A review of pharmaceutical scheduling processes in six countries and the effect on consumer access to medicines

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Abstract

Objective This analysis determined and compared pharmaceutical scheduling arrangements in six selected countries and explored how these different scheduling arrangements affect the availability of medicines to the public for self-medication.

Method A comparison of the pharmaceutical scheduling requirements for medicines in six countries was undertaken in September 2003. The six countries of comparison were Australia, Canada, France, New Zealand (NZ), the United States (US), and the United Kingdom (UK). The World Self-Medication Industry website, in September 2003, listed 216 medicines available in 27 countries. Of these, 104 medicines were available in each of the six countries selected for the study. As different scheduling arrangements pertain to different forms (external, internal) or doses and pack sizes, the total number of medicines and medicine forms for comparison was 119. The scheduling of each of the 119 products was determined and compared across the six countries.

Results Of the 119 medicines and medicine forms available, Australia and NZ have 38 and 34 ‘prescription-only’ medicines and 81 and 85 medicines available without a prescription respectively. UK, Canada and France have 47, 53, and 55 ‘prescription-only’ medicines and 72, 66 and 64 medicines available without a prescription. US, which has only two schedules, ‘prescription-only’ and ‘general sale’, has the highest number of ‘prescription-only’ drugs (66) and the least number of medicines available without a prescription (53).

Conclusion The results indicate that there is a tendency for more products to be made available without a prescription in countries that have schedules with pharmacy involvement (Australia, NZ, Canada, France and UK) and a matching tendency for preparations to be held in ‘prescription-only’ schedules in the USA where ‘pharmacy-only’ schedules do not exist. The presence of ‘pharmacy-only’ schedules provides a structure whereby greater consumer access to medication is available.

Introduction

A range of factors, such as a nation’s economic orientation, wealth, traditions and political system, influence the manner in which medicines are distributed and sold. In Australia, a fundamental tenet of its National Medicines Policy is the safe and affordable access to medicines that consumers need, at a cost individuals and the community can afford. The scheduling of medicines (defined as any drugs or preparations used for the treatment or prevention of disease, is one factor that moderates direct consumer access to medicines in many countries. Different countries use different terms for classifying drugs. The term ‘scheduling’ is used in Australia, Canada and New Zealand (NZ), while ‘classification’ is used in the UK and NZ. The US uses the term ‘classes’ while France uses the term ‘list’. We have opted to use the term ‘scheduling’ in this article. A number of scheduling options for medicines are available, such as prescription-only, pharmacy-only, pharmacist-only and over-the-counter (OTC). Regulatory authorities in a number of countries have used some or all of these options in their medicines scheduling systems.

While consumers have been able to buy a range of medicines, for example aspirin, without a prescription for many years, when a new medicine is introduced into the market, it is scheduled for prescription only. Rescheduling of medicines to a lower non-prescription schedule by regulatory authorities relies on criteria such as low potential
for misuse or abuse, low potential for harm, low incidence of side-effects, efficacy of the medicine and the ability of the consumer to diagnose and manage minor ailments or symptoms. The World Medical Association states that for medicines to be available for self-medication, consumers must be able to recognise the symptoms to be treated, determine that the condition is suitable for self-medication, choose an appropriate product, understand and follow directions, and, evaluate the balance between risks and benefit. Internationally, a range of other factors are driving the rescheduling of medicines from prescription-only to pharmacist-only or OTC. In the UK, factors promoting the rescheduling of drugs from prescription-only medicine (POM) to pharmacy-only (P) include patient empowerment, the rise of consumerism, the decreasing power of the professions, pharmacists’ drive to extend their role, government policy to contain the National Health System drug expenditure, and the commercial gain to the pharmaceutical industry from extending the life of the product. When the status of a medicine changes from prescription-only to OTC availability, a range of issues such as patients’ access to drugs, the cost of healthcare, and safety and quality must be considered.

With increased public access through the widespread availability of non-prescription medicines, previously available only by prescription, there has been an increasing trend in self-medication. In the US, the availability of more than 600 OTC products, containing ingredients and dosages that were available only on prescription 20 years ago, has increased the concept of self-care. In the US, in the third National Health and Nutrition Examination Survey (1988–1994), 76% of those surveyed used non-prescription products. Other surveys conducted in the US have reported that consumers found that the switching of products from prescription-only to non-prescription very convenient, and that consumers want more prescription medicines switched to non-prescription status. A UK study identified four factors influencing the respondents’ decision to purchase OTC drugs. These factors were preference for OTC purchase (87%), knowledge of OTC availability of products (92%) and no current use of other prescribed medicines (97%).

