

COMMITTEE ON CHILDREN AND YOUNG PEOPLE

INQUIRY INTO THE USE OF PRESCRIPTION DRUGS AND OVER-THE-COUNTER MEDICATIONS IN CHILDREN AND YOUNG PEOPLE

ISSUES PAPER No. 1 BACKGROUND ISSUES

Submissions and Further Information

The Committee on Children and Young People invites written comment from interested organisations, groups and individuals regarding any of the matters raised in this Issues Paper. Ideally, comments should be forwarded to the Committee on Children and Young People, Parliament House, Macquarie Street, SYDNEY NSW 2000 by Monday 29 July 2002, although the Committee will continue to accept and consider comments after that date. Submissions may also be forwarded by fax on (02) 9230 2928, or email: children@parliament.nsw.gov.au. Further information on the Inquiry or on how to make a submission can be obtained from Mr Ian Faulks, Manager of the Committee, on (02) 9230 2161. Further information about the Committee on Children and Young People can be viewed on the Committee's web site at: www.parliament.nsw.gov.au/gi/commits/children.

INTRODUCTION

This paper is the first in a series of six Issues Papers produced by the Committee for Children and Young People for the inquiry into the use of prescription drugs and over-the-counter medications in children and young people. This paper provides an overview of the background issues relevant to the series. It includes information about the Committee for Children and Young People, the inquiry, and the purpose of the Issues Papers. Contextual issues of relevance to the series are examined, including legal and regulatory issues. Terminology and acronyms used throughout the Issues Papers are also set out.

Issues examined in this paper

- Outline of the Committee on Children and Young People
- Outline of the Committee's inquiry into the use of prescription drugs and medication by children and young people
- Outline of the nature of these issues papers
- Overview of prescription drugs and medication as the focus of this inquiry
- Outline of the inquiry's focus on 'children and young people'
- Settings where the use of prescription drugs and medication by children and young people occurs
- Responsibility framework
- Legal and regulatory framework
- Overview of the use of prescription drugs and medication by children and young people
- Obtaining prescription drugs and medication
- Doctors and children and young people as patients
- Access and equity issues
- Lack of information about the effects and potential side effects of prescription drugs and medication
- Prescription drugs and medication in the context of illicit drugs

COMMITTEE ON CHILDREN AND YOUNG PEOPLE

The Committee on Children and Young People was established in August 2000, to examine issues affecting children and young people in New South Wales. The Chair of the Committee is Mr David Campbell MP. The current members of the Committee are: Ms Diane Beamer MP; Ms Marie

Andrews MP; Mr Wayne Smith MP; Mrs Judy Hopwood MP; Mr John Cull MP; Ms Jan Burnswoods MLC; the Hon Peter Primrose MLC; the Hon Henry Tsang MLC; the Hon Don Harwin MLC; and the Hon Alan Corbett MLC.

THE INQUIRY

The inquiry into the use of prescription drugs and over-the-counter medications in children and young people commenced in January 2001. It is the first general inquiry of the Committee on Children and Young People. The subject matter of the inquiry reflects the Committee's interest in, and commitment to, issues of health and wellbeing that affect the children and youth of New South Wales.

Terms of reference

The terms of reference for the inquiry provides for the examination of:

- the use of drugs and over-the-counter medications in children and young people as a mental health strategy;
- administration of prescription drugs and over-the-counter medications by non-parental carers (eg. schools, child care workers, juvenile justice workers etc);
- prescription and use of drugs and over-the-counter medications developed for adults;
- challenging behaviour and the use of psychotropic drugs in children;
- purposive 'doping' or sedating of children;
- the ability of children to effectively self-administer over-the-counter medications and drugs;
- use of drugs and over-the-counter medications in sport activities involving children and young people;
- possible alternatives to use of drugs and over-the-counter medications in children and young people;
- use of alcohol and tobacco by children and young people; and
- any other relevant matters.

Submissions to date

The Committee received over 90 submissions throughout 2001 and held several public hearings in the latter half of 2001. Written and oral submissions were received from individuals and organisations in several fields including medicine, child care, education, child welfare, and government. Within the medical field submissions were received from a number of specialities including paediatrics, adolescent health, nursing, psychiatry, psychology, and family medicine. The Committee was also pleased to receive a number of submissions from individuals in their private capacity.

The submissions and the evidence given to the Committee at the hearings form the basis of these Issues Papers. Additional research has also been undertaken. The Committee was reassured of the

relevance of its inquiry by the number of submissions that expressed support for inquiry as timely and important,¹ particularly in relation to the use of psychotropic drugs for challenging behaviour.²

Children's focus groups

The Commission for Children and Young People held focus groups and discussions with children and young people to examine issues raised by the Inquiry. The information derived from the groups and discussions formed the basis of its submission to the inquiry. The Committee has included comments made by children and young people in the focus groups throughout the Issues Papers (in boxed italics marked: '**Children's focus groups**'). The Committee is keen for further direct input to the inquiry by children and young people.

Other research into these issues

Some of the issues covered by the Inquiry have generated a great deal of research by various organisations and individuals. In particular, the use of anti-psychotic drugs such as Ritalin, for children with challenging behaviour has been much researched and debated. For example, the Social Development Committee of the South Australian Parliament recently completed an inquiry into the impact of Attention Deficit Hyperactivity Disorder ('ADHD') on South Australian individuals, families and the community.³ **Issues Paper No. 5**, which addresses this issue, draws together this earlier research as well as other information received through submissions.

Other issues covered by this inquiry however, have not been examined in detail in New South Wales or other Australian jurisdictions. In this sense the Committee is charged with an important and timely opportunity to review and set out the information provided to it through submissions and additional research.

THE ISSUES PAPERS

Purpose

These Issues Papers represent a summary of the major issues presented to the Committee through submissions and in evidence to date. The aim is to encourage a stronger and more informed public discussion in relation to the use of prescription drugs and over-the-counter medications in children and young people.

It is hoped that the Issues Papers will elicit further submissions from individuals and organisations, and thus assist the Committee in obtaining a comprehensive understanding of the issues involved and the areas of interest and concern.

