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Author
Hattingh, Laetitia, Maganlal, Satish, King, Michelle

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THE IMPACT OF THE CHANGING GENERIC MEDICINE SUBSTITUTION LANDSCAPE ON COMMUNITY PHARMACY

H Laetitia Hattingh, Satish Maganlal, Michelle A King*

*H Laetitia Hattingh, PhD, MPharm, BPharm, GCAppLaw, CertIVTAA, AACP, Senior Lecturer, School of Pharmacy, Griffith University, Gold Coast; Satish Maganlal, BPharm, GClinPharm, AACP, Lecturer, School of Pharmacy, Griffith University, Gold Coast; Michelle King, PhD, BPharm, Senior Lecturer, School of Pharmacy, Griffith University, Gold Coast.

Correspondence to: Laetitia Hattingh, PhD, MPharm, BPharm, GCAppLaw, CertIVTAA, AACP, Senior Lecturer, School of Pharmacy, Griffith University, Gold Coast, 4222, Queensland, Australia; email: l.hattingh@griffith.edu.au

ABSTRACT

The Australian generic medicine substitution landscape has changed over recent years. The latest changes included the introduction of incentive payments by the government to community pharmacists to dispense generic medicines instead of more expensive brand equivalents. Generic dispensing places additional time constraints on pharmacists in terms of patient counselling requirements. Substitution also involves an increased need for professional judgement as pharmacists need to ensure the substitution is appropriate for the patient. It is therefore important that pharmacists develop processes and procedures that enable staff to follow good practice standards and guidelines during the dispensing of generic medicines in order to minimise patient risk.

INTRODUCTION

The Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) are key components of the Australian health system as these Schemes facilitate the subsidisation of a large number of prescription medicines. The PBS provides Australian residents and eligible overseas visitors from countries with whom Australia has a reciprocal health care agreement¹ with subsidised access to a list of medicines funded, either partially or completely, by the Commonwealth government. The RPBS provides pharmaceutical benefits for veterans and eligible dependants. Both the PBS and the RPBS form an integral part of Australia’s National Medicines Policy (NMP) as one of the objectives of the NMP is to deliver ‘timely access

¹ Reciprocal agreements are currently in place with nine countries, namely Finland, Italy, Malta, New Zealand, Norway, Republic of Ireland, Sweden, the Netherlands and United Kingdom.
to the medicines that Australians need, at a cost individuals and the community can afford.\textsuperscript{2}

The government has identified that PBS (and RPBS) expenditure has grown at an unsustainable rate,\textsuperscript{3} faster than government expenditure on hospitals, medical benefits and other areas.\textsuperscript{4} In order to ensure that the PBS remains affordable to the Australian government, significant PBS Reforms were announced by the government in November 2006 and introduced in July 2007 following the passing of the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (Cth) (No 111, 2007). The specific aim of these reforms was to:\textsuperscript{5}

... protect patients from higher out of pocket costs, get better value from market competition among brands of generic (off-patent) medicines and recognise the importance of world-class life-enhancing drugs to patients.

A major objective of the 2006 PBS reforms is to achieve more comprehensive PBS pricing of generic medicines whilst ensuring the availability of new medicines in the future. The impact of these reforms on community pharmacy is significant as community pharmacy’s income and financial viability is directly related to the PBS.\textsuperscript{6} As part of the reforms a financial incentive was introduced to pay community pharmacists to dispense generic medicines. Pharmacists are therefore encouraged to dispense generic medicines, provided that the prescriber has approved substitution to occur. However, generic dispensing places an increased responsibility on pharmacists and it is important that pharmacists implement good practice standards and guidelines in order to manage their liability with regard to generic dispensing.

