



Summary

Policies allowing pharmacists to substitute brand name medicines for bioequivalent generic medicines - unless a prescriber actively indicates otherwise - have been in place for more than a decade.

Of concern to the AMA are anecdotal reports that a doctor's prescription directive "Brand Substitution Not Permitted" is being ignored, as well as recent speculation that the Commonwealth is considering policies that would compel doctors to prescribe generic medicines. At the same time, a policy statement on brand substitution, including professional roles and responsibilities, is under development by the Australian Pharmaceutical Advisory Committee.

The results of an AMA fax survey of 386 Australian GPs on brand substitution issues in April 2006 revealed:

- Most GPs do not indiscriminately prevent brand substitution of all their prescriptions, with 80% of doctors surveyed only designating "Brand Substitution Not Permitted" in a minority (one-quarter or less) of patient prescriptions.
- Most GPs decide to disallow substitution on prudent and reasonable grounds, with more than 60% of doctors saying patient safety, patient compliance, and clinical issues were the key factors influencing their decision. Another common consideration was patient requests to stay on a brand name medicine.
- Despite these clinical considerations and advice on scripts, 75% of GPs estimate there have been instances where their prescription has been changed against their advice. Forty per cent of GPs believe this to be happening to up to 1 in 4 scripts marked "Brand Substitution Not Permitted".
- 15% of GPs reported that they had only found out about the medicines change because their patient had an adverse reaction as a result.
- The most common way a GP discovered their script had been changed was through their patients - at their next consultation or when seeking another prescription (68%), or when patients contacted them for advice on the substitution (43%). About 16% of GPs reported that a pharmacist had contacted them about the substitution.
- Discovery of "double-dosing" by patients was another common issue raised by GPs, as well as increased patient confusion due to multiple generic substitutions.
- A majority of GPs (77%) were either somewhat or very concerned about the effect of their scripts being substituted, without consultation or advice, on their patients' health care management.

AMA brand substitution survey

Background

Commonwealth policies that allow pharmacists to substitute brand name medicines for bioequivalent generic medicines - unless a prescriber actively indicates otherwise - have been in place since 1 December 1994. Since the 1980s the AMA has had formal policies opposing the substitution of medicines without the prescribing doctor's permission, as well as any compulsion on doctors to prescribe generically (policies 44/84 and 45/84).

The AMA recently received anecdotal reports that substitution is occurring even when the "Brand Substitution Not Permitted" box has been ticked by GPs on PBS prescriptions. At the same time, it was reported in March 2006 that the Commonwealth was considering PBS cost-saving proposals that would give subsidy preference to one medicine in a class, probably a generic medicine. The AMA warned that such a move effectively amounted to compulsion on doctors to prescribe a generic medicine based on a patient's financial - rather than medical - circumstances.

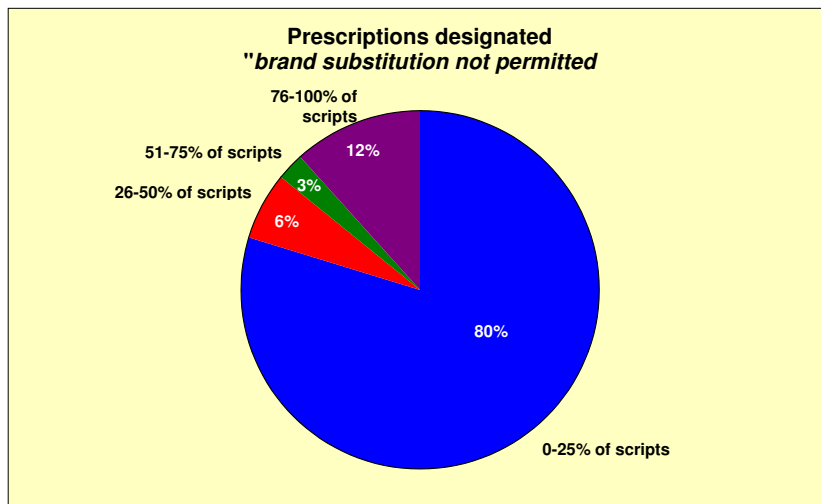
More recently, some media reports suggested that doctors are denying patients access to generic medicines because of the influence of pharmaceutical marketing, following the Australian Competition and Consumer Commission's announcement that it proposes to re-authorise the code governing the pharmaceutical industry's dealings with doctors.

To gauge the extent of brand substitution, its impact and doctors' views, the AMA sent a fax survey to 1,508 privately practising GPs in April, to which 386 doctors replied (a response rate of 25.6%).

