



Australian Government

Department of Health

Therapeutic Goods Administration

Fifty years of
independent expert
advice on
prescription medicines

Historical document





Senator the Hon Fiona Nash
Assistant Minister for Health
Senator for New South Wales
Deputy Leader of the Nationals in the Senate

**Australian Drug Evaluation Committee 1963-2009
Advisory Committee on Prescription Medicines from 2010**

It is a pleasure for me to write this letter of introduction, as we celebrate fifty years of expert, independent advice on the quality, safety and effectiveness of prescription medicines.

This anniversary prompts us to pause and remember the tragic foundation upon which the original committee, the Australian Drug Evaluation Committee (ADEC) was built. The devastating effects of the medicine thalidomide on unborn babies introduced a new era for regulating medicines both in Australia and globally.

This booklet highlights a number of the significant achievements of the ADEC and its successor, the Advisory Committee on Prescription Medicines (ACPM), in facilitating and enabling access to new medicines and in preventing the introduction of medicines that are ineffective or have major safety problems.

As we look back over the last fifty years, it is amazing to reflect on how medicine has changed so many lives for the better. Vaccines and antibiotics have turned common diseases into rare ones, and modern discoveries have increased and improved the range of medicines available to the Australian public.

Advisory committee members are at the forefront of this expanding medical knowledge and this is reflected in the eminence of many past and current committee members. In recent years, consumer participation has become part of the Committee's work, reflecting the importance of the 'consumer voice' in the development of health policy.

The Advisory Committee on Prescription Medicines is well positioned to continue providing specialist expert advice into the future. I thank the past, present and future members of the Committee for their significant contribution.

FIONA NASH

Parliament House Canberra ACT 2600 Telephone: (02) 6277 7440



The thalidomide tragedy

How it led to the formation of the Australian Drug Evaluation Committee

1956

Melbourne hosted the Olympic Games, television arrived in Australia, and the first child with disability caused by the medicine thalidomide was born to an employee of the German pharmaceutical company, who had taken samples home to his wife.



Thalidomide was marketed as a wonder drug—an effective tranquiliser and pain killer useful for insomnia, coughs and headaches—and it helped pregnant women with morning sickness!

It was considered to be safe: in contrast to older tranquilisers, an overdose did not result in death, but simply an extra long sleep.

However, no studies had been conducted to investigate the safety of thalidomide for the unborn child.

In 1961 a German paediatrician, Dr HR Wiedemann, described an 'epidemic' of babies being born with limb malformations, but the cause of this epidemic was unknown.



Linking birth defects to thalidomide

At the end of 1961, the Australian Dr William McBride and the German Dr Widukind Lenz separately worked out the likely cause and effect relationship between thalidomide use in early pregnancy and birth defects.

In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide ('Distival') during pregnancy, as an anti-emetic or as a sedative, to be almost 20%.

WG McBride, The Lancet, Dec 1961

Thalidomide was withdrawn in Australia, Germany and the UK by the end of 1961. Eight months after the withdrawal of thalidomide, babies stopped being born with the characteristic limb defects.

About 40% of babies damaged by the effects of thalidomide died in their first year. But there are adults alive today who are living with disabilities caused by thalidomide.

Australian response to thalidomide tragedy

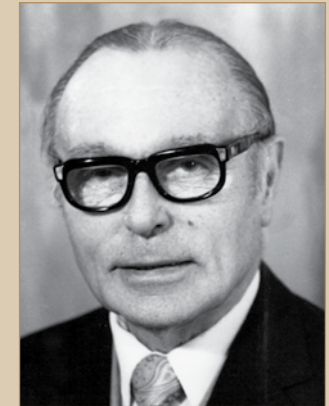
The thalidomide experience brought home to Australians the message that medicines have risks as well as benefits.

'Never again' was the wish of the Australian community, but what was the appropriate response?

It was decided that an independent committee should be set up to monitor the safety of new medicines as well as medicines that were already available. To achieve this, the Australian Government established the Australian Drug Evaluation Committee (ADEC) in June 1963.

'Government control does not absolve drug manufacturers from the responsibility of conducting adequate laboratory and clinical tests to ensure, as far as this is possible, the safety of drugs before they are offered to the public.'