**GENERIC MEDICINES**

Generic medicines refer to medicines which are equivalent to originator brands or innovator products which are no longer protected by a patent. A patent refers to the exclusive right to produce and market a medicine, owned by the company that first developed the medicine, under Intellectual Property laws. This protects the manufacturer’s investment in research, development, marketing and promotion and during the term of the patent, products generate high profits for the manufacturer. Once the patent expires, which is normally 10 years after the medicine was first marketed,\textsuperscript{7} other companies can copy

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{3} According to data from Medicare Australia, in the 2008 calendar year, the Australian government spent $6.9 billion through the PBS and RPBS
\item \textsuperscript{4} Department of Treasury “Intergenerational report 2007” Canberra, The Treasury, April 2007:6
\item \textsuperscript{5} The Hon. Tony Abbott MfHaA. “PBS Reform” media release. Department of Health and Ageing, 16 November 2006
\item \textsuperscript{7} National Prescribing Service “Generic medicines: same difference” (2006) NPS News 44, February
\end{itemize}
\end{footnotesize}
and market the same active ingredient. Companies that produce the generic medicine do not need to match the investment of the originator company and should be able to pass on the lower cost. Generic medicines are therefore normally less expensive than the original product. A 2003 analysis of PBS data indeed indicated that prices of brand name (patented) medicines fall on average more than 30 per cent after patent expiry and the entry of generic medicines.

Generic medicines are often referred to as bioequivalent medicines. The responsibility to ensure bioequivalence of generic medicines in Australia lies with the relevant pharmaceutical companies and the Therapeutic Goods Administration (TGA). Two medicines are considered bioequivalent when they produce such similar plasma concentrations of the active ingredient that their clinical effects can be expected to be similar. Bioequivalence is usually assessed in a small number of healthy volunteers by administering the two products on separate occasions. The peak plasma concentration ($C_{\text{max}}$) and the extent of absorption (area under the concentration–time curve, AUC) of the generic medicine and the original brand are then compared. To be bioequivalent, the 90% confidence intervals (CI) for the ratio of each pharmacokinetic variable must lie between 0.80 and 1.25. This is a numerical index that provides an indication of the certainty of the study results.

The amount of active ingredient in the systemic circulation is used as a measure of the medicine’s clinical efficacy. However, the inactive ingredients, also referred to as excipients, can differ and this may have an impact on patient tolerability. These include diluents, binders, fillers, surfactants, lubricants, coatings and dyes. Although adverse reactions to excipients are rare, pharmacists should discuss with their patients the severity of a particular intolerance and advise them on the most appropriate course of action. Consumer Medicine Information (CMI) leaflets could be used for this purpose as a list of the excipients and dyes in each medicine is contained in the medicine’s CMI.

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10 The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing and is responsible for administering the provisions of the Therapeutic Goods Act 1989 (Cth) and delegated legislation
13 McLachlan A “Frequently asked questions about generic medicines” (2007) Australian Prescriber, April;30(2) pp 41-3
14 These are brand-specific, manufacturer-produced written information about drug products that conforms with special provisions set out in the Therapeutic Goods Regulations 1990 (Cth), targeted at patients.
The same manufacturing codes that apply to branded medicines also apply to
generic medicines. For a generic medicine to be listed on the PBS as a
substitute for the original brand, a manufacturer must demonstrate that their
product is bioequivalent to the original brand in Australia. Interchangeable
medicines are marked in the Schedule of Pharmaceutical Benefits by a letter,
‘a’ or ‘b’, also referred to as ‘flagging’. Brands of any therapeutic substance
marked ‘a’ can be substituted for one of the other brands marked as ‘a’ and
similarly brands marked ‘b’ can also be substituted for each other. However
those marked ‘a’ cannot be substituted with those marked ‘b’. Patients pay
an additional amount if they choose not to have a generic medicine. This
financial ‘penalty’ is referred to as a Brand Premium and is the price
difference between the brand dispensed and the cheapest equivalent brand.
There is no readily identifiable and authorised source of bioequivalence data
to support brand substitution of private, i.e. non-PBS prescriptions.

A medicine patent issue that has impacted on both community pharmacy
practice as well as on patient care is the tendency by pharmaceutical
manufacturers to change a product’s formulation in an effort to extend its
patent. This is referred to as ‘evergreening’, which is an attempt by drug
companies to extend their patents and prevent cheaper generics entering the
market. An example of this occurring was the reformulation of Coversyl (active ingredient perindopril) by Servier in 2006, which caused issues of
concern as the changeover generated confusion and the potential for patient
harm. The perindopril erbumine salt conversion to perindopril arginine,
seemingly to improve product stability, was viewed by many as a ploy and
caused a disproportionate amount of outrage in the pharmacy industry. At the
time there was at least one report of a misadventure in a hospital setting due
to substitution of the old version to the new version without the necessary
adjustment to dosage.