A range of real and potential costs and benefits of switching a medicine from prescription-only to OTC have been identified. Costs include an increase in adverse effects, delay in treatment of serious disease, growth in bacterial resistance, wasted medicines and the ‘cost of learning’ for the consumer. Benefits to society include lower reimbursement expenses, savings in physician time and lower dispensing costs. Benefits to the consumer include a decrease in total price, no monetary and time costs from physicians’ visits, no prescription fees, lower travel costs, less waiting time in pharmacies (time cost) and more time at work (both monetary and time cost).

Rizzo et al (2005) assessed the net benefits of prescription-to-OTC switches from the results of 15 studies that considered 23 medicines-scheduling switches. Results indicated that 10 of the switches were determined to be beneficial, three cases of switches were not considered to be beneficial, and the remaining 10 switches (43%) yielded equivocal results.

Switches that have resulted in savings to individuals and health systems in terms of reductions in both direct and indirect costs and reductions in general practitioner (GP) visits, have been shown in relation to H2 antagonists, second generation antihistamines, and nicotine replacement therapy, and for 16 medicines switched to non-prescription sale in Sweden. However, one Australian study found that savings may not be universally enjoyed. When vaginal antifungals were shifted from prescription-only, they were subsequently delisted from the Pharmaceutical Benefits Scheme (a Commonwealth Government scheme whereby a wide range of prescription medicines are made available to Australians at subsidised costs), with the result that pensioners and health concession card-holders had to pay more. Particularly economically vulnerable groups were severely disadvantaged.

Indeed, the perspective from which the analysis is carried out plays a critical role in assessing the net benefits of prescription-to-OTC switches. From the payer perspective, most studies have shown positive net benefits; however the benefits are not as clear for analyses conducted from the perspective of the consumer. Societal and provider perspectives have not often been addressed.

Switching has quality and safety implications, such as consumer perceptions of risk, information provision/health professional engagement and post-marketing surveillance/pharmacovigilance. While self-care and responsible self-medication can be beneficial for patients and health systems, the increased availability of medications may also have risks, associated with their use to treat illnesses that have been wrongly self-diagnosed, and result in the excessive use of inappropriate medications.

In US studies, respondents reported favouring non-prescription status despite the possibility of considerable risks. In the UK, consumers rarely referred to the risks or dangers of the non-prescription medicines, focusing rather on their benefits, as there seemed to be the widely held belief that regulatory authorities would not allow ‘dangerous’ medicines to be available from community pharmacy.

Responsible self-medication must be accompanied by appropriate health information. Consumers appear to use pharmacists in a variety of ways: as a ‘first port of call’ when treating minor ailments; as facilitators, either confirming their choice of self-care or as an agent, referring them to a GP, as a resource for self-care, and an important source of drug information. As consumers assume greater responsibility for their healthcare, pharmacists can play an important role by serving as an additional information source for consumers and helping them to make informed decisions. The impact of pharmacist advice-giving on the outcomes of self-medication in patients suffering from dyspepsia has been shown to result in a significant improvement in health-related quality of life.

A number of studies have addressed the issue of post-marketing surveillance/pharmacovigilance. One study in developing methods for pharmacovigilance studies for...
ibuprofen, surveyed pharmacy customers and found that ibuprofen was used by 15% of customers with an active or past history of peptic ulcer. Seventeen per cent of those surveyed reported experiencing dyspepsia or heartburn after purchasing ibuprofen but did not seek advice.36 Another study compared reported adverse effects from proton pump inhibitors with the H₂ antagonists ranitidine and famotidine which had been recently switched to OTC status. The authors reported that the switching did not affect the number of reported adverse reactions to these drugs.37 A study assessing smoking cessation rates achieved with nicotine gum and patches in simulated OTC and actual prescription settings concluded that OTC success rates were consistently higher than prescription rates for both gum and patches.38

While the literature acknowledges the different classification or scheduling arrangements that may be adopted and addresses a range of issues associated with switching, it would appear that no studies have been carried out that determine how the different scheduling arrangements affect availability of medicines to the public. The search strategies used for this review are listed in Appendix 1.

