



Singapore OTC Switching Regulation

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Singapore Drug Forensic Classifications

WHEN DO I REQUIRE A PRESCRIPTION?

GSL

GENERAL SALE LIST MEDICINES



- Also known as "over-the-counter" medicines. No PRESCRIPTION required.
- Used to relieve minor symptoms and may include natural and herbal remedies.
- Follow instructions on labels/packages. If unsure or symptoms if persist, please ask your pharmacist!

P

PHARMACY ONLY MEDICINES



- May be purchased under the supervision of your pharmacist. NO written prescription is required from a doctor.
- Intended for the management of minor ailments like cough, cold, fungal infections etc.
- The pharmacist will advise on how to use the medicine and when to seek medical attention.
- Quantity sold may be restricted by law.

POM

PRESCRIPTION ONLY MEDICINES



- Requires a VALID prescription from a LOCALLY-registered doctor.
- Includes antibiotics and medicines for most chronic conditions, e.g. diabetes, high blood pressure.
- Requires close monitoring and follow up with clinic visits.
- Take these medicines as directed. DO NOT STOP without first consulting your doctor.

WHY DO I NEED AN UP-TO-DATE PRESCRIPTION?

Doctors may change doses of chronic medicines frequently according to RESPONSE or SIDE EFFECTS. It is therefore important for you to keep a CURRENT record of the latest prescribed doses of medicines, and fill your most recent prescription instead of old ones.

Bring the most updated medication list with you at every clinic or pharmacy visit and in case of hospitalisation. Show it to your doctor and pharmacist when seeking advice, even if purchasing GSL items, supplements or vitamins.





Source: Pharmaceutical Society of Singapore

<http://www.pss.org.sg/know-your-medicines/safe-use-medicines/safe-use-medicines-singapore>

Singapore Regulatory Environment



Health Products Regulation Group's mission:
To **wisely** regulate health products to meet
standards of **safety, quality and efficacy**

How Health Science Authority (HSA) **enhances public access** to safe and effective treatment:

1. Exemptions for supply of POM without prescription
2. Reclassification: Product-specific

(1) Exemptions for supply of POM without prescription

- **List of 21 active ingredients: Conditions for exemption:**
 - ✓ Dose; Quantity; Labeling; Age restrictions
- Applies to products containing the **same active ingredient** and of the **same strength** for **similar indication/s** which meet the legal requirements for supply by a pharmacist without a prescription, while their legal classification remain as POM.
- Requires patient information leaflets (PILs) for the medicines supplied under this exemption

Active Ingredient	Exemption for supply of POM wo Rx	Effective date
Fexofenadine	<u>As an oral solid prep containing not more than 180mg</u> Indication: For the symptomatic treatment of allergic rhinitis & chronic idiopathic urticaria Max daily dose: 180mg Max supply: 10 tabs Min age: 12 years	1 July 2013

(2) Reclassification: The Basis of Switch Evaluation

Considerations:

1. Patient safety, supplied without HCP supervision
2. Potential for abuse (Public Healthcare Protection)

‘Downward’ switches:

- Medicines may be reclassified from POM to P or P to GSL if they have been deemed **sufficiently safe for use** with **reduced** or **without** medical supervision
- Usually triggered by Companies

‘Upward’ switches:

- Triggered by H S A internal review
- 59 cases from 2011 to 2014 (none in 2002 – 2010)
- Injectables, anaesthetics, higher risk actives e.g. morphine sulphate, codeine (tablets, cough linctus)

Reclassification eligibility criteria – Downward Switch

- ✓ The **use** of the product has been **sufficiently extensive**;
- ✓ The product has been **marketed** for a period of **time sufficient to establish a post-marketing adverse event profile**; and,
- ✓ The product's safety profile gives **no cause** for concern during the marketing period