Results

How often and why GPs designate "brand substitution not permitted"

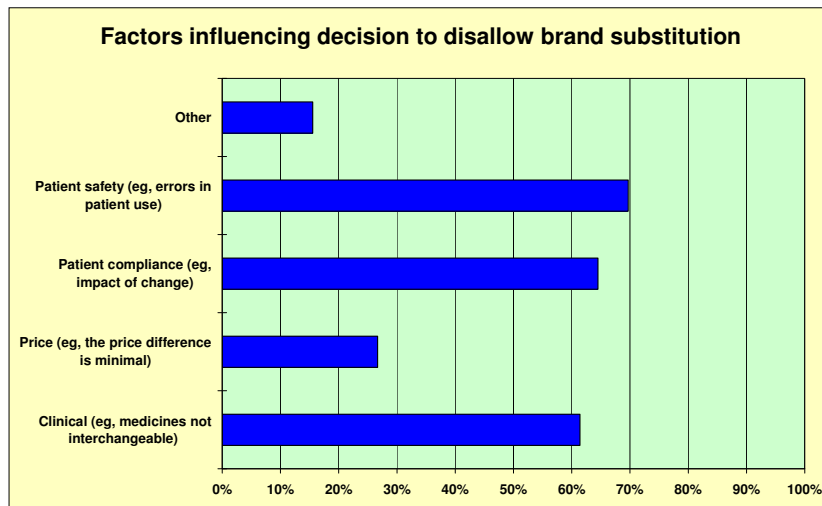
Most GPs (80%) surveyed said they designated "brand substitution not permitted" in less than one-quarter of their prescriptions. Only 15% of GPs disallowed substitution in the majority of scripts.



Patient safety, patient compliance, and clinical considerations were the key factors influencing decisions to disallow substitution.

AMA brand substitution survey

GPs surveyed were asked to indicate which factors influenced their decision not to allow substitution and they could indicate more than one factor where they felt it appropriate. Of the GPs surveyed, the big factors affecting decisions to not allow substitution were the risk of a change in medicine packaging or tablet form affecting their patient's medicine use and compliance (65%), and a belief that the brand and generic medicines are not clinically interchangeable (61%).



Meanwhile, patient requests for brand medicines topped the list of “other” reasons GPs disallowed substitution, with some doctors explaining that a patient's preference, perceived tolerance to a medicine, and the taste, were among their considerations.

A number of GPs also revealed that their frustration with pharmacists' disregard for the “Brand Substitution Not Permitted” instruction had led them to ‘give up’ trying to use it.

“I don't bother, the chemists ignore it,” wrote one GP.

“I have given up ticking the box because of the disregard of the instruction, even when I sent a letter to all local chemists,” wrote another.

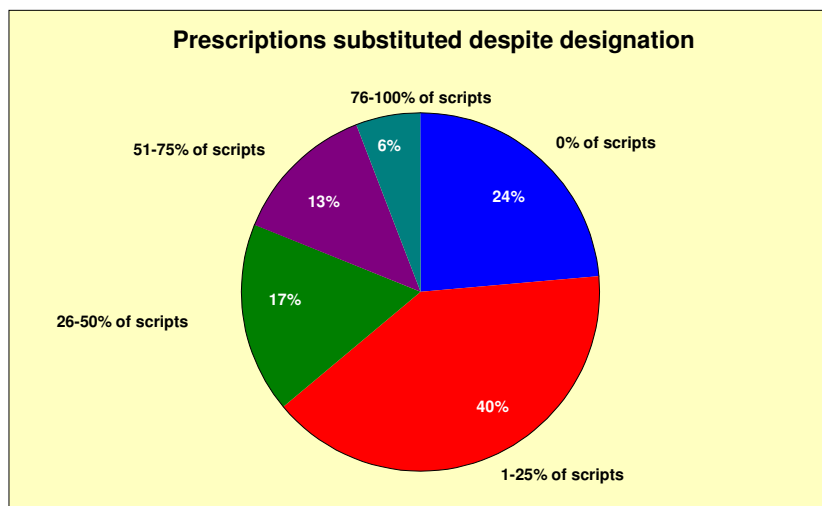
Occasions GPs believe substitution has occurred despite their directive not to do so, and how they find out about it

Where GPs had determined a brand name script should **not** be substituted, three-quarters of GPs believed there had been instances of substitution of medicines.