Aim

The aim of this analysis was to determine and compare the pharmaceutical scheduling arrangements (or legal classification of medicines) in six selected countries, and to explore how these different scheduling requirements affect the direct access of the public to medicines for self-treatment.

Methods

The World Self Medication Industry website,39 which is a comprehensive database providing information on legal scheduling of medicines in different countries, was used to obtain the list of countries. The website lists three tables: the table of OTC ingredients in 14 EU countries; the table of OTC ingredients in 7 new EU and 3 non-EU European countries; and the table of OTC ingredients in 11 selected countries worldwide. A systematic analysis of scheduling processes, which included the identification of guidelines for scheduling, was undertaken for all the countries listed in the tables. To be included in further analyses, countries had to have sufficient similarity to Australia’s processes with respect to:

- the presence of substantial pharmacovigilance processes
- the use of a similar range of medicines
- access to detailed descriptions of scheduling decision-making processes and guidelines
- access to experts in each of these countries who could verify the scheduling arrangements in their countries and answer queries related to scheduling arrangements.

An online search was conducted to obtain information on the pharmacovigilance processes and for descriptions of scheduling decision-making processes and guidelines for each country (refer to Appendix 2 for the search strategy). The available relevant documents were then read by one of the authors (NQ) to assess similarities with Australian documents. An attempt was made to contact representatives from relevant committees in each country. Using the search terms detailed in Appendix 2, we were able to find links to the regulatory authority website for all 35 countries. For six countries the websites were not in English, and attempts to establish contacts with the authorities were not successful. For 15 countries, information was available in English but no relevant information on scheduling processes was found, and again we were not able to establish contact with the relevant authorities. For 13 countries we were able to find relevant information in English. We were able to establish contact with a representative from the relevant committees in five countries, namely Canada, France, New Zealand, UK and US, to verify the information. As these five countries satisfied all inclusion criteria, they were included in the analysis. Other countries such as Germany, Sweden and Switzerland satisfied the first three criteria, however we were not able to establish personal contacts in these countries within the time frame of the project.

A comparative analysis of the scheduling of medicines in the six countries was undertaken with a view to developing an understanding of the ways different scheduling requirements might affect the availability of both prescription and non-prescription medicines to the public. In order to compare the scheduling processes of the selected countries, a list of both prescription and non-prescription medicines available in all six countries and their scheduling requirements was obtained from the World Self-Medication Industry website.9 The list of medicines was obtained from the table of OTC ingredients in 14 EU countries and the table of OTC ingredients in 11 selected countries worldwide. The two tables listed 216 ingredients available in 25 countries in September 2003. It also lists combinations of ingredients that are available in the different countries. The website also provides information on the schedules through which these ingredients are available to the public. The main table lists whether an ingredient is available through a prescription or non-prescription route. Footnotes for ingredients provide additional information on whether the ingredient is available through pharmacy schedules. The terms ‘ingredients’ and ‘medicines’ are used interchangeably in this article.

Of the total of 216 ingredients, 104 were identified as being available, either on prescription or non-prescription, in all six countries. Ingredients that were not available in all of the six countries were excluded. As different scheduling arrangements pertain to different dose forms (external, internal) or doses and pack sizes, the total number of ingredients and dose forms included in the analysis for comparison was 119. For example clotrimazole, an antifungal agent, is available as a topical as well as a vaginal preparation in all the six countries. Other examples of ingredients available in different dosage forms include terbinafine, econazole, nystatin, tioconazole (all
antifungal agents), nitroglycerine (cardiovascular agent) and nicotine. Prochlorperazine, an anti-emetic agent, is available as non-prescription in smaller packs, while larger packs need a prescription. Other examples of ingredients available in different doses and pack sizes include diclofenac, ketoprofen (both anti-inflammatories), cetirizine (antihistamine), hyoscine or scopolamine (antimuscarinic agent), dextromethorphan (cough suppressant), famotidine (gastro-intestinal agent). Epinephrine (adrenaline), a sympathomimetic agent, is available as either non-prescription or prescription in different countries depending on its use. The scheduling of each of the 119 medicines was determined and compared across the six countries.