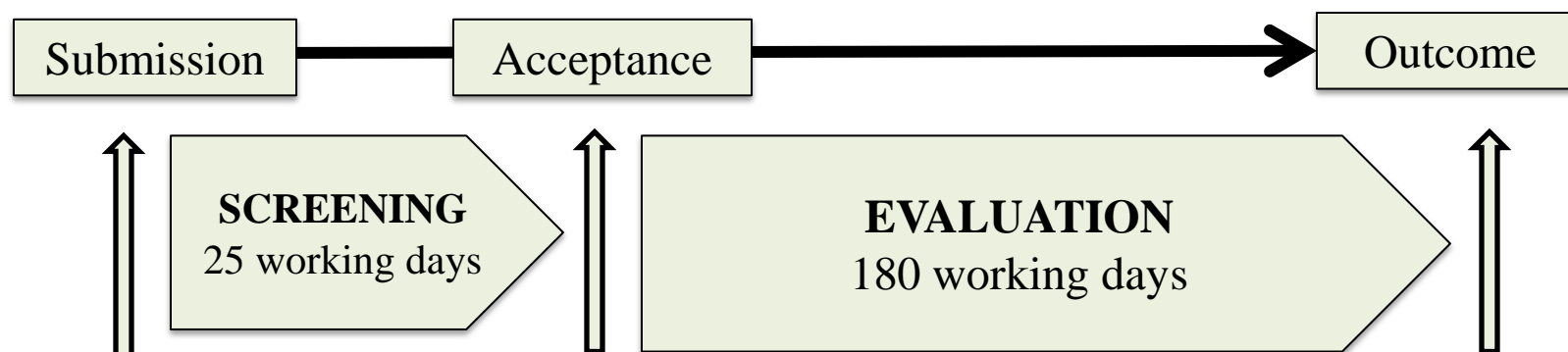
Based on industry experience:
Reclassification status
in other countries



Switch Process: Major Variation 2 (MAV-2)

Abridged evaluation route

Timeline (~10 months excluding stop-clock):



Source: Guidance on Medicinal Product Registration in Singapore (Effective 1 April 2011), Appendix 1

Data requirements



Module 1 / Part I :

- ☐ Table of Contents
- ☐ Introduction / Justification & rationale
- ☐ PRISM application form
- ☐ Product labels
- ☐ Approved SPC/PI/PIL
- ☐ Proof of approval in UK, US, Canada and/or Australia
- ☐ Registration Status in Other Countries

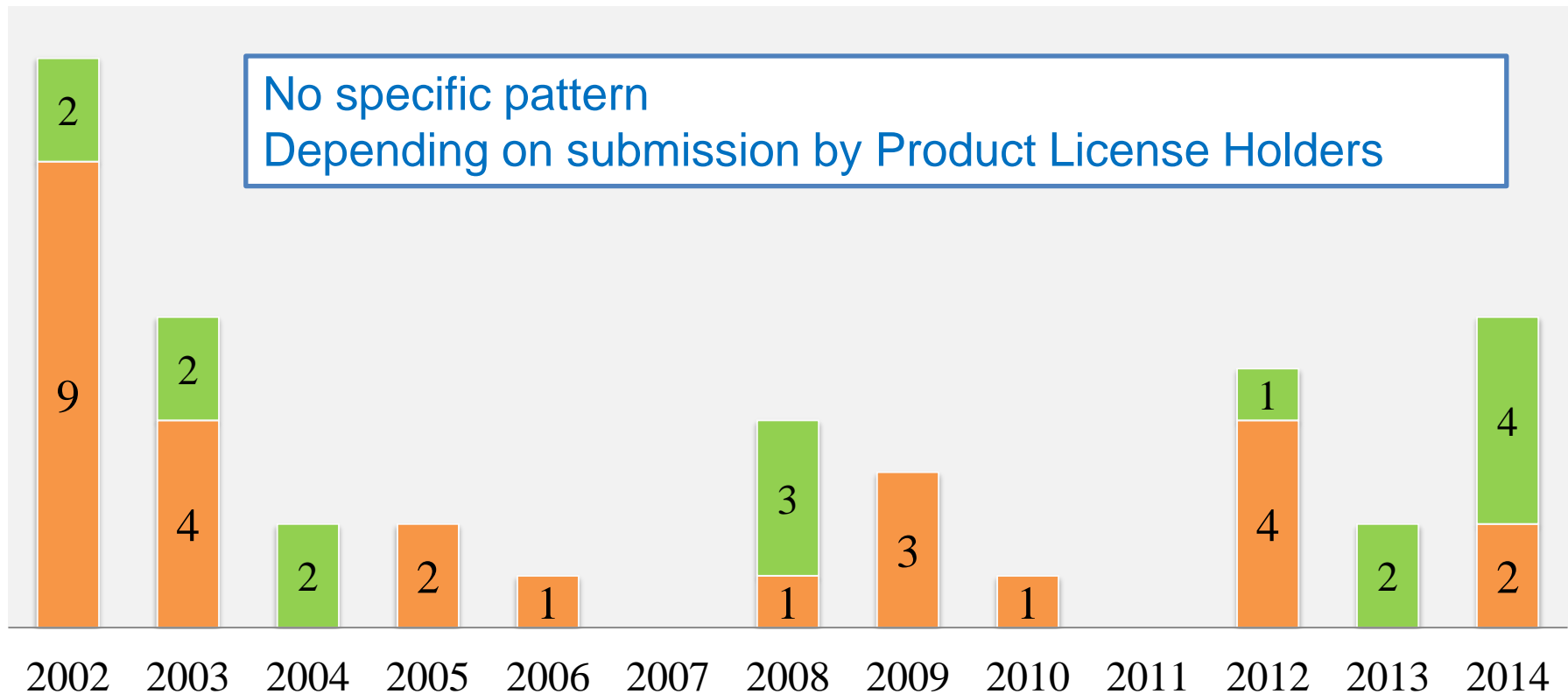
Module 2 / Part IV: Summary of Clinical Safety

