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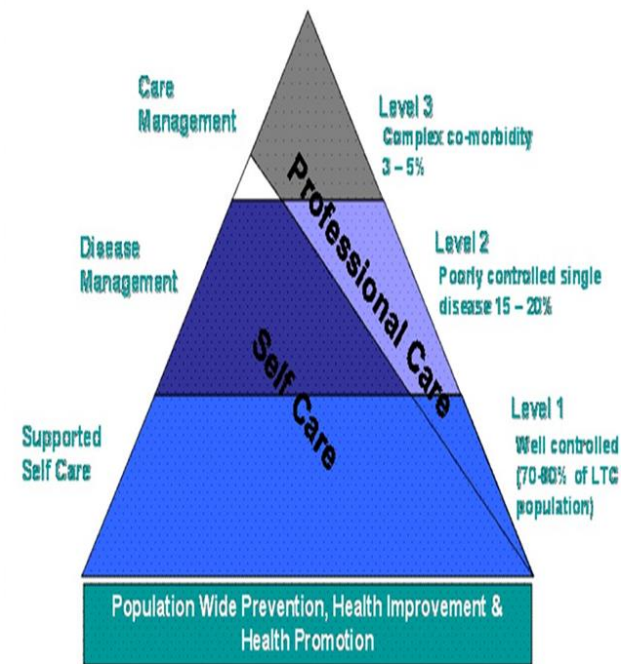
# **UK guidelines on switch – The Benefit Risk Model**

Sheila Kelly, consultant to WSMI

# European Commission

“Non-prescription medicines play an important role since they offer economic as well as social benefits.

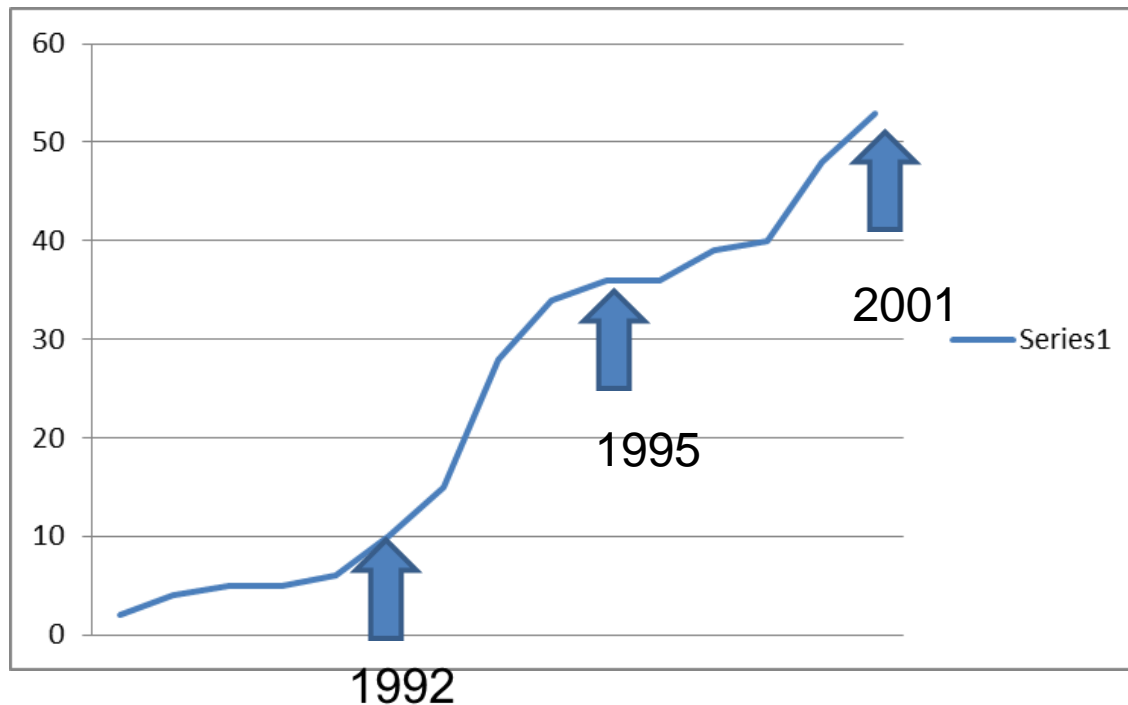
Self-medication empowers people to treat or prevent short term or chronic illnesses which they consider not requiring the consultation of a physician, or which may be treated by the people after an initial medical diagnosis.