ADDITIONAL PRICING REFORMS INVOLVING GENERIC MEDICINES

Increased use of generic medicines causes price competition amongst
generic manufacturers, which directly impacts on PBS sustainability through
the tendering process. There has therefore been increased support by the
government for the use of generic medicines in an attempt to contain the
growth of the PBS. This is demonstrated by that fact that generic dispensing
and prescribing, over recent years, has been facilitated through the following
initiatives:

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15 Therapeutic Goods Adminstration. Australian code of good manufacturing practice for
16 Therapeutic Goods Adminstration. Australian regulatory guidelines for prescription
viewed 20 September 2009
18 Pharmaceutical Defence Limited “Generic brand substitution”,(2007) Melbourne
No 2 Feb p 117
20 Grogan B, “Coversyl reformulation raises issues of concern”, Auspharm 30 October 2006
• The introduction of the Brand Premium Policy (BPP, also referred to as Brand Pricing) in December 1990 to increase price competition between pharmaceutical manufacturers; 
• As of 1994, allowing a pharmacist to supply an interchangeable brand in place of the one prescribed under the PBS, and also requiring patients to pay the BPP; 
• Amendments to the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cth) to promote increased generic prescribing. These changes required, as of February 2003, that computer prescribing programs must by default permit brand substitution for PBS prescriptions; and 
• The introduction of a pricing measure that commenced on 1 August 2005 that meant that the entry of a new brand of medicine equivalent to one already existing on the PBS triggered a mandatory 12.5% price reduction to the price paid by government for that medicine and other medicines that were linked in the same reference group. At the time of the announcement, it was estimated that this measure would have reduced the government’s expenditure by approximately $740 million over a four year period.\(^{22}\)

Although the above measures contributed towards PBS savings, the PBS still grew at a rate of 2.7 per cent and the government paid over $6 billion in PBS subsidies in the 2005-06 financial year.\(^{23}\) This growth was considered unsustainable and the 2006 PBS reforms were subsequently introduced with a long implementation tail through to 2012. Reforms mainly involved price disclosure provisions that apply to pharmaceutical manufacturers and changes to the way PBS-listed medicines are priced. Intended outcomes include savings from off-patent (generic) medicines and improvements to the listing of medicines.

The 2006 reforms *inter alia* require government-mandated and market-based pricing for all off-patent medicines and as of 1 August 2007 medicines listed on the PBS were separated into two formularies, namely F1 and F2, subject to different pricing arrangements. F1 medicines are defined as medicines where there is only a single brand listed and these medicines are therefore not substitutable. These medicines can be either patented or off-patent medicines and no mandatory price reductions apply. F2 medicines are those where there are multiple brands listed and those medicines which, although a single brand, have been deemed interchangeable with multiple brand medicines. A range of price reductions apply to F2 medicines from 1 August 2008 with the type and size of price reduction dependent on the degree of price competition between brands. The amount that the government pays for

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F2 medicines was reduced through a complicated formulary that will undergo ongoing review. F2 pricing can be summarised as:24

- A price drop of 2% per year over three years, from 1 August 2008, is required for those F2 medicines where price competition is low. These medicines are classified as F2A medicines.
- Highly price competitive medicines are classified as F2T medicines and they had a one-off drop of 25% on 1 August 2008.