AI Forbes, Minister for Health, 1967
(preface to the Report of the Australian Drug Evaluation Committee June 1963–December 1966)



Professor Edgar Thomson
CMG, OStJ, MB, ChB, FRACP,
FRIPH, MCPA, FHA, FRACMA,
FRCPA, first chair of ADEC,
1963–1966

Professor Thomson was the founding president of the College of Pathologists of Australia, chair of the Australian Red Cross Society's national transfusion committee and chair of the National Health and Medical Research Council's antibiotics advisory committee.

Thalidomide—now used to treat cancer and leprosy

Since 2008 thalidomide has been authorised to be used to treat a particular type of cancer (multiple myeloma) and it is now also authorised for the treatment of a complication of leprosy (erythema nodosum leprosum).

Thalidomide is supplied under strictly controlled conditions, and with a clear warning stating that even a single dose can cause severe birth defects.

Consumer Medicine Information warning for thalidomide

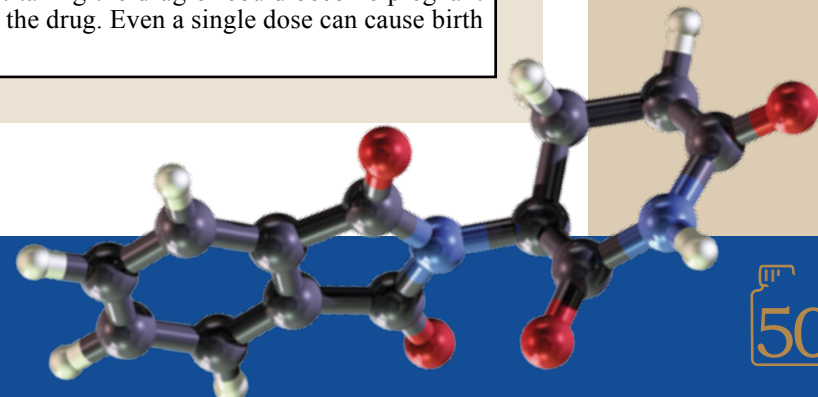
Severe life-threatening birth defects:

Thalidomide has caused severe birth defects when taken during pregnancy. Thalidomide should never be used by women who are pregnant or who could become pregnant whilst taking the drug or could become pregnant within 4 weeks after stopping the drug. Even a single dose can cause severe birth defects.

Product Information warning for thalidomide

Teratogenic effects:

Thalidomide has caused severe birth defects when taken during pregnancy. Thalidomide should never be used by women who are pregnant or who could become pregnant whilst taking the drug or could become pregnant within 4 weeks after stopping the drug. Even a single dose can cause birth defects.



Fifty years of medicines



In the past fifty years our knowledge of medicine has increased exponentially, with technological advances that have allowed new and different types of medicine. With each new development, members of ADEC, and later ACPM, have needed to be at the cutting edge of medical practice.

Medicines are no longer restricted to being small chemically synthesised molecules. Monoclonal antibodies (with names ending in 'mab') can now be designed and produced to target many diseases that were previously difficult to treat effectively, such as cancer and rheumatoid arthritis.

And with the success of penicillin and vaccines, many of the mass killers are no longer the threats they once were (although antibiotic resistance is becoming an ever bigger problem). Instead, medicines are being developed to treat emerging viral diseases, and more emphasis is placed on better therapies for cancer and preventing and treating lifestyle diseases such as cardiovascular disease and diabetes.

Insulin—changing over time

Insulin is life saving for the 122,000 Australians with type 1 diabetes (JDRC website, 2013), and is also used in a similar number of Australians with type 2 diabetes (about 10% of the type 2 diabetes population).

In 1963, when ADEC began, insulin isolated from pig and cow pancreases had been in use for several decades, with various chemical modifications creating long-acting insulins. Over the years, insulins became a recurring feature of ADEC meetings, as new advances led to new insulin medicines.