Possible recommendations for change that have been proposed in submissions have been set out in the Issues Papers. The Committee seeks feedback

on their necessity and desirability for the purpose of framing its recommendations for the final report of the inquiry.

Titles of the Issues Papers

No. 1 Background issues

No. 2 Administration of prescribed drugs and over-the-counter medications to children and young people by non-parental carers and self-administration.

No. 3 Children and young people and the misuse and abuse of prescription drugs and over-the-counter medications.

No. 4 The use by children and young people of prescription drugs and over-the-counter medications developed for adults.

No. 5 The use of prescription drugs as a mental health strategy for children and young people.

No. 6 Alternatives to the use of prescription drugs and over-the-counter medications by children and young people.

PRESCRIPTION DRUGS AND MEDICATION

The term 'prescription drugs' is used to distinguish medicinal drugs that require a prescription from medicinal drugs and other medicinal substances which don't require a prescription (referred to as 'medication'). All prescription drugs and over-the-counter medications are listed in relevant schedules of the NSW Poisons List which regulates how they are to be stored or sold.

Prescription drugs

'Prescription drugs' are therapeutic drugs which can only be purchased with a prescription from a medical professional. Prescription drugs are listed in Schedule 4 of the Poisons List. There are a wide variety of prescription drugs used in the treatment of various ailments suffered by children and young people.

Some of those mentioned in submissions and by children in the focus groups run by the Commission for Children and Young People are listed below.

Depressants:	Sleeping pills, Tranquillisers
Stimulants:	Ritalin, Dexamphetamine
Opiates:	Morphone, Codeine, Pethidine
Others:	Roaccutane (treatment of cystic acne) Oral contraception Antibiotics

Medications

In the Issues Papers 'medications' refers to therapeutic drugs and products that can be bought without a prescription.

"Pain killer type things: Nurofen, Panadol, Panadine, and cold and flu tablets"
Children's focus groups

There are two broad categories of over-the-counter medications.

Open seller - medication that may be brought from a supermarket or pharmacy with no restrictions. Listed in Schedule 2 of the Poisons List. For example, *Antihistamines* (non (low) sedating), *cough and cold preparations* and *paracetamol* (small packets).

Pharmacy only - medication which does not require a prescription but is only available from a pharmacist. This type of medication is usually displayed behind the counter and can only be obtained if served by a pharmacist. These drugs are listed in Schedule 3 of the Poisons List. For example, antihistamines (sedating) and asthma inhalers.

In some instances, it is the type of medication that dictates whether it is classified as an open seller and in others it may be the packet size of a particular drug. For example, smaller packet sizes of paracetamol are available openly, while bulk packets of paracetamol are only available from a pharmacist.

CHILDREN AND YOUNG PEOPLE

In the context of the inquiry the term 'children and young people' is used to describe those people below the age of 18 years. Legally, such people are generally referred to as 'minors'. Throughout the paper children and young people will be collectively referred to as 'minors'.

The distinction between 'young people' and 'children' is not specifically defined in terms of age, however, in general the transition point is held to be the ages of 12/13 years.

SETTINGS

The issue of the use of prescription drugs and over-the-counter medications by children and young people involves several physical settings including: the home; school; child care centres; juvenile justice centres; community care centres; and health care facilities. The settings in which prescription drugs and over-the-counter medications may be administered to children and young people is an important area of interest for the Committee.

RESPONSIBILITY FOR THE HEALTH OF CHILDREN AND YOUNG PEOPLE

Primary responsibility for the health of children and young people rests with parents or guardians. However, the use of prescription drugs and over-the-counter medications by children and young people occurs outside the home in several different settings. In such situations responsibility extends beyond parents and primary carers to non-parental carers. Indeed, in the broader context, responsibility also rests with governments and the community as a whole, given the recognised importance of promoting the health of children and young people. There are many government agencies at both State and Commonwealth levels that have responsibilities in this area. There are also many non-government organisations which may be involved in the use of prescription drugs and over-the-counter medications by minors. Understanding the extent of the involvement of these agencies and organisations is important to an understanding of the issues involved.

Parents

Parents have the primary role for administration of drugs and medications to children and young people, and for providing information about the safe and effective use.

Given the importance of this role that parents have in the management of their children's health and wellbeing, the Committee believes that it is imperative that parents are adequately educated and have adequate resources. Medical and family support services should provide the necessary information and support to parents and families: to disseminate clear and correct information about safe and appropriate use of medication; about their role in advising doctors about their children's symptoms in order to achieve an accurate diagnosis and management of the use of the medication; and about overall health aspects of the use of pharmaceutical's.

Parents who do not speak English or parents with other needs require special assistance in relation to information and support services.

Non-parental carers

'Non-parental carers' are those people, other than the parent or guardian of a child or young person who is caring for the child. There are many instances when a non-parental carer is charged with looking after children and young people. For example, teachers at school and carers in child care centres.

Medical profession

Various fields within the medical profession are involved in the issues explored in these Issues papers. This includes doctors, nurses, ambulance workers, pharmacists, paediatricians, psychologists, and psychiatrists.

Government agencies

Several New South Wales Government departments have responsibility for issues that are touched on by this inquiry. These include:

- Department of Community Services; and
- Department of Education and Training;
- Department of Health;
- Department of Juvenile Justice;
- Department of Sport and Recreation.

Other relevant New South Wales government agencies include the:

- Commission for Children and Young People; and
- Community Services Commission.

Commonwealth Government departments and agencies also have responsibility in some areas covered in the Issues Papers including:

- Australian Institute of Health and Welfare;
- Australian New Zealand Food Authority;
- Department of Health and Aged Care;
- National Health and Medical Research Council; and
- Therapeutic Goods Administration.

Non-government organisations ('NGOs')

There are a myriad of NGOs that work in areas related to the matters covered in the Issues Papers including organisations dealing with drug issues, organisations dealing with child welfare, peak bodies for professions in the medical, child care and education sectors, etc..