Not required for
'me-too'
reclassification

What can the past switches teach us?

'Downward' reclassifications in Singapore (2002 - 2014)

From POM to P From P to GSL



Success Likelihood #1: Patient Safety – Lower risk products

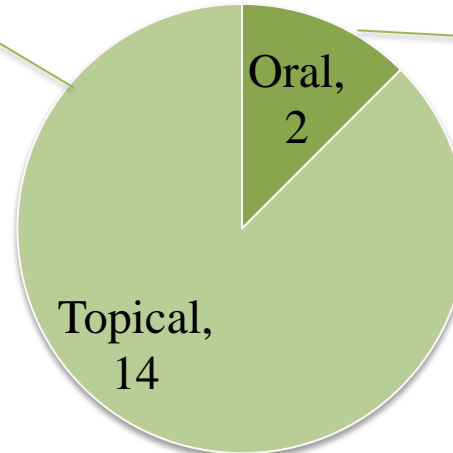
E.g. based on route of administration

Case study: 16 switches from P to GSL in 2002 - 2014

Examples:



Route of Administration



- Clarityn Tablet 10mg
- Clarityn Syrup 5mg/ml

Patient safety/ Public Health Safeguard is paramount!

'Upward' reclassifications in Singapore (2002 - 2014)

■ From GSL to POM ■ From P to POM

Contrast media injections

- For diagnostic imaging
- Parenteral administration

Triggered by ongoing internal review

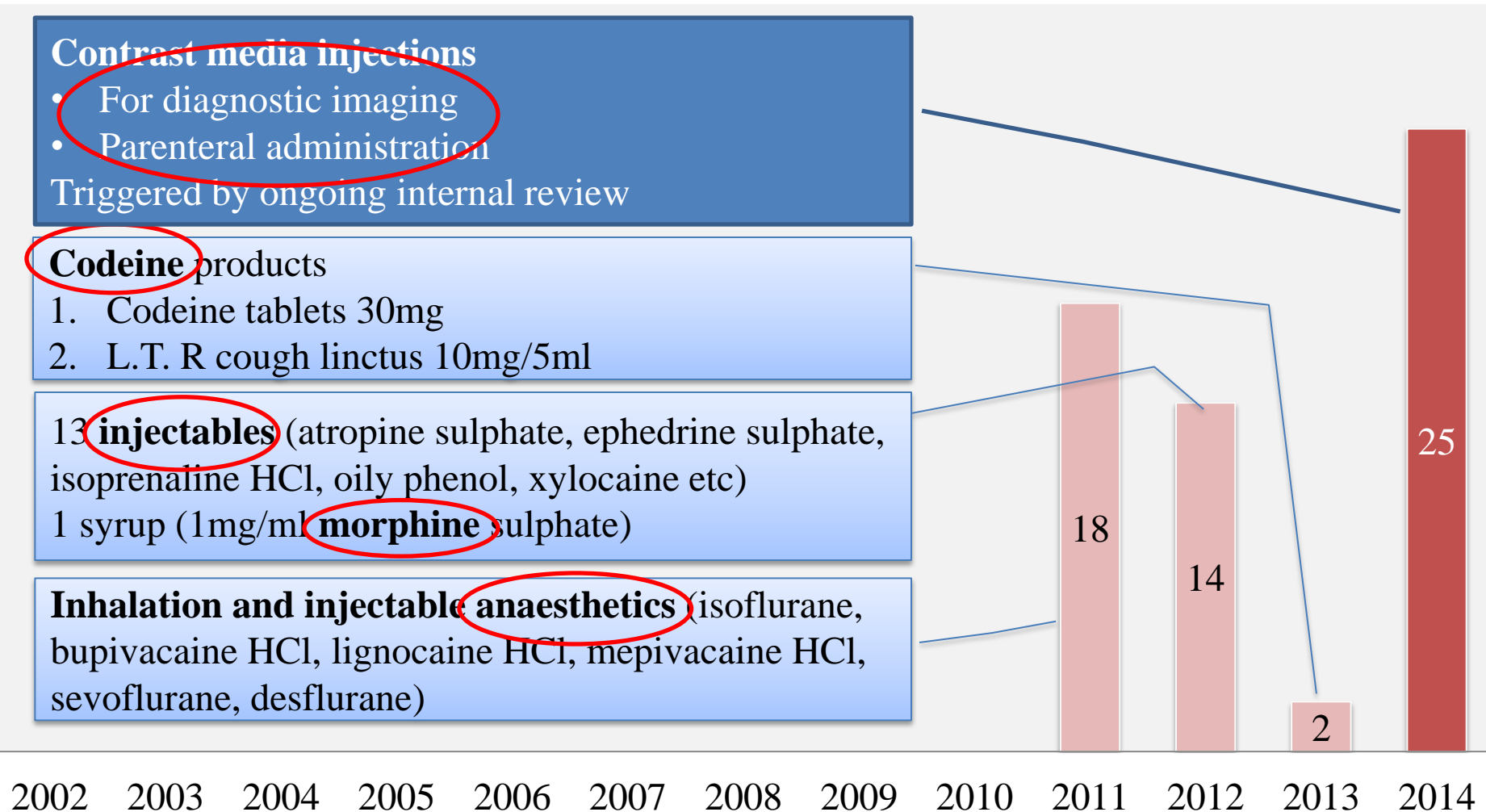
Codeine products

1. Codeine tablets 30mg
2. L.T. R cough linctus 10mg/5ml

13 **injectables** (atropine sulphate, ephedrine sulphate, isoprenaline HCl, oily phenol, xylocaine etc)

1 syrup (1mg/ml **morphine** sulphate)

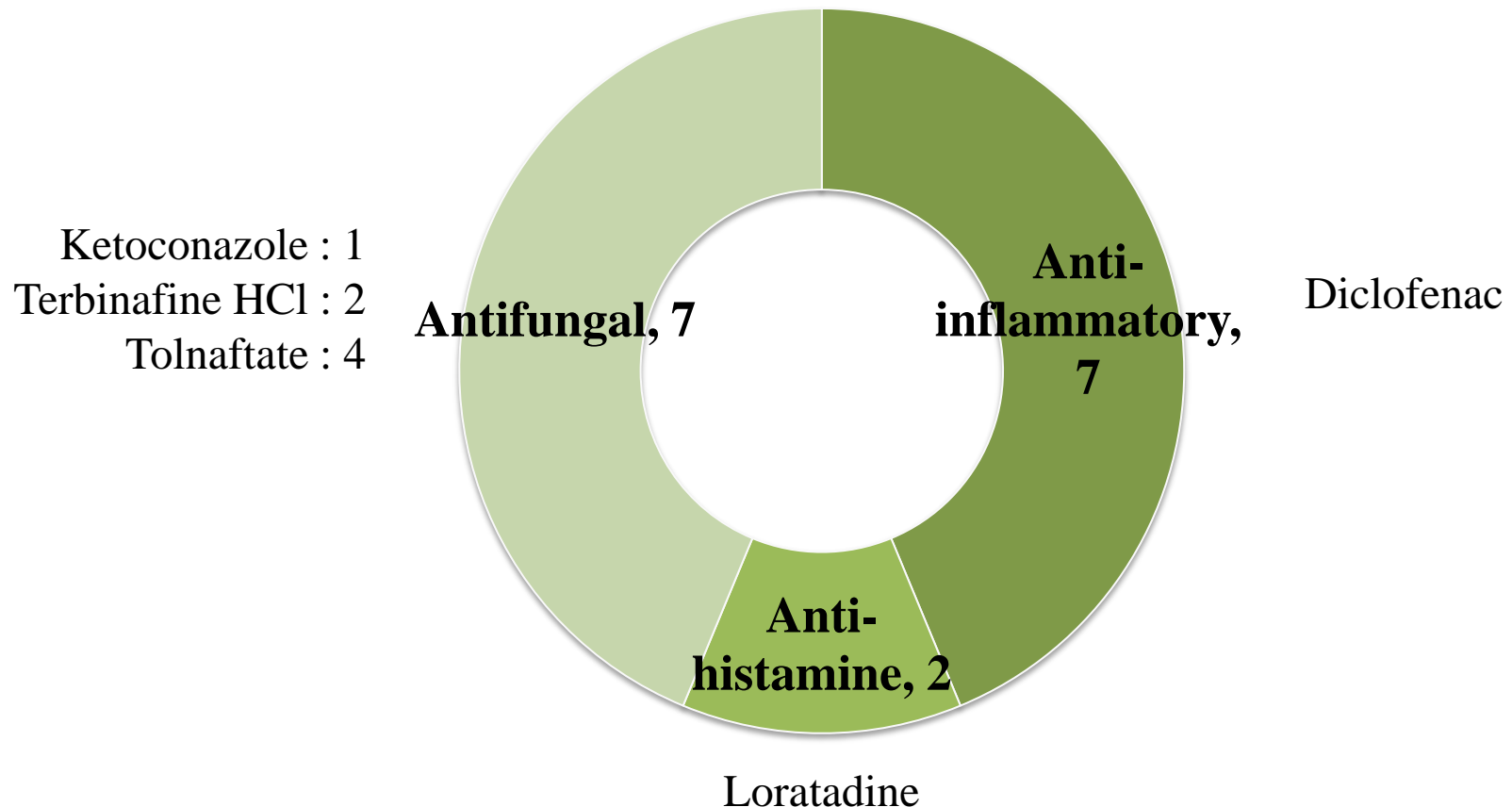
Inhalation and injectable anaesthetics (isoflurane, bupivacaine HCl, lignocaine HCl, mepivacaine HCl, sevoflurane, desflurane)