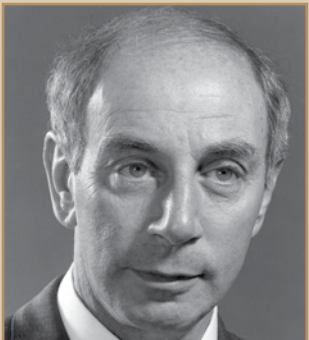
ADEC and insulin: 1974 to 2008

- | | |
|--------------|---|
| 1974 | higher purity pig insulin (mono-component insulin) |
| 1978 | recommended replacing the two available strengths of insulin with a single strength, 100 U/mL, to make dose calculations easier. |
| 1984 | insulin with the same structure as human insulin, but synthesised from pig insulin (human monocomponent insulin). |
| 1985 | human insulin produced using bacteria and recombinant DNA technology—the first medicine to be produced in this way. |
| 1986 | concern over the number of insulin products containing a fixed combination of short-acting and long-acting insulins. Later (1990) recommended restricting ratios to 50:50 and 30:70 to avoid confusion. |
| 1989 | ADEC insisted on the pharmaceutical company conducting an educational program when pig insulin was withdrawn from the Australian market for commercial reasons. |
| 1995 | first human insulin analogue (insulin lispro) that had a rapid onset of action, useful for administration close to meal times. |
| 2001 | insulin analogue (insulin aspart, NovoRapid) to be administered using continuous subcutaneous infusion with a pump: ADEC emphasised that only TGA-authorized pumps to be used. |
| 2002
2008 | extensions of indications supported for various insulin analogues, both for use in children and for type 2 diabetes. |





Sir Arthur William (Bill) Morrow DSO, MB, BS, MRCP, FRACP, FRCP, FACP, second chair, 1967–1975



Dr Stanley Goulston AM, MB, BS, MD, M Phil, FRCP, FRACP, third chair, 1976–1982

Sir William and Dr Goulston worked together to establish Australia's first specialist gastroenterology unit at the Royal Prince Alfred Hospital, which is now named the AW Morrow Gastroenterology and Liver Centre.

Selected achievements of the first three decades

First actions

At its second committee meeting, ADEC recommended that a Registry of Adverse Reactions to Drugs be established so that there was a central place for reports of adverse reactions to be stored. Fifty years later, this internal card index system has become a publicly searchable database on the TGA website: the Database of Adverse Event Notifications.

ADEC also prepared a form for reporting adverse reactions and a covering letter from the chairman, Dr Edgar Thomson. This form, with the covering letter, was sent to all doctors in Australia on five occasions, as well as to State Health Departments, medical colleges and hospitals. Now the 'blue card' is still available, but online and telephone reporting is also possible.



In the first three years – 1963 to 1966

In the first three years 112 ADEC resolutions were forwarded to the Minister. These resolutions were about new medicines proposed to be marketed and actual or potential safety issues with those already available in Australia.

By December 1966, in response to 760 adverse reaction reports:

- 4 medicines were banned for safety reasons
- 27 warning letters were published by ADEC in the Medical Journal of Australia to warn Australian doctors about particular safety issues
- 17 warning letters about safety issues were sent to doctors by pharmaceutical companies after communication with ADEC
- 30 amendments to advertisements were made
- 3 medicines were voluntarily withdrawn by the manufacturer.

Doctors were advised that long-acting sulfonamides should not be given to children for 'trivial reasons' because there had been 82 cases of serious reactions (Stevens-Johnson syndrome) in Australia and overseas.

Guidance to enable access to specialised medicines

Today, we understand that guidelines are a necessary part of regulating medicines, enabling pharmaceutical companies and the regulator to have a common understanding of the experiments and clinical studies required to investigate quality, safety and efficacy.

In the sixties and seventies there were no internationally accepted guidelines.

ADEC stepped in and set up subcommittees to develop relevant guidelines. This occurred for:

- parenteral nutrition, that is, a sterile food substitute that is administered through an intravenous drip
- radiopharmaceuticals: radioactive medicines used as imaging agents.

Creating access to anticancer medicines

In the seventies Australians affected by cancer were getting frustrated. They didn't have access to experimental treatments available in the US, and some of them were very promising.

ADEC sent a delegation to the US National Cancer Institute, and negotiated for Australian oncologists to be able to use particular experimental anti-cancer medicines, with the condition that the same protocol would be used in Australia as in the US.

A sunburnt country...uniquely Australian considerations

In 1982 there was an application for a new medicine for arthritis (benoxaprofen), but some people participating in the clinical trials had unpleasant skin reactions to light (photosensitivity reactions).

When the Department investigated further, it was discovered that similar reactions were also occurring in the UK, where it had been marketed for a couple of years. In fact, a small number of the UK reactions were serious and potentially fatal.

ADEC considered the medicine unsuitable for Australians.