International

The *World Health Organisation* provides guidance on several issues examined in the Issues Papers such as advertising medicinal drugs.

OVERVIEW OF THE USE OF PRESCRIPTION DRUGS AND OVER-THE-COUNTER MEDICATIONS BY CHILDREN AND YOUNG PEOPLE IN NEW SOUTH WALES

Sources of information

The Australian Institute of Health and Welfare ('AIHW') notes the general difficulty of gaining a detailed understanding of the consumption of pharmaceuticals in Australia.⁴ When it comes to children and young people the difficulties seem to be magnified.

While various organisations in Australia collect statistical information relevant to various aspects of this inquiry, there are considerable gaps in information, particularly in relation to people below the age of 18. Many data sets relating to the use of prescription drugs and over-the-counter medications

either concern only adults, or do not differentiate between adults and children. For example, the AIHW publishes a series on statistics of drug use in Australia, which includes information on the use of prescription drugs.⁵ The data is collated from the records of prescriptions submitted for a subsidy payment under the Pharmaceutical Benefits Scheme ('PBS') and the Repatriation Pharmaceutical Benefits Scheme ('RPBS'). However, these statistics do not reveal the percentage of prescriptions that were issued to minors, because the data on prescriptions gathered by the PBS from chemists does not identify individual characteristics such as age.

Overall, the Committee is concerned about the apparent lack of information about the use of prescription drugs and medication by children and young people in New South Wales. However, there are some statistics available that help us piece together at least an outline the picture of the use of prescription drugs by children and young people in New South Wales.

The main information sources that have been brought to the Committee's attention are outlined below with some general statistics noted. Relevant statistics from these and other sources are referred to throughout the Issues Papers.

Australian Bureau of Statistics: The Australian Bureau Statistics ('ABS') gathers some statistics that relate specifically to the use of prescription drugs and medication, while others concern broader subjects and contain *some* information on prescription drugs and over-the-counter medications and children. Examples of relevant publications include: 'National Health Survey: Use of Medications, Australia'; 'Taking our medication'; 'Australian Social Trends 1997 – Protecting the health of our children'; and 'Australian Social Trends 1998 – The Use of Medication.'

National Drug Strategy Household Survey – DHAC: The *National Drug Strategy Household Survey* series has been the principal data-collection vehicle used to monitor trends in drug use in Australia. The survey is conducted by the DHAC and AIHW. Surveys have been conducted nationally in 1985, 1988, 1991, 1995 and 1998.⁶ The survey is conducted on people 14 years and older. It includes some questions on the illicit use of prescription drugs and over-the-counter medications. Another survey was conducted in 2001 and the results are due out shortly.

Australian School Students Alcohol and Drugs Survey: The Australian School Students Alcohol and Drugs Survey is a collaboration between State cancer council, State health departments and DHAC. The survey has been conducted every three years since 1984 with the last survey conducted in 1999. Until 1996, the main focus of the survey was on smoking and alcohol use, but since 1996 it has also included illicit drug use. The survey canvases a randomly selected sample of students aged between 12-17 years. The latest relevant report from the

survey is the *Australian secondary students' use of over-the-counter and illicit substances 1996*.⁷

Bettering the Evaluation and Care for Health – BEACH: The BEACH program is run the General Practice Statistics and Classification Unit, a collaborating unit of the University of Sydney and the AIHW. Its purpose is to describe aspects of general practice including the type of medical services provided by collecting detailed information on approximately 100 consecutive patients of a rolling sample of 1,000 GPs each year.⁸ The latest data published is for the period 2000-2001.⁹

In relation to children and young people, the data pertains to approximately 18,000 consultations with children aged under 18 in New South Wales. It includes details of medications prescribed by general practitioners in New South Wales or advised for over-the-counter purchase or provided from their fridge or drawer.¹⁰

Other research and data: The Committee is aware that other organisations and individuals are undertaking research and surveys in this area. For example, work is being done by medical researchers to gain a greater understanding about the use of prescription drugs and over-the-counter medications by children and young people.¹¹

The Committee is interested in receiving information on other available statistics in this area

General statistics of use of prescription drugs and over-the-counter medications

In a 1999 survey of secondary school students, analgesics were the most commonly used drug (licit or illicit). By the age of 12 over 95% of students had used analgesics in their lifetime with over 35% having used them in the week before the survey.¹²

General statistics of illicit use of prescription drugs and medication

A 1999 survey of secondary students found that the use of tranquillisers other than for medical purposes among students was low with 80% of students never having used tranquillisers.¹³

In the same survey the use of steroids without a doctors prescription was very uncommon, with around 2% of all students having ever used steroids. The results also suggested that the students who were using steroids used them regularly.¹⁴

Vaccinations

Immunisation is a simple, safe and effective way of protecting children against harmful diseases, including diphtheria, whooping cough, tetanus, polio,

measles, mumps, rubella, Haemophilus Influenza type b (Hib) and hepatitis B, which can cause serious complications and sometimes death.

The *Australian Childhood Immunisation Register* commenced in January 1996. The Register was developed in response to a decline in childhood immunisation in Australia and the alarming increase in preventable childhood diseases. Children under seven years of age enrolled in *Medicare* are automatically included on the Register. Children who are not eligible to enroll in *Medicare* can be added when a doctor or immunisation provider sends the details of a vaccination to the Register.

The Register records details of vaccinations given to children under the age of seven who live in Australia, helping Australian parents to ensure that their children grow up healthy and are fully immunised. The Register helps parents keep track of the first six years of their children's immunisation. It provides parents with a history statement when their child turns one, two and five years. Doctors, immunisation clinics, local councils, and some hospitals can provide vaccinations.¹⁵

When considering the rate of use of prescription drugs and over-the-counter medications in the community and within particular groups in the community (e.g., children and young people) it is important to consider a number of issues:

- Changes in community attitudes and perceptions to the use of various products to maintain or enhance good health and to cure various health conditions. Are community perceptions that are highly reliant on the use of pharmaceuticals fostering a culture of 'normalisation' of use of drugs and medications, including illegal drugs, by children and young people?
- How does the availability, quantity and cost of various pharmaceutical products on the market (marketing of various over-the-counter medications (including slimming products, energy products, dietary supplements, etc.) impact on the general health and wellbeing of children and young people. What is the impact of marketing strategies of pharmaceutical and health industries on the consumption of these products by children and young people?
- How does the rate of consumption of drugs, medications and other pharmaceutical products (including alternative medicine products) relate to trends in the general health and wellbeing of children and young people?