A system of price disclosure for F2 formulary medicines applies which is designed to ensure that government reimbursement is consistent with the actual market price. F2A medicines may be subject to disclosure-based reductions from 1 August 2009 while F2T medicines may be subject to such reductions from 1 January 2011. These price disclosure measures, known as Weighted Average Price Disclosure (WADP), were recommended to save the government money as data indicated that the purchase prices for many generics, paid by the Australian government through the PBS, were higher than in other countries.25 It was estimated that the patents for over 100 medicines were expected to expire in the ten years leading up to 2017 and the price disclosure components of the reforms would therefore translate into significant savings to the government. Indeed, Federal Treasury’s second Intergenerational Report, which was released in April 2007, estimated that these reforms could save the PBS an estimated $3 billion over 10 years.26

The 2006 reforms specifically addressed measures to increase the uptake of generic medicines as the percentage of generics dispensed in Australia was relatively low compared to other countries in the western world. Data indicated that the Australian generic uptake before the introduction of the 2006 PBS reforms was less than 30 per cent, compared to over 50 per cent in the US, 44 per cent in the Netherlands and 70 per cent in Denmark.27 Financial incentives were introduced for pharmacists to dispense generic medicines when available and from 1 August 2008 pharmacists received an additional $1.50 when they dispense a generic, premium-free medicine; this incentive has now increased to $1.53.

To increase consumers’ awareness of generic medicines, the government committed to the provision of a public awareness campaign to increase their knowledge and usage of generic medicines. However, the government dramatically reduced the funding available for the awareness campaign in the 2008-09 budget from $20 million to $5 million.28 Yet, reports indicate that

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24 Department of Health and Ageing, n 23, p 2  
27 The Pharmacy Guild of Australia, Media release: Guild and Generic Health to promote generic medicines, 6 November 2008  
television and radio advertising of generic medicines\textsuperscript{29} in combination with information on various websites and handouts\textsuperscript{30} seemed to have increased public awareness of generic medicines since the introduction of the 2006 PBS reforms.

When the reforms were announced it was estimated that there would be an average saving of $2.76 per prescription.\textsuperscript{31} Research that involved a survey of 150 pharmacists, conducted by the specialist health care market research company Cegedim Strategic Data (CSDA) during the first quarter of 2009, found that 79 per cent reported a rise in generic substitution while 19 per cent stayed the same.\textsuperscript{32} The pharmaceutical industry also reported an increase in generic volumes since the introduction of the reforms.\textsuperscript{33}

The government, through the PBS, is the major purchaser of medicines in Australia and it is therefore important for pharmaceutical manufacturers to have their medicines PBS listed. A recent dispute between Sanofi-Aventis/Bristol-Myers Squibb and Apotex, that involved the anti-clotting medicine clopidogrel, served to demonstrate the financial benefit that manufacturers receive in having their medicines PBS listed. The Federal Court, at the end of September 2009, declared the relevant Australian patents that covered the Plavix\textsuperscript{32} brand invalid, thereby ending the Sanofi-Aventis/Bristol-Myers Squibb PBS listing monopoly. It was estimated that Plavix\textsuperscript{32} generated $423 million in PBS and RPBS prescriptions between August 2007 and August 2009.\textsuperscript{34} The end of the patent opened up arguments over how much Apotex had lost in being held back from PBS listing for two years and a battle started over the payment of a $40 million bond to Apotex. This bond was originally put up by Sanofi as security against damages to be awarded to Apotex should the appeal in the patent revocation case failed, as was indeed the final Court outcome.

**GENERIC MEDICINE SUPPLY FRAMEWORK**

The PBS is regulated by the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cth) under Part VII of the *National Health Act 1953* (Cth). The Repatriation Pharmaceutical Benefits Scheme (RPBS) provides pharmaceutical benefits for veterans and eligible dependants, subsidised by the Department of Veterans’ Affairs (DVA) through the *Veterans’ Entitlements Act 1986* (Cth). The range of medicines and dressings available through the

\begin{itemize}
  \item \textsuperscript{29} The Pharmacy Guild of Australia, n 27
  \item \textsuperscript{30} National prescribing Service, *Generics campaign*
  \item \textsuperscript{31} Packam B, “Deal to cut drug prices”, Sydney Herald Sun 17 November 2006, p 3
\end{itemize}
RPBS is more comprehensive than those available through the PBS. Both the PBS and RPBS are administered by Medicare Australia.