Results

Pharmaceutical scheduling arrangements in the six countries

In general, there are four schedules through which medicines are available to the public – general sale, pharmacy-only, pharmacist-only and prescription-only. The first three schedules are referred to as non-prescription schedules in this paper. Table 1 summarises the different scheduling systems in the six countries.

The decision-making process for scheduling switches in the six countries is outlined below.

**Australia**

Australia has four schedules through which medicines are made available to the public: schedule four or prescription only; schedule three or pharmacist-only; schedule two or pharmacy-only and general sale. The scheduling applies according to the ‘Standard for uniform scheduling of medicines and poisons’ (SUSDP). The National Medicines and Poisons Schedule Committee (NDPSC) makes decisions relating to switches of medicines from prescription-only to pharmacist-only or pharmacy-only sale, or to general sale. The decision to switch schedules depends on safety, abuse potential, level of diagnosis required, level of management required, incidence of side-effects or adverse effects, capacity to mask disease or compromise management, patient choice and accessibility, public health issues (e.g. antibiotic resistance), harmonisation and scheduling consistency with New Zealand, and therapeutic index. Safety and levels of diagnosis and management required are key markers for making decisions about scheduling or scheduling switches.

**Canada**

In Canada, medicines are divided at the federal level into prescription and non-prescription. The provinces adopt further subdivisions into: schedule one prescription medicines; schedule two pharmacist assist (behind the counter); schedule three pharmacy self-selection; unscheduled general sale – all retail outlets. The key concepts in determining the scheduling of medicines are safety and efficacy. When consideration is given to the transfer of medicines from prescription to non-prescription schedules, Barbara Wells, Executive Director, National Association of Pharmacy Regulatory Authorities (personal communication September 9, 2003) indicated that the following major questions must be addressed: does removal of physician control endanger the public, and/or increase the risk of significant adverse effects; is the medicine safe; have potential adverse effects been overlooked in randomised controlled trials; is there evidence of good compliance in

<table>
<thead>
<tr>
<th>Country</th>
<th>Medicines available for general salea</th>
<th>Medicines available from pharmacies without prescriptionb</th>
<th>Total medicines available without prescriptionc</th>
<th>Medicines for which a prescription is requiredd</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>All outlets</td>
<td>Pharmacy medicine S2</td>
<td>Restricted medicine S3</td>
<td>Prescription medicine S4</td>
</tr>
<tr>
<td>Australia</td>
<td>All general sale outlets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>All general sale outlets (GSL)</td>
<td></td>
<td>Pharmacist supervision required (P)</td>
<td>Prescription only (POM)</td>
</tr>
<tr>
<td>Canada</td>
<td>All retail outlets</td>
<td>Schedule III non-prescription</td>
<td>Schedule II</td>
<td>Schedule I</td>
</tr>
<tr>
<td>France</td>
<td>–</td>
<td></td>
<td>Only for certain controlled substances and only in some states</td>
<td>Prescription list</td>
</tr>
<tr>
<td>US</td>
<td>All general sale outlets</td>
<td></td>
<td></td>
<td>Prescription only</td>
</tr>
</tbody>
</table>

a Substances (medicines) available from general sale outlets such as pharmacies and supermarkets.
b Substances (medicines), the safe use of which may require professional advice from a pharmacist and which should be available from a pharmacy or where a pharmacy service is not available from a licensed person. No prescription is required.
c Substances (medicines), the safe use of which requires professional advice and which should be available to the public from a pharmacist without prescription.
d Substances (medicines), the use or supply of which should be by or on the order of persons permitted by the state or territory legislation (usually doctors or veterinarians) to prescribe, and should be available from a pharmacist on prescription.
adhering to labelled instructions and warnings; what are the patterns of consumer use and misuse?

**New Zealand**

New Zealand has four schedules matching those of Australia: prescription-only, pharmacist-only, pharmacy medicine, and general sale. New Zealand regulations state that:

Medical products which may be available without prescription shall show a substantial safety in use in the treatment of minor ailments or symptoms usually capable of rapid and spontaneous relief which are easily identifiable by users and do not justify a medical consultation.42 (p175)

In order to achieve schedule changes, the NZ Medicines Classification Committee considers whether there are: consumer and public benefits; ease of self-diagnosis, or pharmacist diagnosis; relevant comparative data for like compounds; local data or special considerations; significant interactions with other medicines; significant contraindications; likelihood for the development of resistance; potential serious adverse effects; potential for misuse or abuse.