Research conducted by the General Practice Statistics and Classification Unit (a collaborating unit between the Australian Institute of Health and Welfare and the Sydney University), shows that each year, there are 9.5 million encounters between general practitioners and children and young people as patients, and there are 11 million medications prescribed, advised for over-the-counter purchase,

or supplied by general practitioners to children and young people in New South Wales.

The Committee heard evidence suggesting over-prescription of antibiotics in children, particularly by general practitioners and for children with viral upper respiratory tract infections. This issues is examined in further detail in **Issues Paper No 3**.

The Committee is interested in receiving further information regarding trends in the use of prescription drugs and over-the-counter medications by children and young people and the effects of this use on the health and development of children and young

ACCESS AND EQUITY ISSUES

There are many issues of concern in relation to the access of children and young people to paediatric and other health services in Australia. These range from the great disadvantage that clinical and health services for children and young people experience in comparison to those used by adults, and include the lack of clinical research, development and funding in these services to ensure safe and accessible products and therapies; to the inadequate access to quality services by children and young people from disadvantaged backgrounds or those with special needs.

Lack of access to adequate services and pharmaceuticals by children and young people contravenes the philosophy of equal access and equity regarded highly by all government agencies responsible for these services, including the objectives and goals of Australian Medicines Strategy of the Commonwealth Department of Human Services and Health: "to provide affordable and equitable access to necessary medications".

Cost of medication and services

In a 1995 publication the AIHW stated that socially and economically disadvantaged children experienced poorer health. Disadvantaged children were less likely to access health services and when they did, they were less likely to be able to afford the cost of medication.¹⁶

Advocacy and guardianship

Children and young people with disabilities, and particularly those living in out-of-home care, are more likely to be disadvantaged within the health care system, particularly in relation to their participation in direct decision making relating to their own health or in policies that impact on their health and wellbeing.

The Committee identified a considerable public concern in relation to the lack of advocacy procedures and mechanisms for organizations and agencies that work with children and young people. The Committee calls for further evidence in relation

to the adequacy of the advocacy system for children and young people in relation to health treatments.

Despite recent policy attention to the issue of guardianship of people with disabilities, the children guardianship system seems to be lagging far beyond the adult guardianship system. While the adult guardianship system sets out clear procedures for care and consent requirements in accordance with medical and other intrusiveness, children are often 'caught up' in a framework that includes their parents, carers, etc..

Vulnerable children and young people

Children with disabilities may undergo a complex medication regime and they often need assistance and supervision to ensure that they are taking their medication regularly and correctly. This process can be more difficult for some children with disabilities who do not live with their parents, and their correct use of medication depends on appropriate information being conveyed to the carer, the availability of the carer, etc..

Children and young people with intellectual disabilities may be further at risk from inappropriate use of psychotropic drugs that are commonly used for mental health disorders, such as drugs and medications that suppress and not treat the symptoms, or as restraints rather than a curative process (tranquilizers and anti-psychotic drugs). Often these drugs would produce adverse side effects in people with intellectual disabilities that exacerbate the pre-existing symptoms of the disability, which in turn can be misunderstood as part of the condition that need to be treated:

...people who have poor communication skills cannot tell you when they are in pain. So this does have a relationship, because often some of these aggressive behaviours may be hidden pain, demonstration that I am feeling pain but I cannot tell you...¹⁷

In relation to use of drugs and medications to treat challenging behaviour on people with disabilities, the Committee found that there are no clear monitoring systems that allow a thorough clinical assessment before a decision to use psychotropic medication is prescribed, and also the continuous review and monitoring of the use of the medication in a rigorous way. Such systems are particularly needed for people with disabilities in the out-of-home care, where clients tend to change residence and carers frequently.

The Committee is concerned that the health systems for treatment and care for people with intellectual disabilities are not adequately resourced and that people with permanent intellectual disabilities are often treated in the same way as people with mental health problems. The Committee is also concerned with the lack of medical research and professional resources into the treatment of intellectual disabilities and mental health for children and young people, which may lead to inadequate and hazardous treatment of people with these disabilities and disorders:

...We do not have a lot of evidence to know how the

drugs that are typically used with mental illness react to people who have more complex intellectual cognitive problems. For example, there is evidence that the overuse and incorrect use of medication in very young children can affect future brain development...¹⁸

Access to specialist doctors: paediatricians, child psychiatrists, youth doctors etc.

The Committee found that there are inadequate access and equity to specialist doctors, mainly due to the cost of these services, but also the availability of these doctors across all areas.

The Committee also found that the existence of specialised youth doctors and youth clinics could contribute very positively to a better children and youth health.

The Committee is concerned with evidence that children and young people with depression are experiencing difficulties in accessing specialist services, particularly with view that Australia has among the highest rate of youth suicide in the world. The treatment of depression is not dependent on specialised psychiatric services that are not covered by Medicare, and the Committee notes that there are many free community and mental health services. However, there seems to be a perception in the community that mental health issues must only be addressed by specialist services that are often too costly, and these believes would often lead to parents and young people not seeking help at all.

...in the national survey parents were asked why they did not use the services available and 50 % said that they were too expensive. That is a bit of a concern as there is supposed to be a free access to health care...¹⁹

National survey data suggests that children with complex multiple and severe disorders are rarely getting the help they need²⁰

PRESCRIPTION DRUGS AND MEDICATION IN THE CONTEXT OF ILLICIT DRUGS

It is useful to consider the use of prescription drugs and over-the-counter medications in the context of illicit drug use.

In terms of *abuse* the focus of Government and substance abuse support type organisations to date has mainly been on the abuse of illegal drugs, such as cannabis, heroin and amphetamines, and alcohol and tobacco.

