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## WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

# Switching around the world: Australia

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*Very briefly, I'd like to take you this afternoon through the setting in which switch occurs in Australia, what it took to turn the tide, the mechanics of applying for switch, an assessment of its impact and how I think what we've heard today relates to the WSMI Guiding Principles document.*

### Brief history of switch in Australia up to 1994

Any discussion of Switch in Australia must start with a reminder that in Australia the classification of substances is multi-tiered.

#### A Multi-tiered System of Classification

- Schedule 4 Prescription medicines
- Schedule 3 "Pharmacist Only"
- Schedule 2 "Pharmacy Only"
- Unscheduled General sale

Prescription medication is Schedule 4 or higher, while non-prescription medication is divided into Pharmacist Only or Schedule 3 products, Pharmacy Only or Schedule

2 products and unscheduled products which are open sale. S2 and unscheduled products may be advertised. It was only recently that the ban on advertising was lifted on some Schedule 3 products. You may have read in *SWITCH Newsletter* as recently as last year about what Steve Francesco called our "lamentable", "backward" regulatory situation regarding advertising.

This regulatory system of incremental access is an artefact of the generally conservative, paternalistic nature of scheduling in Australia.

#### Conservative Approach

- Reactive
- Sponsors initiate switch
- NDPSC covers more than medicines



Historically, a conservative approach has been taken toward switch as well as initial classification. The system is reactive – that is, manufacturers must initiate switch by lodging an application with the National Drugs and Poisons Schedule Committee. This committee schedules not only medicines but also agricultural and veterinary products, household chemicals and paints. By contrast, under the New Zealand system, the classification body reviews only medicines.

## 1994 changes in the system leading to improved outcomes

Until 1994, the NDPSC was made up of representatives of the states and territories. PMAA successfully lobbied for a change to the committee composition and suggested the criteria that should be used in classification. An Industry representative (PMAA's Scientific Director, Bronwyn Capanna) was appointed to the committee along with a consumer representative, a pharmacy representative and a representative of the regulatory authority (TGA).

### Changes in NDPSC since 1994



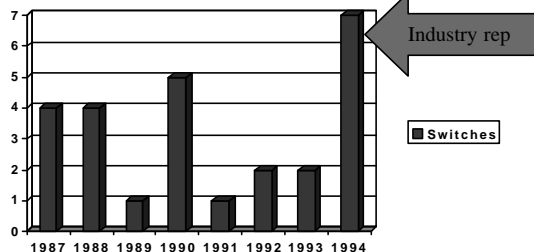
Representation from

- Industry
- Consumer
- Pharmacy
- TGA

Criteria for classification

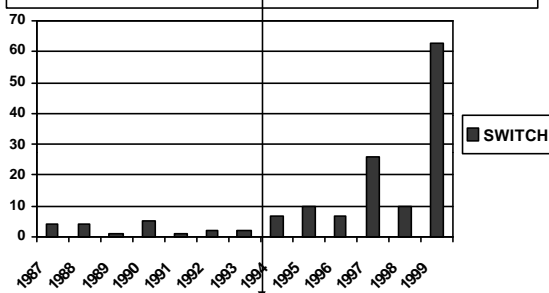
Bronwyn Capanna

### 1987-1994 Switch Outcomes



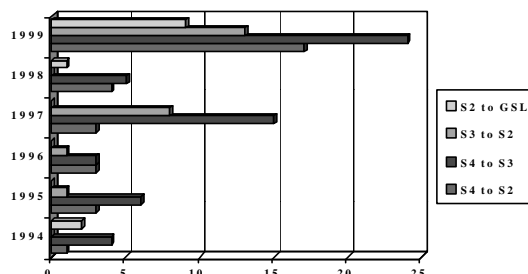
As you will see, these changes in composition led to dramatically better outcomes for switches. First, you see that there is overall improvement.

### Review of Switch



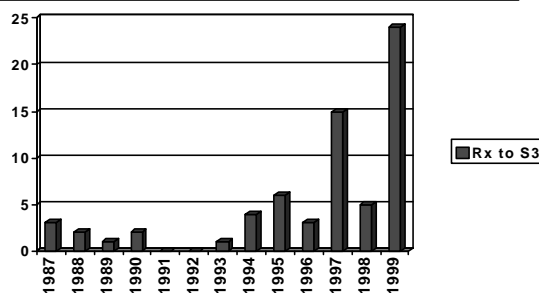
Since 1994, you'll note that we have had even better outcomes. In this slide, you can see that the change is particularly dramatic in certain schedules – for instance, in prescription to Schedule 3 switches.

### Switch Outcomes by Schedule

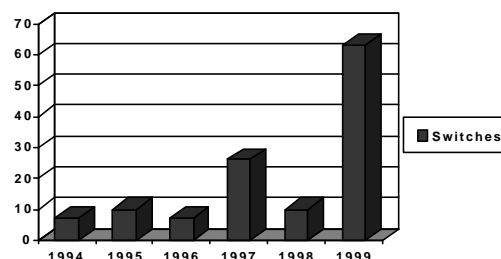


With Industry representation and a changed climate, since 1994, we've seen marked improvement.

### Rx to Schedule 3



### 1994-Present



In addition to industry representation, work under way to harmonise scheduling with New Zealand has allowed PMAA to seek adherence by the bureaucracy to principles of fair play as they were articulated by the Council of Australian Governments (COAG). In short, the COAG principles form a deregulatory philosophy, which places the onus on regulators.