Although suggestions were made that using sunscreen would make the medicine acceptably safe, ADEC held its ground. The medicine was never available in Australia—and it was withdrawn worldwide at the end of 1982 because of the photosensitivity reactions and apparent liver toxicity.





Sir John Lewtas (Jock) Frew
OBE, MD, FRCP, FRACP, FACP,
fourth chair, 1982–1985

Sir John was one of the last of the honorary physicians of the Royal Melbourne Hospital, and described himself as a 'relic' of the honorary system. Sir John had an interest in Malaysia and Singapore, having been a prisoner of war there, and was an Honorary Fellow of the Academy of Medicine of Singapore.

Quality and bioavailability

In the late 1960s it became apparent that a lack of studies measuring bioavailability—how much medicine gets into the blood and how quickly this happens—could have significant clinical impact.

An example of this was when reports were received in 1968 concerning overdose symptoms in Australians and New Zealanders taking the anticonvulsant medicine phenytoin sodium.

These patients had taken the correct number of capsules, and the capsules contained the correct quantity of medicine, yet their blood contained excessive concentrations of the active medicine. It was discovered that all of the overdosing events occurred with a new formulation, in which one of the inactive ingredients had been changed.

With this new understanding of how much bioavailability can vary between products and how important this is clinically, ADEC set out some circumstances in which all companies would be required to provide bioavailability data.

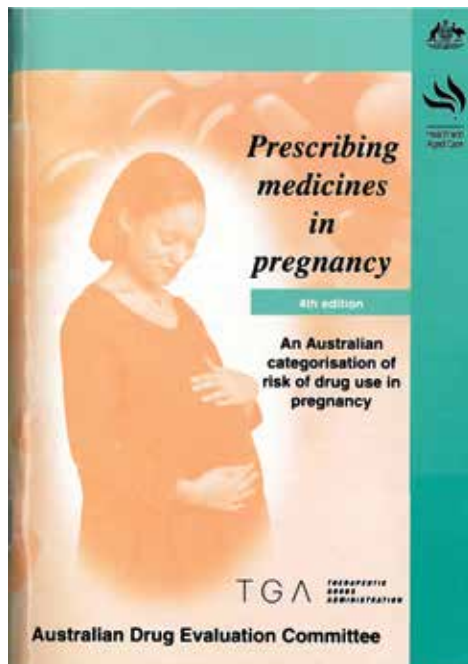
Data fabrication

The importance of bioavailability was well established in the eighties, but these studies cost companies money; the temptation to invent data proved too much for one company.

A special meeting of ADEC was convened in 1986 when this company's fraud was discovered, which affected a total of 33 medicines. ADEC recommended that repeat bioavailability studies should be required within the year, and this resulted in 15 of the medicines being removed from the Australian market.

This reinforced the importance of regulating the quality and bioavailability of medicines. The best way to provide expert advice on such issues was considered to be a separate group of experts, so a working group was set up, with a subcommittee formally established in 1989.

Today, the Pharmaceutical Subcommittee makes recommendations on the pharmaceutical chemistry, quality control, bioavailability and pharmacokinetics of prescription medicines.



Prescribing medicines in pregnancy

One of the achievements of ADEC that many health professionals are familiar with is the pocket-sized booklet *Prescribing medicines in pregnancy*.

The 1999 booklet was the fourth edition, with each edition containing a hundred or so additional medicines. The categorisation system is unique to Australia, and was created by ADEC as an adaptation of the Swedish system, as a way of being concise.

Instead of a booklet, the Therapeutic Goods Administration now has an online database *Prescribing medicines in pregnancy* <<http://www.tga.gov.au/hp/medicines-pregnancy.html>>, which is regularly updated with the latest information from Product Information documents.

Every prescription medicine has a 'Use in Pregnancy' section as part of the Product Information document. ACPM scrutinises this section and provides relevant advice.

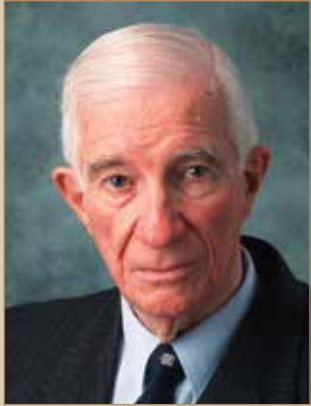
Medicines are not simply placed into a category; many are accompanied by statements relevant to their medicine class, such as general anaesthetics or medicines for asthma.