The abuse of prescription drugs and over-the-counter medications is only recently finding its way onto the national drug agenda in Australia. This may be commensurate with the level of abuse of prescription drugs and over-the-counter medications compared to illicit drugs, but is also indicative of the fact that relatively little is known about the extent and nature of the problem.

The Commonwealth Government's *National Illicit Drugs Campaign* identifies a range of drugs as problematic, including some prescription drugs.²¹ Prescription drugs identified including depressants such as sleeping pills and tranquillisers, stimulants such as methylphenidate (Ritalin), and opioids such as morphine, codeine, and pethidine. The Campaign forms a component of National Illicit Drug Strategy. The first stage of the campaign targets parents and encourages them to talk to their children about illicit drugs. The second stage will target youth. The aim of the campaign is to prevent young people experimenting with illicit drugs in the first place by teaching young people and their families about the dangers of drugs and by promoting healthy family life.

"Lots of legal drugs can be addictive, but most people taking them don't know they're addictive or what the side effects are. There needs to be more information when a drug is prescribed or bought."

Children's focus groups

LEGAL AND REGULATORY FRAMEWORK

Registration of therapeutic goods

Therapeutic goods are broadly defined as goods which are represented in any way to be, or which are likely to be, taken to be for therapeutic use. The definition also encompasses ingredients or components in the preparation or manufacture of a substance to be used for therapeutic use.

Therapeutic use means use in connection with the prevention, diagnosing, curing of alleviating of a disease, ailment, defect or injury in persons or animals; the influencing, inhibiting or modifying of a physiological process in persons or animals; and the testing of the susceptibility of persons or animals to a disease or ailment²².

Scheduling of drugs in Australia²³

The *Standard for the Uniform Scheduling of Drugs and Poisons, September 1998* has been adopted by legislation in each Australian State and Territory. The Standard groups poisons into Schedules that require similar regulatory controls over their availability. Poisons are listed in nine schedules according to the degree of control recommended to be exercised over their availability to the public. Poisons for therapeutic use are included in Schedules 2, 3, 4 and 8 with progression through these schedules signifying increasingly strict controls.

Schedule 2 Pharmacy Medicine

Pharmaceuticals which can only be supplied through pharmacies: substances the safe use of which may require advice from a pharmacist and which should be available from a pharmacy only, or where a pharmacy service is not available, from a licensed person.

Schedule 3 Pharmacist Only Medicine

Pharmaceuticals which must be supplied by the pharmacist in the pharmacy: Substances, the safe use of which requires professional advice but which should be available to the public without a prescription.

Schedule 4 Prescription Only Medicine

Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription. In other words, substances which in the public interest should only be supplied upon written subscription of a medical practitioner, nurse practitioner authorised to prescribe the substances.²⁴

Schedule 8 Controlled Drugs

Drugs of addiction: Substances which should be available for use by require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Advertising²⁵

Commonwealth legislation governs the advertising of all 'therapeutic goods' in Australia. All advertisements and generic information provided about prescription drugs and medication directed to the public must comply with provisions of the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods Advertising Code* ('the Code').

As noted above, all prescription drugs and medication must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. Once the goods are on the ARTG the sponsor may begin to promote the product to consumers. The Code places controls on the advertising of therapeutic goods to ensure advertisements are socially responsible, truthful, appropriate and not misleading.

All advertisements for prescription drugs and medication directed to consumers, published or broadcast in mainstream media, must be approved before publication or broadcast.²⁶

In regard to children and young people, the Code specifically states that an advertisement for therapeutic goods must not be directed to minors. The only exemptions to this requirement are tampons, topical preparations for acne, sunscreen SPF15+; condoms and personal lubricants; bandages and dressings; devices for management of chronic conditions under medical supervision; cold sore preparations and lip balm.²⁷

Products containing Schedule 3, 4 or 8 ingredients cannot be advertised to consumers unless the ingredient appears in appendix H of the Standard for

the Uniform Scheduling of Drugs and Poisons.²⁸ Prescription drugs cannot be advertised. You can advertise some Schedule 3 and all Schedule 2 drugs. Information about advertising on the Internet is set out below.

Labeling

The *Therapeutic Goods Act (Cth)* also governs the appearance and content of labels.

Pharmaceutical Benefits Scheme

Most medicines available on prescription are subsidised under the Commonwealth Government's Pharmaceutical Benefits Scheme ('PBS'). The PBS helps improve the health of all Australian residents by ensuring they have access to necessary and lifesaving medicines at an affordable price.²⁹

The Schedule of Pharmaceutical Benefits lists all items approved for subsidy under the PBS. Submissions for PBS listing of new drug products are normally made by the sponsor or manufacturer, however submissions from medical bodies, health professionals, or private individuals and their representatives may also be considered.

The Pharmaceutical Benefits Advisory Committee assesses applications for listing of medicines on the PBS to ensure that all products listed as benefits meet the criteria specified in the National Health Act. The criteria for listing include efficacy and safety compared to other available therapies (including non-drug treatments) and cost-effectiveness.

Medicare

Children and young people are generally listed on the same Medicare card as their parent's. However, young people over the age of 15 years may be enrolled on their own Medicare card. To transfer a person over the age of 15 years on to a Medicare card of their own they will need to attend a Medicare office with identification and complete an application.³⁰

Consent to medical treatment by children and young people

Until a child is old enough to consent to his or her own medical treatment, prescriptions can only be given for a minor with the consent of the minor's parent or guardian.

When a young person is competent to consent to their own medical treatment, she or he can receive a prescription without parental (or guardian) consent.

The Commissioner for Children and Young People advised the Committee that issues of confidentiality and consent to health care of young people were major concerns raised by representatives of more than thirty youth and health-related organisations at a National Youth Health Summit organised by the

Australian Medical Association held in Canberra in July 2001.³¹

The Commission for Children and Young People has lobbied the Government to clarification of the law in this area.

