is an infection."

The new look for *Therapeutic Notes* is similar to that of *Prescriber Update*. A different paper colour has been use to differentiate between the two publications. The first 'new look' issues appeared in May this year and the Section has been pleased with the positive response.

Therapeutics Section Publications

The following publications can be ordered from:

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

1. Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods – Part 1 ($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. Code of Good Manufacturing Practice for Cosmetics (1982).
4. Guidelines for preparing Data Sheets (Jul 1987, Sept 1987, Oct 1987, Feb 1989).
5. Guidelines for compiling applications for contact lens solutions (Oct 1988).
6. Guidelines for labelling cosmetic products (1990).
7. Guidelines as to acceptable levels for micro-organisms in cosmetic products (1989).
8. Guide to requirements for labelling medicines and related products (1989).
9. Comparative Pharmacokinetic Guidelines.
10. Draft Guidelines on Aerosol Preparations.
11. Generic Topical Medicines Guidelines.
12. Paracetamol Dosage for OTC Sale, Dispensing Packs, and general use (1992).
13. Fees for Service: Supplementary Information.
14. Notice to Applicants: EC Guide on New Medicine Applications ($20 including GST).
15. Guidelines for Classification of Products - as either medicines, related products, dietary supplements, or cosmetics.
16. Guidelines for Submission of Proposals to Change the Classification of a Product.
17. Guidelines for GMP Certification Requirements.
18. Medicine Distribution Guide (Nov 1989) under review.
19. Guidance Notes for Evaluation ($50 +GST)

In Our Next Issue

- **All about medicines control**
- **Laying down the law – Medicines Legislation Review**
- **Introduction of code of compounding and dispensing**

Update on Medicines Act Review

Work on drafting the discussion paper on the review of the Medicines Act has gone well according to Project Manager, Susan Martindale and her team. Current work revolves around analysing the environment in which the legislation will work after the Health Reforms. "It is important that any suggested changes to the legislation fit in with the direction of the Health Reforms if the new Act is to work well for industry and the consumer," says Susan. With the constantly changing health environment this analysis is a major undertaking, but one that must be completed before the next stage of the review can begin. The next edition of the *Therapeutics Section Bulletin* will feature a profile on the Medicines Act Review.

Therapeutics Section Bulletin correspondence should be forwarded to:

Margaret Ewen, Therapeutics Section
Department of Health, PO Box 5013, Wellington
(PH) (04) 496-2107, (FAX) (04) 496-2340

Department of Health
TE TARI ORA

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