Regulation 19 of the National Health (Pharmaceutical Benefits) Regulations 1960 (Cth) provides details about PBS prescription requirements. Prescribers should indicate whether brand substitution is not permitted and according to the 2003 amendments to the National Health (Pharmaceutical Benefits) Regulations 1960 (Cth), prescribers should not be using a computer default which results in all prescriptions being indicated as ‘brand substitution not permitted’. Apart from complying with Regulation 19, prescribers also need to follow state and territory drugs and poisons legislation when writing PBS prescriptions. Generic substitution by pharmacists without reference to the prescriber is permitted where:

- The patient agrees to the substitution;
- The two items are identified as bioequivalent in the Schedule of Pharmaceutical Benefits;
- The prescriber has not indicated on the prescription that substitution is not to occur; and
- Substitution is permitted under the relevant state or territory legislation.

The supply of pharmaceutical benefits is regulated under sections 85 to 98 of the National Health Act 1953 (Cth). A person cannot receive a pharmaceutical benefit unless it is supplied by an approved pharmacist on presentation of a prescription written in accordance with the National Health Act 1953 (Cth). In terms of the National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007 (No PB 42 of 2007), approved pharmacists are required to comply with the Pharmaceutical Society of Australia’s Code of Professional Conduct and

35 At the present time doctors, dentists and approved optometrists may prescribe pharmaceutical benefits. Prescribers require a prescriber number, issued by Medicare Australia.
38 Pharmaceutical benefits are mainly supplied by ‘approved pharmacists’ under Section 90 of the Act. Section 4 defines a pharmacist as: [A] person registered as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists, and includes a friendly society or other body of persons (whether corporate or unincorporate) carrying on business as a pharmacist.
39 Section 89 of the National Health Act 1953 (Cth)
40 The Pharmaceutical Society of Australia is the national professional organisation for all pharmacists in Australia. More information about the Society is available at http://www.psa.org.au/
Professional Practice Standards. This determination is binding on a pharmacist, approved under section 90 of the National Health Act 1953 (Cth).

The Code of Professional Conduct, consisting of nine principles by which members of the profession interact with clients, other health professionals and the community, has been endorsed by the pharmacy registering authorities and should form the basis of pharmacists’ activities. Principle one of the Code states that ‘The primary concern of the pharmacist must be the health and wellbeing of both clients and the community’. Pharmacists therefore have an ethical obligation to consider patients’ wellbeing when they dispense a generic medicine. Pharmacists would be placed in a difficult legal position when basing substitution decisions solely on cost. Other issues, such as the potential for patient confusion, must also be considered as well as the appropriateness of the non-active ingredients.

Several of the Professional Practice Standards specifically apply to generic dispensing. For example: the Dispensing and Counselling Standard, the Guidelines for pharmacists on PBS brand substitution and the guidelines stipulating when to issue a CMI leaflet. Similar to the Code, the Professional Practice Standards have been endorsed or adopted by the pharmacy registering authorities. The authorities therefore use the Code and the standards and guidelines as admissible evidence in disciplinary proceedings and it is important that pharmacists implement the criteria as specified in these documents during generic dispensing. However, the implementation of certain criteria may be challenging to apply in practice on every occasion due to time pressures, creating risks for pharmacists.

Pharmacy dispensing software has been changed since the 2006 PBS reforms to prompt pharmacists about generic substitution. Dispensing programs can be set up so that a message will appear during dispensing when a brand is chosen that will not result in the pharmacy receiving the generic dispensing incentive. If a more expensive brand with the BPP is chosen, a notice appears asking if the dispenser wishes to continue dispensing. Substitution of a medicine for another brand during dispensing is simplified by the use of assigned keystrokes which display a list of generically substitutable brands for selection. It is noted that the use of these generic

42 Until national pharmacist registration is implemented in mid-2010, the pharmacy registering authorities have the responsibility for the registration and discipline of registered pharmacists through state and territory legislation and provide for the regulation of the profession throughout Australia.
substitution methods is only activated when there is a bioequivalent medicine available to be substituted.  