Possible recommendation

The New South Wales government clarify the law relating to the consent of minors to medical treatment and health professionals' obligations of confidentiality towards young patients.³²

NSW Health Guidelines

The prescription of any drug can only be supplied by medical practitioners who are subject to NSW Health Department Guidelines.³³

Illegal use and possession of prescription drugs

The use of prescription drugs without a prescription from a doctor is illegal (as well as very dangerous).

Possession of prescription drugs without a prescription is also illegal:

'Using benzos is illegal without a prescription from a doctor, or keeping, selling or giving benzos to someone else is illegal. If you are caught you could get penalties starting from a \$2,200 fine and/or two years in jail.'

Discrimination

New South Wales and Commonwealth anti-discrimination legislation renders it unlawful to discriminate against a person on the grounds of their disability, in relation to many aspects of public life including education, and the provision of goods and services and accommodation.³⁴

Given the wide definition of 'disability' under the legislation it is likely that many of the illnesses requiring the use of prescription drugs and medication would be covered by the legislation.

Discriminating against a child or young person because of their use of prescription drugs or medication may be unlawful.

OBTAINING PRESCRIPTION DRUGS AND OVER-THE-COUNTER MEDICATIONS

Pharmacies

As indicated in the previous section, prescription drugs can only be sold in pharmacies, while medications can be sold in pharmacies or other retail stores depending on whether they are Schedule 2 drugs etc.

People may ask a pharmacist for advice about pharmacist only or open seller over the counter medication. Or, they may decide for themselves.

The Pharmacy Guild of Australia has a code of practice regarding the sale of prescription drugs and medication in its member pharmacies.³⁵ However, it does not relate specifically to children.

Pharmacists have an important role in advising and informing children and young people about the appropriate use of medication, dosages and side effects, in a non-stigmatising manner. Pharmacists are placed in a favourable position to reinforce a GPs advice, to provide further information about the medication or about alternatives in a convenient manner.

Possible recommendation

That the Pharmacy Guild of Australia develop and implement strategies to improve their relationships and image with young people and families and that young people are involved in designing this strategy.³⁶

Supermarkets and other outlets

As noted above, Schedule 2 medication are 'open sellers' which means that they are available from supermarkets or other retail stores that stock such products. There is no regulation of these products and no age requirement for their purchase.

From your doctor

Doctors prescribe drugs and may recommend certain over-the-counter medications.

Sometimes a general practitioner will provide drugs directly to a patient that are only available on prescription. For example, a general practitioner may provide a teenage girl with a sample packet of the oral contraceptive pill to try for a 'trial'. A doctor may also provide patients with a sample packet of ant depression medication to trial.

The interaction between doctors and children and young people as patients is examined later in this paper.

Obtaining medical information and products over the Internet

The Committee is interested in the ability of children and young people to obtain prescription drugs and medications and related information over the Internet.

The Committee is aware that if used cautiously, the Internet can be an easy source of information about health concerns. However, it is concerned that the Internet also offers promoters of fraudulent health products easy access to consumers, including children and young people from all over the world.

The Internet poses particular challenges in the regulation of direct-to-consumer advertising of prescription drugs.³⁷ In Australia, advertising prescription drugs for sale directly to consumers is prohibited by Commonwealth law. (check the source of this).³⁸ The promotion of pharmaceuticals to the general public via the Internet is also prohibited by the Australian Pharmaceutical Manufacturers Association (APMA) Code of Conduct.³⁹

However, both the United States and New Zealand permit direct-to-consumer advertising of prescription drugs.

There are several issues to note regarding medical products purchased over the Internet:⁴⁰

- Not all symptoms need medical treatment – people may be lured, by Internet advertising to purchase and use medical product unnecessarily.
- For all but the simplest of ailments, a health care professional should generally be consulted before a person decides to treat themselves, or change medication.
- Products may not be what they seem: Safety, efficiency and quality assurance may be lacking; Labeling may differ from country to country – products with the same name may be different in different countries; and Instructions for use may be inadequate.
- Products may be fraudulent and harmful to health. Health scams not only waste consumers' time and money, but in extreme cases may harm their well being, especially if they abandon traditional or prescribed treatments in favour of 'miracle cures'.
- If it sounds too good to be true, it probably is. Beware of products or treatments that are advertised as a quick and effective cure-all for a wide range of ailments or for an undiagnosed pain. Be cautious of testimonials claiming amazing results. Watch out for promoters who use phrases such as 'scientific breakthrough' and 'miraculous cure'.
- Reimbursement may not be possible.
- Products bought from other countries may not be allowed into Australia.
- Your personal information (as well as credit card details) may not remain confidential

The Committee notes that the Australian Competition and Consumer Commission (ACCC) and other consumer and health protection authorities from Australia and about 20 other countries conduct a yearly 'Internet Sweep' to check thousands of web sites to uncover "shonky" health claims.

The Pharmacy Guild of Australia has produced three facts sheets providing advice to consumers.⁴¹ While

they do not specifically address the issue of access by children and young people the advice they give is relevant to children and young people as well as adults.

The World Health Organisation has published a guide to finding reliable information on medical products on the Internet.⁴²

Issues of concern to children and young people

The issues listed above are relevant to children and young people as well as adults. Among the sites that might appeal to young people are those promoting products that claim to promote weight loss, promising extraordinary results by using pills, liquids and devices and reduce blood alcohol levels or the effects of hangovers.

The Committee would like to hear from people with particular concerns about children obtaining medical information and products over the Internet.

The Committee welcomes information about the availability of prescriptions drugs and medications over the Internet and concerns regarding access by children and young people

DOCTORS AND CHILDREN AND YOUNG PEOPLE AS PATIENTS

The ability of children and young people to consent to medical treatment was outlined above. A second key element to the ability of children and young people to access health care and prescription drugs when required is their ability to seek the advice of a doctor.

Several submissions to the inquiry addressed the issue of the ability of children and young people to confidently and comfortably consult a doctor.⁴³

The availability of youth friendly general practitioners (and pharmacists) is very important in achieving appropriate use of drugs and medications by children and young people. Evidence has shown that children and young people feel more comfortable with a general practitioner who engages in a friendly discussion directly with the child or young person, is able to communicate with them and has a high regard for confidentiality.