**United Kingdom**

The UK has three schedules of medicines: prescription-only medicine (POM), pharmacy only (P) and general sale (GSL). Before a medicine can be switched from POM to P, ministers must be satisfied that it would be safe to allow it to be supplied without a prescription. Similarly, before a medicine can be switched from P to GSL, ministers must be satisfied that it ‘can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist’.43

The government authority responsible for the regulation of medicines in the UK, the Medicines and Healthcare products Regulatory Agency, specifies the criteria for switching a drug from POM to P schedule.43 These are: indications suitable for self-medication, including self-diagnosis (for example a recurrent attack of a condition which had been physician diagnosed on first attack); the medicine has an acceptable margin of safety during unsupervised use, including safety in overdose or following accidental misdiagnosis; the medicine is not a new drug substance for which further post-marketing evidence of safety is required; the medicine does not present a hazard to the community (indirect danger) from unsupervised use as might occur with development of resistant flora to antibiotics; the medicine has no major abuse or dependence potential and is not for parenteral use.

France

France has four drug schedules: prescription, list A (list I) – this includes substances or preparations and medicines presenting high risks for health. The prescriptions are non-refillable by a pharmacist without written authorisation of the prescriber; prescription, list B – this includes substances with addictive risks such as controlled narcotics and certain psychotropics; prescription, list C (list II) – this includes substances or preparations and medicines presenting direct or indirect risks for health, these prescriptions are refillable by a pharmacist, examples include the non-steroidal anti-inflammatory drug aceclofenac, the antihistamine ketotifen eye drops and insulin; non-prescription – this includes all other medicines which, with the exception of aspirin, must be sold only in pharmacies. In rural areas where there is no pharmacy, physicians may be authorised to dispense drugs. Safety, efficacy, and quality are the factors considered when a drug approval decision is made.44

United States

The US has only two relevant schedules for medicines: prescription or non-prescription. However there are several exceptions to the two-schedule system. In some states, selected schedule V controlled substances, such as the narcotic buprenorphine or the stimulant pyrovalerone, are available without a prescription but must be dispensed by a pharmacist. Insulin is a non-prescription product in some states, but can be dispensed only by a pharmacist. In Florida pharmacists can prescribe a limited list of prescription drugs without a prescription having been written by another health professional. In some states pharmacists have a ‘dependent’ prescribing authority in which typically they can prescribe drugs under protocols established by supervisory physicians.44

The crucial question that determines whether medicines are available to consumers without prescription is whether patients alone can achieve the desired medical results without endangering their safety. Key concepts of US legislation include: safety – including toxicity, potential for misuse, minimal side-effects; effectiveness – effective for short-term treatment; diagnosis – can the consumer self-diagnose; management – are routine tests needed; information – can patients understand correct use.

In general, all the countries consider the criteria of safety, potential for abuse, adverse effects and level of diagnosis, for making decisions about rescheduling.

Table 2 provides a comparison of the scheduling requirements of the 119 ingredients (including different dose forms) available in the selected countries.

The results show that of the six selected countries, NZ had the highest number of the identified medicines available without a prescription, 85, followed in descending order by Australia, UK, France, Canada and the US, which had the smallest number (53). Conversely, New Zealand had the lowest number of identified medicines for which a prescription was required (35), followed in ascending order by Australia, UK, Canada, France and the USA, which had the greatest number (66).