SAFE USE OF GENERIC MEDICINES

In addition to the professional practice standards and guidelines, the National Prescribing Service (NPS) has also developed criteria regarding the dispensing of generic medicines and recommends that substitution should occur only after consultation with the patient, with their informed consent, and after considering the following:  

- The patient’s ability to understand and manage the change;
- Whether the presence of particular inactive ingredients (e.g. lactose) limits their choice of brands; and
- Whether packaging differences might present problems.

NPS further identified the following points that should be discussed and clarified with patients:

- Advise that alternative brands contain the same amount of the same active ingredient and are as effective and safe;
- Reassure that all medicines registered in Australia are required to meet the same strict quality standards;
- Explain which medicine the new brand will replace and that the patient should not take both medicines at once;
- Identify and discuss any differences in appearance between the old brand and the new one;
- Provide the active ingredient name and point it out on the packaging and/or Consumer Medicine Information (CMI); and
- Provide the CMI for the new brand.

Generic dispensing therefore places additional responsibility on pharmacists as they need to ensure the systems are in place to determine which patients agree to have generic medicines dispensed and that those patients receive the appropriate counselling.

Generic substitution increases the risk for medication errors to take place. This risk is increased at all levels, namely at the hospital, pharmacy, and at patient level. A recent Victorian pharmacy error clearly indicates the importance of public education on the necessity to check the active ingredients of medicines. This error, which led to the hospitalisation of a seven-year-old asthmatic boy, involved the incorrect dispensing of Risperdal® (risperidone) instead of Redipred® (prednisolone). The boy’s parents subsequently gave him large doses of risperidone for his asthma. An important factor that contributed to this potentially fatal incident was the fact

that the parents did not identify the error, even though the boy’s father said that they had been issued at least two bottles of the wrong medication by their pharmacy. He further commented: “It comes in the same size bottle; it’s liquid and looks the same. We just thought this other drug was a generic brand of the same drug.” These comments suggest system failures in both the dispensing and patient counselling processes and the need to educate patients to focus on active ingredients rather than on the brand names.

An analysis of the Pharmacists Board of Queensland disciplinary case data similarly indicates that generic substitution contributes to errors. In one case the patient specifically indicated that the substitution of a generic substance directly contributed to her confusion:

[the patient] noticed the label underneath stated Aldazine 100 (thioridazine tablets) and assumed that she had been given a generic brand as she was always asked a question regarding dispensing a generic equivalent when presenting prescriptions at the pharmacy.

This case emphasises the important role pharmacists have in the counselling of patients when substitution has taken place. The increased error risk involved with generic substitution is also a reality in hospital practice. One such an example is a case reported to the United States Agency for Healthcare Research and Quality. The case involved a patient suffering from toxic doses of the antiepileptic carbamazepine, which was a result of a change in the carbamazepine brand to a generic formulation that tended to settle out of suspension significantly faster than the original brand. Failure to shake the bottle prior to administration resulted in the initial doses being diluted with the remaining solution becoming increasingly concentrated which subsequently resulted in a toxic dose. This case specifically highlights the importance of having a very cautious approach with regard to substitution of anti-epileptic medicines.

ANALYSIS OF PHARMACISTS’ OPINION ABOUT THE REFORMS AND GENERIC SUBSTITUTION

Pharmacists have been criticised by doctors for substituting generic medications when not appropriate and not in the patient’s best interest, with patient safety being compromised in some instances. A need was therefore identified to determine the processes and procedures in place in community pharmacies regarding generic dispensing. Ethical approval from the Griffith University Human Research Ethics Committee was subsequently obtained to research ‘The impact of an increased demand for generic substitution on the practice processes and procedures followed by community pharmacists’. A

50 The Bendigo Advertiser, Ethan’s nightmare - boy rushed to hospital drug mix-up, 21 August 2007.
53 Wilson P, “GPs urge action on illegal generic substitution”, Medical Observer 10 April 2009 pp 1 & 4
face-to-face interview tool was developed, considering the literature and national practice guidelines, and was validated and tested on a practitioner. It consisted of both open and closed ended questions which focused on determining pharmacists’ opinions, perceptions, experiences and their knowledge of the 2006 PBS reforms regarding generic medicines and the effect of these changes on pharmacy practice.