"A separate youth doctor might be good because you could talk to them about things that you wouldn't want to talk to your parents or normal family doctor about."

"Doctors should just spend some time chatting. Gain some trust. Kick my parents out"

Children's focus groups

Confidentiality also seems to be a big issue for children and young people. For example, a teenage

girl who is seeking a prescription for the oral contraceptive pill may have concerns that her parents may find out, particularly if the doctor is a family doctor.

Reassuring patients about the duty of confidentiality owed to them by doctors may allay this fear.

I think doctors need to improve their doctor/patient skills in the areas of communication skills and confidentiality
Children's focus groups

The Commission has made the following suggestion for improve the interaction between children and young people and the medical profession.⁴⁴

Possible recommendation

That the Royal Australasian College of Physicians develop programs on engaging young people as part of a doctor's formal Continuing Medical Education, to enhance their skills in engaging, communicating with and treating young people.

LACK OF INFORMATION FOR CHILDREN AND YOUNG PEOPLE ABOUT PRESCRIPTION DRUGS AND MEDICATION

The effective use of drugs and medications is directly connected to the availability of accurate information about the product and the condition being treated, to children, young people and their parents.

A re-occurring theme in the submissions received by the Committee was the lack of information for children and young people, as well as adults about prescription drugs and medication.

The Committee has found that the information given to parents and their children about medications is often limited and confusing. There is no adequate education provided to children and young people about the dangers of sharing of drugs and medications with others, the possible danger of using the medication together with other medication or illegal drugs.

The Committee received evidence that children are more likely to use medication according to the directions on the prescription than teenagers, possibly due to parental supervision. The Committee also heard that adolescents are more likely to share medication with others, not to finish the course of medication, or to use over-the-counter medication inappropriately, for example, using laxatives as a slimming aid, or not taking some tablets of the pill in order to suppress menstruation.

Education materials at school are limited to illegal drugs, which severely disadvantages children and young people in relation to making informed choices about the use of pharmaceuticals. The educational emphasis on illegal drugs only, fosters a perception that over-the counter medications are safe.

The Committee was advised that only a small portion of all marketed drugs has been studied in children, and a majority of drugs that are commonly used or could potentially be used in children are often not licensed for such use. This is addressed in **Issues Paper No. 4**.

TERMINOLOGY USED THROUGHOUT THE ISSUES PAPERS

Antibiotic	A wide group of medications used in the treatment of infections caused by bacteria.
Analgesics	Preparations for the relief of minor aches and pains containing one or more of the following: salicylic acid; codine; other non-steroidal anti-inflammatory drugs or paracetamol.
Benzodiazepines	A group of drugs called minor tranquilisers prescribed by a doctor to help people with anxiety or sleep problems. There are approximately 30 different types and each is sold under several brand names. Eg. diazepam is sold as Valium or Antenex.
Complementary and alternative medicine	A group of therapeutic and diagnostic disciplines that exist largely, but not exclusively, outside the institutions where conventional health care is taught and provided. It includes a wide range of medicines and therapies such as acupuncture, naturopathy, diets, massage, and herbal medicine.
Children	People under the age of 12.
Child care centres	Includes, day care, after school hours care, preschool etc.
Disability Services	Large institutional, group homes, hostels and mini residential centres providing residential accommodation to children, young people and adults with disabilities.
Mental illness	A general term that refers to a group of illnesses affecting the mind.
Non-parent carers	People apart from parents and guardians who, from time to time, are responsible for the care of children and young people, including teachers, child care workers, juvenile justice workers.
NSW Poisons List	The <i>NSW Poisons List</i> lists poisons into nine schedules according to the degree of control recommended to be exercised over their availability to the public.
Obsessive Compulsive	The main features of obsessive-compulsive disorder are recurrent obsessions

Disorder	and/or compulsions.
Off label	Drugs used for groups other than those approved by regulatory bodies. For example, drugs designed and tested for adults and used on children.
Out of home care	Care provided for a child or young person away from their usual home, by a person who is not their parent or relative, for reasons of care and protection.
Over the counter medication	Medication that can be bought without a prescription. Includes substances such as antacids, analgesics, cough mixtures, anti-fungals.
Paediatrician	Paediatricians provide specialist medical services to children from birth up to and including adolescence.
Parent	Includes parents <i>and</i> guardians unless stated otherwise.
Pharmacist	Pharmacists compound and dispense pharmaceuticals and other drugs and medicines and conduct research on production, storage, quality control and distribution of drugs and related supplies.
Polypharmacy	The use of two or more drugs in combination.
Prescription drugs	Drugs for which a prescription is required.
Prn	<i>Pro re nata</i> - medication that is prescribed for use 'as required' rather than according to a predetermined administration schedule.
Psychotropic drugs	The collective term given to the wide ranging medications used for mental health problems.
Schedule 8 drugs	Drugs contained with Schedule 8 of the <i>NSW Poisons List</i> , which are addiction producing or potentially addiction producing.
Tourette syndrome	A neurological disorder characterised by involuntary body movements and vocalisations called tics.
Young people	People between the ages of 12 and 18.

ACRONYMS USED THROUGHOUT THE ISSUES PAPERS

AAPTC	Australian Association of Paediatric Teaching Centres
ACCC	Australian Competition and Consumer Commission
ACWA	Association of Child Welfare Agencies
ADHC	NSW Department of Ageing, Disability and Home Care
ADHD	Attention Deficit Hyper-activity Disorder
ADRAC	Adverse Drug Reactions Advisory Committee
ANZFA	Australia New Zealand Food Authority
ASDA	Australian Sports Drug Agency
APMA	Australian Pharmaceutical Manufacturers Association
BEACH	Bettering the Evaluation and Care of Health
CAM	Complementary or Alternative Medicine
CCYP	Commission for Children and Young People (NSW)
CRC	Convention on the Rights of the Child
CSC	Community Services Commission (NSW)
DHAC	Commonwealth Department of Health and Aged Care
DoCS	Department of Community Services (NSW)
GP	General Practitioner
HIC	Health Insurance Commission
NESB	Non-English Speaking Background
NGO	Non-Government Organisation
NHMRC	National Health and Medical Research Council
 OCD	Obsessive-Compulsive Disorder
OTC	Over-The-Counter
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
TS	Tourette Syndrome
WHO	World Health Organisation

¹ Evidence from Dr Daryl Efron, Centre for Community Child Health, Royal Children's Hospital, Melbourne, Royal Australian College of Physicians, 11 September, 2001, p 38.