Success Likelihood #2: Precedence

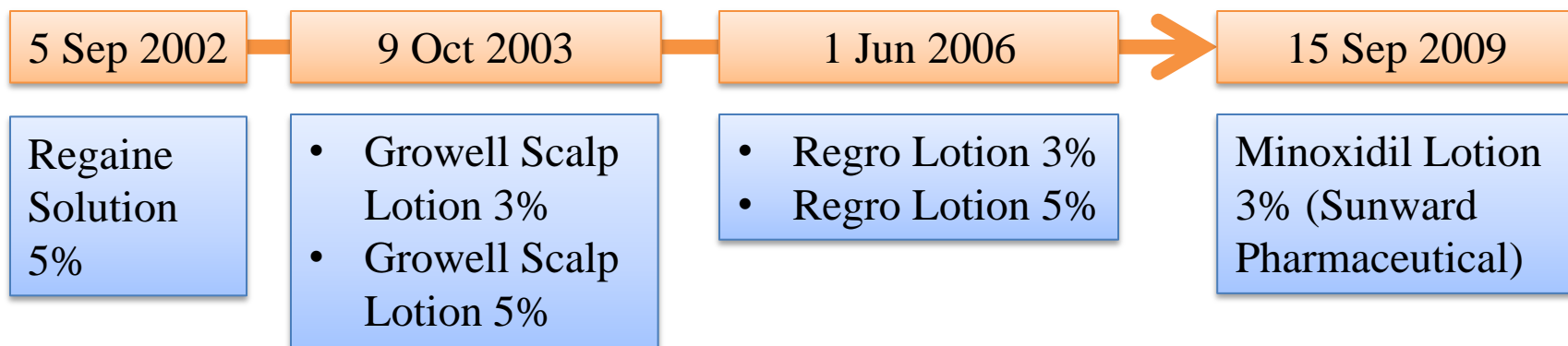
Products with similar therapeutic area/APIs are likely to have the same forensic classification

Case study: 16 switches from P to GSL in 2002 - 2014



Precedence: 'Me-too' reclassification

Minoxidil (switched from POM to P)



Switches benefit Public Healthcare System and Consumer Self-care



Structured System &
Process for Switch

- ✓ Government Policy:
Encourage public access
- ✓ More treatment choices
- ✓ Lowers healthcare costs
- ✓ Patient safety remains assured
& no potential abuse
- ✓ Pressure of Ageing population



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Thank you