Ten Gold Coast\textsuperscript{54} pharmacists were selected to be interviewed, following a stratified sampling process during which 50 pharmacists were invited to participate. The ten pharmacists were regarded as representative of place of work (banner versus independently owned pharmacy), position in the pharmacy (owner versus employee), years of experience, pharmacy location and gender. Participants therefore represented a wide range of demographics and experience. (Table 1)

Table 1: Demographics of pharmacists interviewed (n=10)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Percentage (%)</th>
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<tr>
<td>Male</td>
<td>50</td>
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<tr>
<td>Female</td>
<td>50</td>
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<table>
<thead>
<tr>
<th>Years of practice</th>
<th>Percentage (%)</th>
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<td>&lt;10 years</td>
<td>40</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>60</td>
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<table>
<thead>
<tr>
<th>Position</th>
<th>Percentage (%)</th>
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</tr>
<tr>
<td>Employee</td>
<td>70</td>
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<table>
<thead>
<tr>
<th>Pharmacy type</th>
<th>Percentage (%)</th>
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<tr>
<td>Banner group</td>
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<td>Independent</td>
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The ten face-to-face interviews were conducted during December 2008 and January 2009 and ranged between 13 and 32 minutes. Interviews were voice recorded and subsequently transcribed for thematic analysis. Although the interviews covered a wide range of issues, three themes will be discussed in detail, namely (1) patient safety, (2) pharmacy procedures and (3) financial implications.

**Patient safety**

Although the participants all agreed that generic medicines are safe, there were concerns about promoting generic medicines to patients that could become confused about different brands, especially non-English speaking patients:

> We are always cognitive of the potential to push patients into taking generics where it may not be appropriate...We think there is the potential to push upon people generics against their wishes and that can be dangerous. Particularly

\textsuperscript{54} The Gold Coast is a city with approximately 450,000 people located in South East Queensland and was selected for the study as being representative of urban and semi-rural Queensland.
people from non-English speaking backgrounds and they’re the one’s we’ve identified we should be very much aware of the benefit potentially and just maintaining what ever they’re on, if it’s an original brand then so be it.

Other instances requiring special caution that were mentioned included elderly patients and patients with special needs or certain allergies. Five of the participants said they would not substitute brands for patients on medicines with a narrow therapeutic index while the other five said they would but with caution:

…we haven’t made a blanket policy not to change that at this stage – although that’s something that I guess always is being considered, by me and the other pharmacists, it’s pretty hard to get a very clear definition of when it should be done or not. I mean legally we can change it if it’s ‘a’ flagged. Various articles in various journals suggest that it shouldn’t be done, and then others will have a contrary viewpoint. So, in general terms, we still have at this stage been substituting them.

With regard to narrow therapeutic medicines, participants indicated that they would discuss with patients/carers the benefits and the risks involved with substitution.

The majority of participants reported that they differentiate between substituting ‘acute’ medicines (treatment lasting one to two weeks) versus ‘chronic’ medicines (treatment to last longer than two weeks). The study found participants were more likely to substitute items that are for the treatment of acute conditions:

….. the acute medications are much easier to substitute and it’s pretty rare that people will insist on taking an original brand and I guess from our perspective as well we can see no real benefit for people taking an original brand that’s acute medication, for example an antibiotic.

The participants indicated that they had concerns about patients with repeat prescriptions receiving different brands with each dispensing, which could potentially cause confusion if adequate labelling was not provided. The importance of recommending to patients with chronic conditions (requiring repeat prescriptions to be filled on a monthly basis) to use one pharmacy was highlighted. However, one participant emphasised that it is a well known fact that most patients use more than one pharmacy and subsequently end up using different generic brands:

All be it, it’s something that probably does happen to some extent. It’s not the preferred option. Ideally the patient that’s changed to a generic where possible should generally be kept on that generic.