² Submission 11, Mr Philip Barton; Submission 12, Mr Graham Turner; Submission 16, Ms Anne Babb; and Submission 30, Ms Helen Dickenson; Submission 28, Erik and Rita Levin.

³ For further information see the Committee's website at: www.parliament.sa.gov.au/committee/stand06.shtml

⁴ p 24.

⁵ The latest publication is: Drug Statistics Series Vol 8, 'Statistics on Drugs Use in Australia 2000', Miller M, Draper, G, *Australian Institute of Health and Welfare*, Canberra, May 2001. Note that prior to 1999 data was also sourced from the Pharmacy Guild Survey of community pharmacies.

⁶ The report on the results of the 1998 survey can be found on the National Drug Strategy website at:
www.nationaldrugstrategy.gov.au

⁷ *Australian secondary students' use of over-the-counter and illicit substance in 1996*, Monograph Series No. 33, Commonwealth of Australia 1999.

⁸ *Australian Bureau of Statistics*, 'Illicit Drug Use, Sources of Australian Data', 2001.

⁹ Britt H, et al, *General Practice Activity in Australia 2000-01*, AIHW (General Practice Series No. 5).

¹⁰ Submission 51, Dr Helena Britt, Associate Professor and Director of Family Medicine Research Centre, GP Statistics and Classification Unit, University of Sydney.

¹¹ For example, Dr Lim from the Royal Children's Hospital in Melbourne is conducting a survey of medication usage by children from English speaking families in Melbourne: Submission 93, Dr Noel Cranswick, Director, Australian Paediatric Pharmacology Research Unit, Royal Children's Hospital, Melbourne.

¹² *Australian secondary students' use of over-the-counter and illicit substance in 1996*, Monograph Series No. 33, Commonwealth of Australia 1999, p 3 and 31. Note that these statistics do not distinguish between medical and non-medical use.

¹³ *Australian secondary students' use of over-the-counter and illicit substance in 1996*, Monograph Series No. 33, Commonwealth of Australia 1999, pp 3 and 31.

¹⁴ *Australian secondary students' use of over-the-counter and illicit substance in 1996*, Monograph Series No. 33, Commonwealth of Australia 1999, pp 5 and 32.

¹⁵ For further information about the register see the HIC web site at:
www.hic.gov.au/yourhealth/our_services/aacir.htm

¹⁶ Mathers' (1995) xxx

¹⁷ Parmenter, p.34

¹⁸ Evidence of Professor Parmenter, 18 June 2001, p. 31.

¹⁹ Evidence of Professor Rey, 18 June 2001, p.37.

²⁰ Evidence of Professor Raphael, 18 June 2001, p 25.

²¹ For information about the campaign view the web site at:
www.health.gov.au/pubhlth/nidc/index.htm

²² Therapeutic Goods Act, Sect. 5

²³ The Information in this section is based on the Pharmacy Guild of Australia's pamphlet 'Australian Drug Scheduling System'.

²⁴ Nurses authorised under s 17A of the *Poisons and Therapeutic Goods Act 1996* (or a dentist or veterinary surgeon).

²⁵ This information is taken from the TGA web page at:
www.health.gov.au/tga/docs/html/therad.htm

²⁶ The Minister for Health and Aged Care or a selected delegate is responsible for approving advertisements. As part of the co-regulatory arrangements, this responsibility has been delegated to industry (the Australian Self Medication Industry and the Complementary Healthcare Council).

²⁷ *Therapeutic Goods Advertising Code*, cl 4.1.2(j) and Appendix 5.

²⁸ Reg 6(109e) of the *Therapeutic Goods Regulations*.

²⁹ For further information about the PBS see the web site at:
www.health.gov.au/pbs/index.htm

³⁰ For further information about Medicare see the website at: www.hic.gov.au/yourhealth/our_services/am.htm

³¹ Submission 50, NSW Commission for Children and Young People, p 15.

³² Submission 50, NSW Commission for Children and Young People, para 8.3(ii).

³³ Submission 83, the Hon Carmel Tebbutt, Minister for Juvenile Justice.

³⁴ *Anti-Discrimination Act (NSW)1977* and *Disability Discrimination Act 1992* (Cth).

³⁵ See Submission 74, Mr Stephen Greenwood Executive Director, National Secretariat, Pharmacy Guild of Australia.

³⁶ Submission 50, NSW Commission for Children and Young People, para 8.5(i).

³⁷ Bennett B, New Challenges for Old-Laws? 'The Development of E-Health in Australia', *Sydney Law Review*, 2001 Vol 23: 405-422, p 419.

³⁸ *Therapeutic Goods Act 1989* (Cth), ss 42C and 42D.

³⁹ Australian Pharmaceutical Manufacturers Association, *Code of Conduct*, Edition 134, para 9.4.

⁴⁰ These points are based on the Pharmacy Guild's factsheets and the WHO's guide to medical products on the Internet.

⁴¹ Pharmacy Guild of Australia, *Fact Sheets*: 'Medical Products on the Internet – Be Sceptical'; 'Medical Products on the Internet – Points to Ponder'; and 'Medicine by Mail Order and the Internet'.

⁴² To view this guide see the WHO website at:
www.who.int/medicines/library/qsm/who-edm-qsm-99-4/medicines-on-internet-guide.html

⁴³ For example, Submission 50, NSW Commission for Children and Young People, para 7.4 and 8.3

⁴⁴ Submission 50, NSW Commission for Children and Young People, para 7.4 and 8.3