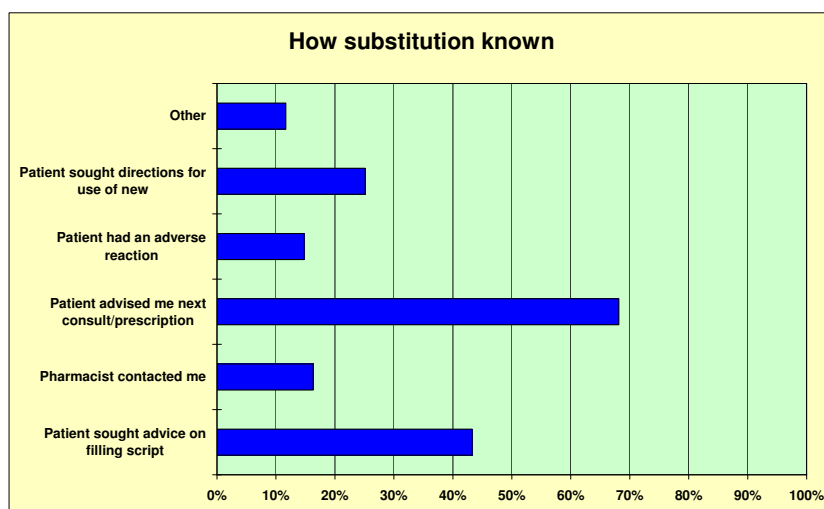
Forty per cent of GPs believed that up to 1 in 4 of their scripts marked “Brand Substitution Not Permitted” had been changed; while a further 17% of GPs believed this happened in up to 1 in 2 such scripts.

Almost one-quarter of GPs believed their instructions to not substitute had been followed on all occasions.

AMA brand substitution survey



GPs were asked how they found out about substitution occurring against their express request and they could again indicate more than one way of finding out where they considered it appropriate. The most common way a GP found out about substitution of their prescription was through the patient, at the next consultation (68%); when the patient sought advice on filling the script (43%); and advice on how to use the new medicine (25%). More seriously, 15% of the time a GP only found out about substitution of a medicine when their patient had an adverse reaction as a result.



Of the “other” ways 45 GPs reported they had found out about substitution of a medicine, nine doctors found out in the context of their own medication management review with the patient.

“Medication reviews and examined their boxes. Pharmacist rarely, if ever, contacts. Many times patients can have three-plus brands of same drug - very confusing for patient and very dangerous,” wrote one GP.

The confusion of patients was sometimes the only signal to GPs that a patient’s medication had changed. Some GPs reported *“Confusion with name change”*, *“Confusion of patients re: colour and brand”*, *“Confusion when [patient] admitted as to what tablets taking”*.

Discovery of double-dosing of medicines was also noted by eight other GPs. One of those GPs wrote that he/she found out about the prescription substitution when the patient had to be admitted to hospital because of double-dosing.

AMA brand substitution survey

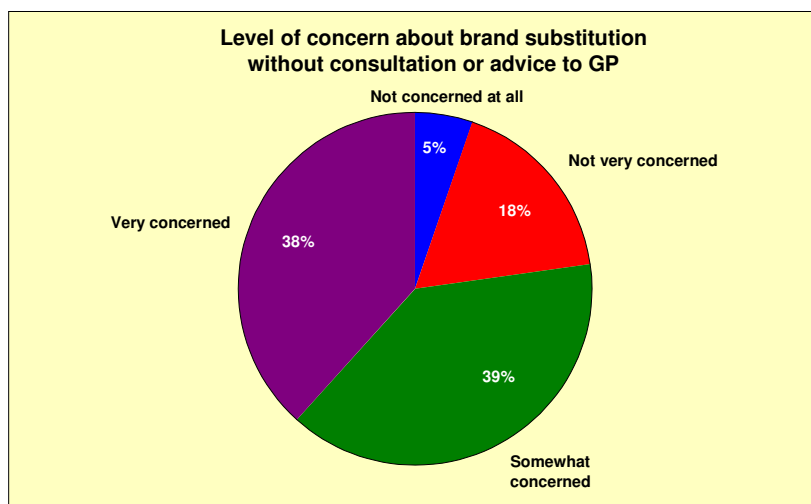
In addition to double-dosing problems, some GPs also identified the increased confusion caused by the multiple substitution of the different generic substitutes.

“What is also disconcerting is that substitutions can vary from month to month, increased confusion!” wrote one GP.

The dispensing pharmacist only contacted the GP in 16% of cases, suggesting that inter-professional consultation or advice is possible but not widespread.

Levels of GP concern

A majority of GPs (77%) were either somewhat or very concerned about the effect of brand substitution, without consultation or advice back to them, on their patient’s health care management.



In the context of the results throughout the survey, the higher levels of GP concern appear to be strongly linked to the need for consultation rather than a blanket rejection of the notion of generic substitution.

**AMA Federal Secretariat
Canberra
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