In 2013 there were 3700 visits every month to the Prescribing medicines in pregnancy database

All general anaesthetics carry the potential to produce central nervous system and respiratory depression in the newborn infant...

The benefits of asthma control outweigh any potential for an adverse pregnancy outcome.





Professor Mervyn Eadie AO, MD, PhD, FRACP, FRCPEd, fifth chair, 1985-1993

Professor Eadie is one of the University of Queensland's most highly regarded academics, having been professor of clinical neurology and neuropharmacology since 1977. Following retirement in 1997 Prof Eadie has continued to publish at a prolific rate, particularly in the area of the history of neurology, as well as continuing in medical practice and university teaching.

Evolving committee structure

The original committee

From 1963 to 1991, ADEC only consisted of six or seven members eminent in the fields of clinical medicine and pharmacology.

Findings were often communicated to other health professionals by publications in the *Medical Journal of Australia*.

ADEC set up its first subcommittee in 1970, the Adverse Drug Reactions Advisory Committee (ADRAC), to deal with the increasing reporting of adverse reactions.

Later, other subcommittees were formed with specific briefs to provide the necessary expertise in specialist areas, particularly in emerging areas of medicine with new regulatory concerns.

Expanding ADEC membership

In the eighties various reviews came to the common conclusion that there was a need for a comprehensive national approach to the regulation of therapeutic goods.

The Commonwealth focus shifted from the point of import to the point of supply with the passing of the *Therapeutic Goods Act 1989*, and the relevant parts of the then Department of Health, Housing and Community Services were named the Therapeutic Goods Administration, or TGA.

The States and Territories remained responsible for the control of the retail supply of therapeutic goods, scheduling and the regulation of wholesalers.

And from the beginning of 1992 the membership of ADEC was increased, so that in addition to the core members there were also between ten and twenty associate members, each with complementary expertise.



Reforms to separate pre- and post- market regulation

In 2009 reform processes began to separate premarket and postmarket regulation. The aim was to prevent any possible conflict of interest that might arise from the same experts being involved in both premarket and postmarket assessment of medicines and to ensure that sufficient resources were directed towards postmarket regulation.

This change was in line with international trends, and involved changes to the committees as well as the internal structure of the TGA. New committees were formed with the word 'advisory' in the names. This emphasises the advisory nature of the committees, with the decisions being made by the TGA.

ADEC met for the last time in December 2009, and its successor, the Advisory Committee on Prescription Medicines (ACPM) was formed in January 2010. The ADEC subcommittee that dealt with postmarket issues (the Adverse Drug Reaction Advisory Committee) was replaced by the Advisory Committee on the Safety of Medicines (ACSM).

Consumer perspectives

ADEC initiated the production of consumer-oriented information about medicines. Today, this is known as Consumer Medicine Information and is commonly provided by community and hospital pharmacists when they dispense medicines, as well as being available on the TGA website.

With the changes in 2010, the Therapeutic Goods Regulations were amended so that all the statutory committees, including ACPM, also contain an expert in consumer issues.

Publication of committee advice

The TGA has been publishing ADEC and ACPM advice since December 2009, together with the information provided to the committee, the final decision and a summary of any appeal (Australian Public Assessment Reports—AusPARs).

The TGA publishes the approved Product Information and Consumer Medicine Information on its website. This information is examined and commented on by ACPM.



Professor Susan Pond AM, MD DSc, FTSE, sixth chair, 1994–1996

Professor Pond's influence spans innovation and entrepreneurship in the fields of science, medicine, and biotechnology in Australia and internationally. Currently, she is Chair of the Australian Initiative for Sustainable Aviation Fuels, Vice President of the Academy of Technological Sciences & Engineering and board member of the Australian Nuclear Science and Technology Organization and Innovation Australia.

The role of the ACPM today

The ACPM provides advice and makes recommendations about prescription medicines to the TGA, the Secretary of Health and the Minister/Assistant Minister of Health. This advice is an important component of the decision making process undertaken by the TGA in relation to prescription medicines.

The members carefully consider the information available and provide advice on the questions posed by the TGA decision-makers as well as how the Product Information and Consumer Medicine Information might be worded to communicate effectively the available information.