**Discussion**

The decision-making process for scheduling switches in the six countries appear to be based on a relatively consistent set of principles. The analysis of the placement of medicines within available schedules in the countries of comparison indicates that there is a greater tendency for preparations to be made available without prescription in countries that have ‘pharmacy-only’ schedules (France, UK) and ‘phar-
macy-only’ as well as ‘pharmacist-only’ schedules (NZ, Australia and Canada). In countries such as the US where a ‘pharmacy-only’ schedule does not exist there is a greater tendency for preparations to be held in ‘prescription-only’ schedules. In countries with a single ‘pharmacy-only’ schedule, where there is no distinction between ‘pharmacist-only’ and ‘pharmacy medicines’, all medicines are treated as if they were in the higher schedule, and direct consumer access to medicines is more restricted than in countries with two pharmacy schedules. Australia and NZ have the most liberal medicine-scheduling arrangements, as indicated by the numbers of non-prescription medicines available. The presence of a ‘pharmacy-only’ schedule provides a structure which provides scheduling authorities the opportunity to grant greater direct consumer access to medication. The results provide some support for the view that a structure offering two pharmacy schedules allows greater consumer access to medicines than one offering a single schedule. The situation in Canada is, however, not consistent with this view. In Canada, pharmacy technicians and pharmacy assistants are not legally allowed to handle sales for ‘pharmacist-only’ medicines, and may not offer advice on pharmacy medicines. This may lead to a slightly more restrictive environment in which the application of the schedules in practice is more like their application in a single non-prescription schedule environment, such as the UK. A second reason for Canada’s results being anomalous could be its proximity to the US, which may influence scheduling decisions.

The perceived advantages and disadvantages of the respective models of scheduling from the analysis of the scheduling arrangements in the six countries are provided in Table 3.\(^18,44\)

### Limitations

One limitation of the study was the selection of the six countries. One of the selection criteria was access to experts in each country, and as the researchers had limited resources, countries such as Germany, that also satisfied the other selection criteria, were excluded because we were unable to establish personal contacts in those countries. A second limitation was the reliance on data from only one source; the World Self-Medication Industry website.\(^39\) However, we were not able to locate any other comprehensive database that would provide the information on scheduling of medicines. While it is possible that the data from the website may be inaccurate for other countries, the authors were assured that the data for Australia are accurate. Another limitation of the study was that no statistical testing was done to see to what extent the ranking could have happened by chance.

### Implications of the findings

These results raise many questions which have implications for key stakeholders in the health system such as consumers, pharmacists, the pharmaceutical industry and policy makers.

#### Consumers

The presence of several different schedules within the non-prescription schedules appears to allow greater direct access to medicines by the consumers. This means increased scope for self-medication or management of self-diagnosed conditions. This increased direct access to medicines is balanced by either the legislative protection offered by the requirement for provision of information and education by a pharmacist in the case of pharmacist-only medicines, or in the case of pharmacy-only medicines, the information from trained pharmacy assistants and appropriate referral to the pharmacists. There are also cost implications for consumers. For example, in the US, the absence of a ‘pharmacy-only’ schedule suggests that the greater number of medicines for which prescriptions are required would lead to higher health costs to the

### Table 2

A comparison of the scheduling status of 119 medicines (including different forms) available in Australia, New Zealand, the UK, US, Canada, and France

<table>
<thead>
<tr>
<th>Country</th>
<th>Medicines available for general sale(^a)</th>
<th>Medicines available from pharmacies without prescription(^b)</th>
<th>Total medicines available without prescription(^c)</th>
<th>Medicines for which a prescription is required(^d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>10</td>
<td>75</td>
<td>85</td>
<td>34</td>
</tr>
<tr>
<td>Australia</td>
<td>13</td>
<td>68</td>
<td>81</td>
<td>38</td>
</tr>
<tr>
<td>UK</td>
<td>6</td>
<td>66</td>
<td>72</td>
<td>47</td>
</tr>
<tr>
<td>Canada</td>
<td>13</td>
<td>53</td>
<td>66</td>
<td>53</td>
</tr>
<tr>
<td>France</td>
<td>1</td>
<td>63</td>
<td>64</td>
<td>55</td>
</tr>
<tr>
<td>US</td>
<td>53</td>
<td>0</td>
<td>53</td>
<td>66</td>
</tr>
</tbody>
</table>

\(^a\)Substances (medicines) available from general sale outlets such as pharmacies and supermarkets.
\(^b\)Substances (medicines), the safe use of which may require professional advice from a pharmacist and which should be available from a pharmacy or where a pharmacy service is not available from a licensed person. No prescription is required.
\(^c\)Substances (medicines), the safe use of which requires professional advice and which should be available to the public from a pharmacist without prescription.
\(^d\)Substances (medicines), the use or supply of which should be by or on the order of persons permitted by the state or territory legislation (usually doctors or veterinarians) to prescribe, and should be available from a pharmacist on prescription.
consumer. On the other hand, the relatively large number of medicines (53) available for general sale may result in lower health costs to the consumers purchasing these products. Overall however, without the intermediate pharmacy schedule, consumers in the US must pay for doctor consultation fees and prescription prices for medicines for 56% of this selected parcel of medicines, compared to only 29% in NZ.