*Pharmacy procedures*

55 Narrow therapeutic index medicines are also referred to as critical dose medicines. These are medicines for which relatively small variations in plasma concentrations may cause significant adverse effects or loss of efficacy. Reference: National Prescribing Service. *Critical dose medicines and brand substitution*, Australian Pharmacist Vol 28 No 2 Feb 2009
All of the participants had protocols in place that applied to receiving prescriptions and patient consent for generic substitution which either included a notation on the prescription or filling in a separate form. The interviews covered questions which included who is likely to take in the prescription, who offers substitution, which patients would not be offered substitution and what training staff received about generic substitution. The majority of participants said that a pharmacy assistant was the most likely person to receive a prescription. All participants indicated that their staff previously received training about generic medicines. Seven of the participants made use of dispensing software to prompt dispensing staff about the financial incentive for generic dispensing.

The impact on workload in the dispensary since the changes was not significant as participants indicated that dispensary staff were already familiar with generic substitution. However, the majority of participants indicated that there was an increase in workload for pharmacists in terms of counselling patients about substitution as this task should ideally be done by a pharmacist or intern (pre-registrant pharmacist). The following two responses illustrate this increase in workload, answering the question ‘In your pharmacy, who is most likely to provide patient counselling regarding a generic brand substitution?’:

Pharmacist or pre-reg pharmacist. Pharmacists have bigger trust and people tend to listen to them. Staff can start from the beginning but if they are reluctant or not sure the pharmacist can talk about the details.

It could be a pharmacist and I include pre-registration pharmacists under that definition but it could also be a pharmacy assistant just due to work load. Ideally pharmacist but to be honest not in all situations would a pharmacist be the person to do it but certainly they would be the preferred person if they were available.

Financial implications

With regard to financial viability of pharmacies as a result of the PBS reforms, the responses varied. Five of the participants expressed that the PBS changes resulted in no effect on financial viability, four expressed a negative impact and one had no opinion. All of the participants agreed that the long-term effects were unclear and that the profession was at an uncertain stage regarding its financial viability as profit-margins were getting smaller. When the effect of the changes on pharmacy practice was discussed the majority of participants were concerned about the future of community pharmacy.

DISCUSSION

The research confirmed that the recent PBS changes involving generic substitution impacted on pharmacy practice in a variety of ways. Although the participants indicated that the increased substitution rates had not significantly increased pharmacy support staff workload, they pointed out that it placed additional burdens on pharmacists. Overall, participants were comfortable
with the quality of generic medicines and with substituting, provided that the substitution did not put patient safety at risk. The participants were well aware of instances when substitution may be inappropriate.

The participants were concerned about the financial viability of community pharmacy and were uncertain about the potential future effect of the PBS reforms on profit margins. Research in the nursing profession has indicated a direct relationship between low morale and reduced quality of care. It is therefore possible that the current uncertainty in the profession could impact on pharmacists’ morale, which could indirectly impact on the quality of community pharmacy services. This uncertainty is not in patients’ interest. The financial impact of the PBS reforms on community pharmacy has indeed been a topic of ongoing discussion in pharmacy media and at conferences. Community pharmacy is under pressure to ensure the sustainability of the PBS. Federal Health Minister, Nicola Roxon, recently indicated that industry discounts and incentives for pharmacists were still adding too much to medicine prices for patients. She was quoted: “These discounts are not being passed on to the consumer – in this case, patients and the Pharmaceutical Benefits Scheme... The Government does not accept that taxpayer funds should help prop up profits, particularly during the current economic crisis”. The current economic environment, in combination with the PBS reforms, pose significant difficulties for many pharmacies and pharmacists need to have change management processes in place. The WADP mechanism of price disclosure could potentially impact on the discounts from generic manufacturers currently enjoyed by pharmacies.

The generic PBS landscape has changed significantly over recent years and these changes directly impact on the financial viability of community pharmacy, pharmacist workload and patient safety. Pharmacists are required to use professional judgement and not supply a generic brand if there is any doubt the generic will cause patient confusion or harm; the patient’s health outcome should be the prime consideration in any brand substitution decision. Other issues, such as the appropriateness of the non-active ingredients, must also be considered. The growing generic market and government push towards substitution has increased generic dispensing, which places increased responsibility on pharmacists that should be managed in community pharmacy practice.

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57 Most of the main speakers at the 2009 Australian Pharmacy Professional Conference focused on the PBS reforms. More information available at http://www.appconference.com/
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