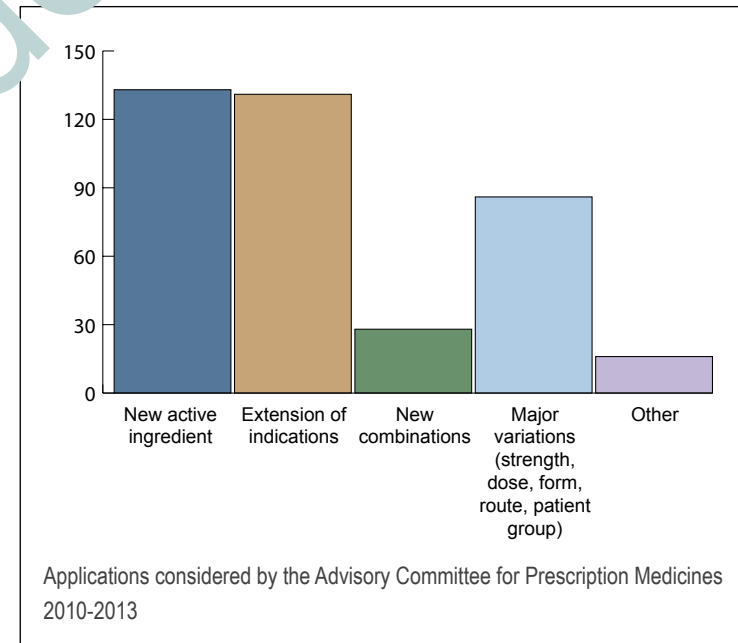
Current expertise

Committee members are appointed by the Minister and must have expertise in at least one of the fields specified in the Therapeutic Goods Regulations.

Our current 30 members together cover an impressively wide range of expertise, come from highly regarded Australian institutions and include professors and a number of Members of the Order of Australia.



The agenda papers for one meeting in 2003 sometimes weighed four kilograms. Nowadays, all the information is able to be viewed on laptops or tablets, but the amount of information has not diminished: for a single agenda item one committee member was asked to read almost 8000 pages.



Types of medicines considered by ACPM

Looking at the medicines considered by ACPM over the past four years, we can see the impacts of demographic changes in our community and the changing patterns of illness.

With our ageing population and lifestyle-related problems such as obesity, the health landscape is now dominated by chronic illnesses such as diabetes and cancer.

New vaccines continue to be an important preventative health strategy, with twenty positive recommendations for vaccines, including vaccines for invasive bacterial illnesses such as pneumococcal, meningococcal and haemophilus influenzae B (HiB) disease, and vaccines for pandemic influenza strains A(H1N1) and A(H5N1) and the first quadrivalent seasonal influenza vaccine.

Cancer

It is not surprising that of the applications supported by the ACPM over the last four years, 24 new medicines and 28 extensions of indications and other major variations were for cancer treatment. Not only the sheer volume of new cancer medicines, but the complexity and mode of action have changed over time.

The era of 'personalised medicine' has seen new cancer treatments linked to particular genetic variations, necessitating identification of these 'biomarkers' to identify the eligible cancer subgroup for whom these medicines