Pharmacists
With a greater number of medicines being made available to the public without prescription, there is a need for the pharmacists to take greater responsibilities for the sale of non-prescription medicines and to ensure that the increased access is balanced with safety and quality outcomes. Systems are required to assist consumers to make appropriate choices either to self-medicate, to choose a non-medication-related option or to seek medical advice. Practitioners should ensure that the medication that the consumer has chosen is appropriate, safe and effective for the condition, and that the patient has the knowledge and skills to monitor the outcome. For some situations, it may be appropriate for the pharmacy assistants to assist the consumers, while in others, input from the pharmacist will be necessary. Protocols need to be in place to ensure that the consumer receives the full benefit of self-medication. The ‘National standards of practice for the provision of pharmacist only and pharmacy medicines in community pharmacy’ which have been developed in Australia to ensure that all community pharmacies provide appropriate and consistent professional advice, and the quality care process surrounding their adoption is a good example of such protocols.

Pharmaceutical industry
The industry benefits from having a flexible scheduling system, because of increased returns due to increased access to markets and, in some countries, increased ability to advertise direct to the consumer. The greater access to

Table 3  Comparison of scheduling arrangements used in Australia/New Zealand/Canada, the USA and the UK/France and the perceived advantages and disadvantages of the respective models of scheduling18,44

<table>
<thead>
<tr>
<th>Scheduling arrangements</th>
<th>Perceived advantages</th>
<th>Perceived disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia/New Zealand/Canada</td>
<td>• Flexible approach is likely to provide a wider range of products without a prescription</td>
<td>• Not all pharmacists may fulfil professional responsibility of providing appropriate counselling</td>
</tr>
<tr>
<td>• Pharmacist-only: pharmacist involvement required, consumer access prohibited</td>
<td>• Professional advice available at point of purchase</td>
<td>• Costs of individual items may be higher to consumers (but are likely to be balanced by lower GP costs and lower costs to consumers in time and convenience)45</td>
</tr>
<tr>
<td>• Pharmacy-only: pharmacist involvement discretionary, consumer self-selection possible</td>
<td>• Indicates to consumers that professional advice is needed for some medicines</td>
<td>• General sale</td>
</tr>
<tr>
<td>UK/France</td>
<td>• Professional advice is available at point of purchase</td>
<td>• Not all pharmacists may fulfil professional responsibility</td>
</tr>
<tr>
<td>• POM: prescription-only</td>
<td>• Simplicity of schedules</td>
<td>• More limited range of medicines available without a prescription</td>
</tr>
<tr>
<td>• P: pharmacy-only; pharmacist involvement discretionary, consumer access prohibited</td>
<td></td>
<td>• Restricts all scheduled items to areas that prevent consumer self-selection</td>
</tr>
<tr>
<td>• General sale</td>
<td></td>
<td>• Professional advice not always available</td>
</tr>
<tr>
<td>USA</td>
<td>• Better consumer access – medicines available at a wider range of outlets</td>
<td>• Consumers have fewer choices for self-medications</td>
</tr>
<tr>
<td>• Prescription only</td>
<td>• Consumer assesses own level of need</td>
<td>• Medicines perceived as ‘safe’</td>
</tr>
<tr>
<td>• General sale</td>
<td>• Lower medicine costs due to competition and availability of medicines in stores with lower overhead structures</td>
<td>• Greater demand for detailed labelling and clear printed information</td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td>• Costs to consumers and health system</td>
</tr>
</tbody>
</table>
patients by the pharmaceutical industry must be balanced by ethical promotion of their medicines.