Source: Communication from the European Commission of 10 December 2008

“Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector”

# Switch in the UK



- **MHRA Guidelines set out clear process and timelines for switch**
- **Every time they are updated applications increase**
- **Nonprescription medicines have evolved from short term illness through recurring illness and prevention of illness**

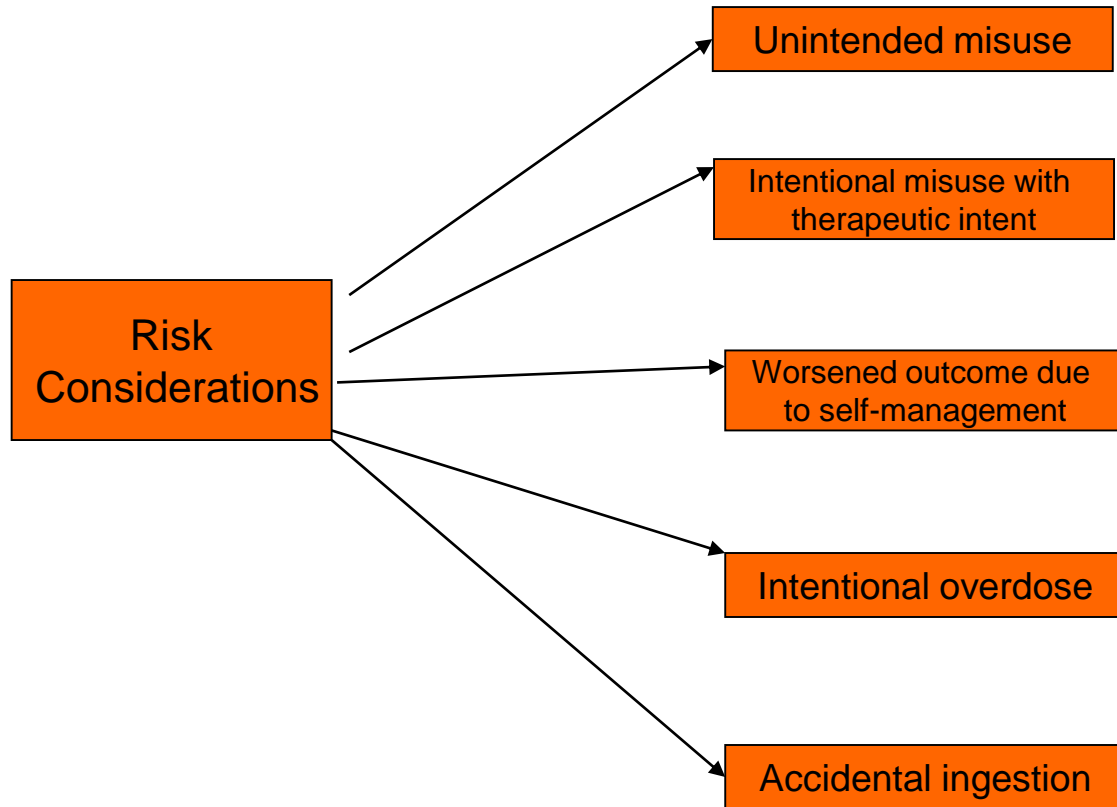
# Good governance in non prescription medicines

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- A clear beneficial impact on public health;
- Respond to the needs/demands of citizens and healthcare professionals,
  - in terms of patient empowerment,
  - timely access
  - improved quality of life and care;
- Fulfilling unmet medical needs and addressing conditions that would otherwise remain untreated;
- Products addressing conditions that can be self-managed with or without initial diagnosis by a health professional;



## ***Evaluating safety in switch***



Common Domains for  
Nonprescription Drugs

- Fulfilling unmet medical needs and addressing conditions that would otherwise remain untreated

## ■ Triptans for the treatment of migraine

- Most common chronic debilitating chronic condition – 60% untreated
- Patients think its just a headache and use analgesics which can cause chronic daily headache

## ■ Emergency contraception

- is more effective the sooner it is taken after sex.
- Its availability in pharmacies offers the benefit of an additional supply route, and confidential access for women who might be wary to visit their family doctor.