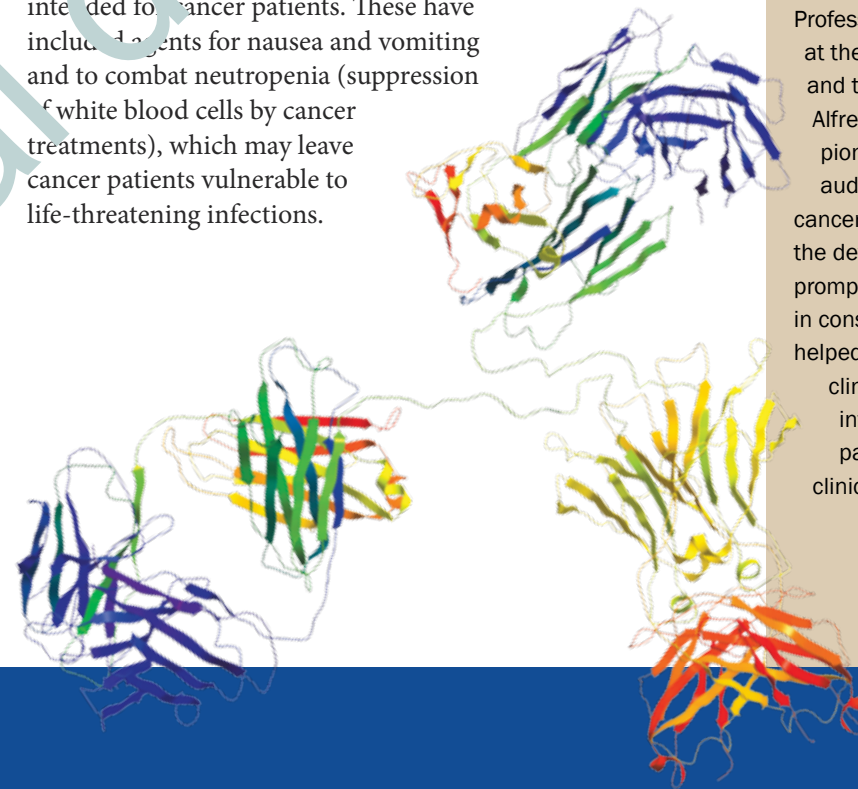
will potentially work most effectively. These medicines (for example trastuzumab emtansine) are now often delivered clinically to patients in much smaller quantities, with the part of the medicine that is toxic to cancer cells bound to an antibody (ie. an antibody-drug conjugate), which increases their effectiveness and reduces side-effects by targeting cancer cells. Monoclonal antibody agents, or 'mabs', have not only revolutionised cancer care, but have challenged our ACPM members to be current with advances in medicine development.

ACPM has also made ten positive recommendations for medicines that, while not for treating cancer, are intended for cancer patients. These have included agents for nausea and vomiting and to combat neutropenia (suppression of white blood cells by cancer treatments), which may leave cancer patients vulnerable to life-threatening infections.



Professor Martin Tattersall AO, ScD, MA, MD, FRCP, FRACP, seventh chair, 1997–2007

Professor Tattersall works at the University of Sydney and the Royal Prince Alfred Hospital. He has pioneered consultation audio-recordings to assist cancer patient recall and the development of question prompt lists for patient use in consultations. He has helped to develop a cancer clinical trial website to inform Australian cancer patients of available clinical trials.



Diabetes

Diabetes, particularly type 2, has increased significantly over the past two decades: the rate of diabetes in the Australian population was 1.5% in 1989, but 4.2% in 2011-12 (AIHW, 2013). Over the last four years the ACPM has recommended the registration of 13 new hypoglycaemic agents, with new classes of agents including the 'gliptins' and the emergence of fixed dose combination medicines, often in combination with the older, but still highly-effective, biguanide medicine metformin. These have improved the variety of treatment options available for patients.

CNS medicines

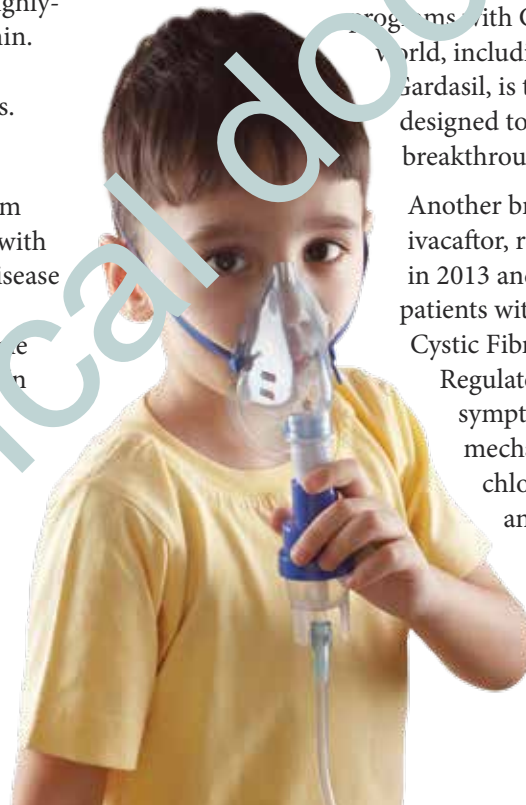
The treatment of central nervous system disorders has progressed significantly with three new medicines for Parkinson's disease and seven positive recommendations for registration of medicines for multiple sclerosis during this four year period. In particular, the orally-acting agents for multiple sclerosis have been a breakthrough in the treatment of this degenerative neurological disorder. ACPM has recommended authorisation of three medicines to treat epilepsy and six for mental health indications, including four for schizophrenia.