**Policy makers**

There are potential benefits to the health system resulting from flexible scheduling. For example, the existence of ‘pharmacy-only’ schedules has the potential to reduce demand on GP services, which is important in the current workforce situation, resulting in overall savings to the health system. While the literature indicates that more open access usually decreases costs to individuals and the health system, there are few data on clinical safety and quality implications of these moves. Australian research, which indicates that medication-related problems are a major public health issue, has focused mainly on prescribed medicines. There are very little data on the consequences of self-prescribed medicine use. There is a need for international comparative studies which not only compare indicators of clinical safety and quality issues across these countries, but also examine the medicine-related needs and expectations of consumers, health professionals and policy makers.

**Note:** This analysis was part of a larger study conducted by the Quality Use of Medicines and Pharmacy Research Centre, University of South Australia in collaboration with the University of Sydney, in response to the recommendations of the Review of Drugs, Poisons and Controlled Substances Legislation that the two separate pharmacy schedules in Australia (schedules 2 and 3) be combined. The review suggested that the risk to an individual purchasing a schedule 2 product may be as high or higher than the risk to a person purchasing a schedule 3 product, and questioned whether there was any evidence to support the benefits of retaining schedules 2 and 3 as separate schedules. The data on the legal status of drugs worldwide were obtained from the World Self-Medication Industry website in September 2003 (www.wsmi.org/otc.htm). The website has been updated since then with a listing of 218 drugs.

**References**

A search was conducted in databases (Medline and International Pharmaceutical Abstracts) from 1966–2005 using the search terms individually and in combinations:

- ‘non-prescription’ or ‘over-the-counter’ or ‘non-prescription’ and ‘scheduling’ or ‘schedule shifts’ or ‘switches’ or ‘switching’ (121 articles)
- ‘Rx to OTC switch(es)’ or ‘prescription to non-prescription’ or ‘non-prescription’ (147 articles)
- ‘consumer access’ (44 articles)
- ‘access to non-prescription/OTC/medicine/s’ (73 articles)
- ‘self-care’ and ‘OTC’ (97 articles)
- ‘OTC’ (117 articles).
- ‘Rx to OTC’ (147 articles)
- ‘non-prescription’ (13 articles found – 5 articles were found to be relevant)
- ‘risk management’ as it related to non-prescription medicines.

Of the searches 10 articles were deemed to have useful information about the economic benefits of switches. Only two articles yielded information on health outcomes due to the prescription (Rx)-to-non-prescription switches.

The addition of the search terms ‘health outcomes or outcomes’ and ‘non-prescription’ revealed four articles, of which only one was deemed useful.

A search was also carried out for literature on ‘risk management’ as it related to non-prescription medicines. Three articles were found none of which were relevant.

Research was also conducted in the database Scopus from 1960 to the present. The following search terms were used:

- ‘Rx to OTC’ and ‘International Journal of Pharmacy Practice’ (1 article – not relevant)
- ‘non-prescription’ and ‘International Journal of Pharmacy Practice’ (33 articles – 2 articles were found to be relevant)
- ‘self-care’ and ‘OTC’ (117 articles).

A search was also conducted in the database EMBASE from 1994 (due to database constraints) to the present. The following search terms were used:

- ‘prescription to OTC’ or ‘Rx to OTC’ or ‘prescription to non-prescription’ (13 articles found – 5 articles were found to be relevant)
- ‘non-prescription’ or ‘over-the-counter’ or ‘OTC’ and ‘schedule’ or ‘switch’ (39 articles – 8 articles were found to be relevant)
- ‘access’ and ‘non-prescription’ or ‘OTC’ or ‘over-the-counter’ (45 articles – 10 articles were found to be relevant)
• 'self-care' and 'OTC' (4 articles – 0 articles were found to be relevant)
• 'self-care' and 'OTC' or 'over-the-counter' or 'non-prescription' (34 articles – 3 articles were found to be relevant, excluding articles already found in other searches).

For an article to be considered relevant, any of the following criteria had to be satisfied. The criteria were based on the aims of the study:

• articles incorporating an economic assessment of Rx to non-prescription switches
• articles evaluating health outcomes due to Rx to non-prescription switches
• articles related to consumer access due to Rx to non-prescription switches
• articles assessing role of the pharmacist in self-care.

The literature search was conducted to inform the introduction and was not a part of the study.

Appendix 2: online search strategy – search engine www.google.com.au

Search terms used were:

• pharmacovigilance in (name of country)
• drug regulatory authorities in (name of country)
• legal classification of drugs in (name of country).