## COAG Principles

- minimise the impact of regulation
- increase predicability of outcomes
- reflect international standards and practices
- review regulation regularly
- check flexibility of standards and regulation
- ensure transparency and procedural fairness

The general trend toward the adoption of the least restrictive schedule has been to our benefit. To facilitate the process, PMAA proposed a priority list of substances for harmonisation with New Zealand known as the Top 20 initiative. Twenty key substances were identified for expedited consideration and to serve as models for future scheduling harmonisation.

## Trans-Tasman Harmonisation Top 20 Initiative

- Priority substances
- Expedited consideration
- Serves as a model

### The mechanics of switch in Australia

Now I'd like to turn to the mechanics of switch in Australia. National Drugs and Poisons Schedule Committee (NDPSC) meets quarterly.

## Mechanics of Switch

- NDPSC meets quarterly
- Application 3 months prior
- 30 days advanced public consultation
- If approved, further consultation
- Seven months to come into effect
- But, if comment is received, it is considered at next quarterly meeting

An application for a change in scheduling must be filed three months before it is considered by NDPSC at its quarterly meetings. 30 days of advanced public consultation is allowed. If the change is approved, it comes into effect seven months after the meeting at which it was considered. This period is designed to allow for publication of results, further public comment and legislation change. If further comment is received, that comment is considered at the next quarterly meeting. In short, the process at the best of times takes the better part of a year.

## At Best

3 months + 7 months = Switch

## More Commonly

3 months + 7 months + 2 months = Switch

## If an Application is Rejected

- **Appeals** on issues of due process
- **Reconsiderations** on technical or other grounds

*Appeals* are considered on issues of due process only. A *reconsideration* may be requested on technical or other grounds—often in reaction to comment received.

### Three significant recent switches


In policy rather than economic terms, the most significant recent switches in Australia may well be fexofenadine, aciclovir and guaiphenesin.

- Fexofenadine is not really a “switch”. On the basis that it is a derivative of terfenadine—which was non-prescription at the time of the application—fexofenadine became the first new chemical entity to premier at Schedule 3. All others had a history of prescription status before entering Schedule 3.
- Aciclovir was on the market in Australia only as a prescription eye product. No approval had been given for topical use in herpes. Thus, another medicine entered the market specifically designed as a non-prescription product.

- Guaiphenesin, recognised as very safe, was allowed to go on general sale—the first medicine in ten years to switch to GSL. The ice seems to be broken.

### Assessing the current state of switch in Australia

### Assessing the Current Switch Situation



- Improvement since 1994
- Greater transparency
- Amenable to harmonisation
- More responsive to consumer trends

To paint with a broad brush, we have an improved situation in Australia, especially since 1994, in which the procedural elements of switch have become more transparent, more amenable to trans-Tasman harmonisation, and more responsive to changing consumer circumstances.

This last element is important to any assessment of switch in my country. The trend toward an increasingly self-reliant and confident consumer has been shown in research undertaken by PMAA. It is demonstrated in consumer demand for better consumer medicine information (CMI).

### Trend toward Complementary Medicines

- Self-reliance
- Self-selection
- Awareness of health issues




Consumers' great interest in recent years in complementary medicines and alternative therapies can be seen as a trend toward self-reliance and self-selection as well. Active participation in health and well being can be seen as evidence of a consumer trend toward awareness of health issues and a desire to take responsibility for one's own health care. In Australia, these consumer trends create a climate increasingly congenial for switch.

In addition, the case-by-case lifting of the ban on Schedule 3 product advertising made switch a more attractive option for manufacturers.

### The Impact of Chronic Conditions

- Ventolin (inhaled salbutamol)
- Asthma Card
- Counselling by Pharmacists



To assess the effect of switch, we must also consider the impact on consumers with chronic conditions. As you may already know, Ventolin (inhaled salbutamol) is Schedule 3 in Australia. To prevent reverse switch and to help asthmatics enjoy easy access while preventing Ventolin over-use, Asthma Cards have been introduced. For a nominal fee, consumers purchase at the Pharmacy an Asthma Card that is then used by the Pharmacist to record purchase dates. This record helps to flag increases in Ventolin purchases and allows pharmacists to counsel asthmatics appropriately—even if they purchase Ventolin at different pharmacies.

While I have provided you with statistics on the rate of switch, I unfortunately cannot provide you with health outcome data. This is an area ripe for future research. For instance, the impact of performance-based labelling should be addressed – does it allow more products to be accessed through “general sale” in countries where that exists and does it allow consumers to practice responsible self-medication for an increasing number of chronic conditions?

### Conclusions

As I've listened to my colleagues today, I'm convinced that we can all make use of the *WSMI Guiding Principles* at the local level to raise issues and improve access. For instance, it may prove valuable to point out to my Australian stakeholders that in many of the countries to which we like to compare ourselves, classification criteria begin with the assumption that medicines are non-prescription. It may prove a timely reminder as we seek harmonisation with other countries that most do not make the distinctions between Pharmacist Only, Pharmacy Only and general sale.

As Señor Bolaños clearly explained, a positive attitude toward responsible self-medication from Government is key to switch. Understanding world trends helped to create this positive attitude.

In short, the *Guiding Principles* can help us locally by reminding us to put in place standards that are best practice, and where possible, avoid parochialism.