Breakthroughs

The advice of the ACPM was the key decision maker in assessing the expanding number of important new therapies.

ACPM made a world leading recommendation to register the Australian-developed quadrivalent vaccine for human papillomavirus to prevent cervical cancer in women (March 2010). Subsequently in August 2011, ACPM recommended broadening the indication for use in young men. Vaccination programs with Gardasil are now operating throughout the world, including developing countries. This vaccine, Gardasil, is the first registered vaccine in the world designed to prevent cancer: what an important breakthrough!

Another breakthrough in modern medicine is ivacaftor, recommended for authorisation by ACPM in 2013 and used to treat the 5% of cystic fibrosis patients with the genetic mutation G551D in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) protein. Instead of relieving symptoms, ivacaftor targets the actual disease mechanism of cystic fibrosis, by increasing the chloride transport of G551D CFTR. This is an example of a medicine being suitable for a subgroup of patients who need to be identified using a genetic biomarker before the medicine is used.



Other important advances and emerging trends

Other important recommendations by ACPM have been in the area of antiviral treatments for Hepatitis B and Hepatitis C. And there have continued to be improvements in combination therapies for HIV AIDS—a well known example of a previously untreatable disease becoming more manageable as a result of new medicines.

The first new oral anticoagulant (NOAC) for the prevention of venous thromboembolism was authorised in 2010, with subsequent recommendations for registration of several other in-class agents. For suitable patients, the NOAC medicines mean that for the first time many do not need regular 'INR' blood tests, which are necessary for the older oral anticoagulant warfarin.

One worrying trend is the decreased number of new antibiotics in the development 'pipeline' and the rise and use of antimicrobial resistance in the hospital and community settings. While ten positive recommendations have been made by ACPM for the entire anti-infective class, including systemic anti-fungal agents, topical antibiotics, and inhaled agents for chronic lung infection, only two antibiotics have been authorised for systemic treatment of bacterial infections in the last four years.

Objective and impartial advice

It is essential that the advice given by ACPM is objective and impartial. Occasionally a committee member will have a personal interest in a particular matter. When this situation arises:

- The member declares the potential conflict of interest.
- The committee, in the absence of the member, decides whether the member may be present during relevant deliberations.
- All declarations and how they are dealt with are recorded in the meeting minutes.

The TGA decision maker is aware of all this before making the final decision.

The depth of knowledge of ACPM members and their significant level of expertise across a wide range of clinical disciplines has meant that TGA decision makers have received the very best advice prior to our registration decisions for prescription medicines.



Associate Professor Geoffrey Herkes MB, BS, PhD, FRACP, last chair of ADEC (2008-2009), first chair of ACPM (from 2010)

Associate Professor Herkes provides expertise in neurology, conducts research in neuropharmacology and epilepsy, and works at the Royal North Shore Hospital, where he was Head of the Department of Neurology from 2008 to 2013.

Further reading

Australian Institute of Health and Welfare (AIHW) 2013
<<https://www.aihw.gov.au/diabetes/>>

Australian Dictionary of Biographies
<<http://adb.anu.edu.au/>>

JDRF website 2013 <<http://www.jdrf.org.au/>>

McEwen J. A history of therapeutic goods regulation in Australia. 2007
<<http://www.tga.gov.au/about/history-tg-regulation.htm>>

McEwen J. Australian Drug Evaluation Committee (ADEC) 40th anniversary. 2004. *Int J Pharm Med* 18: 225–226.

Report of the Australian Drug Evaluation Committee, June 1963–December 1966. available from three public libraries: <<http://trove.nla.gov.au/work/21724002?q&versionId=26106912>>

TGA website <www.tga.gov.au>

Acknowledgements

Particular thanks are due to Dr John McEwen, author of *A history of therapeutic goods in Australia*; the chairs Prof Mervyn Eadie, Prof Susan Pond, Prof Martin Tattersall and A/Prof Geoffrey Herkes, and the Royal Australasian College of Physicians for provision of photographs.

Cover illustration

Coloured computer-generated ribbon diagrams of a monoclonal antibody—a type of medicine that is creating many new and exciting treatment possibilities.

In the background are much larger scale diagrams of the thalidomide molecule—it was the inappropriate use of thalidomide that led to the formation of the Australian Drug Evaluation Committee.

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