## ■ BPH

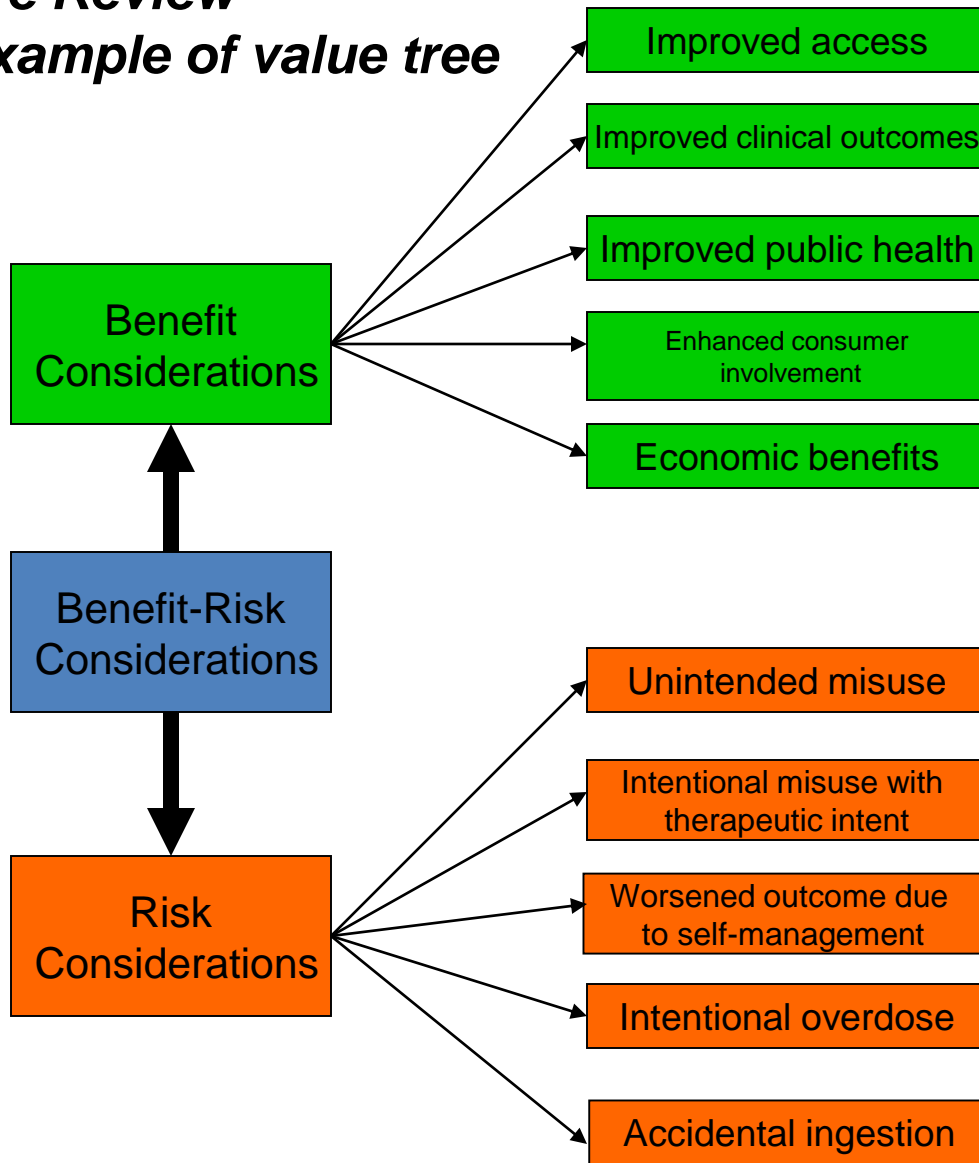
- One in four men over 40 suffer from BPH
- They think its something they have to put up with
- Treatment can end years of misery

People need information to learn that products are available and this needs support from health professionals  
A diagnosis need not mean dependency on a doctor



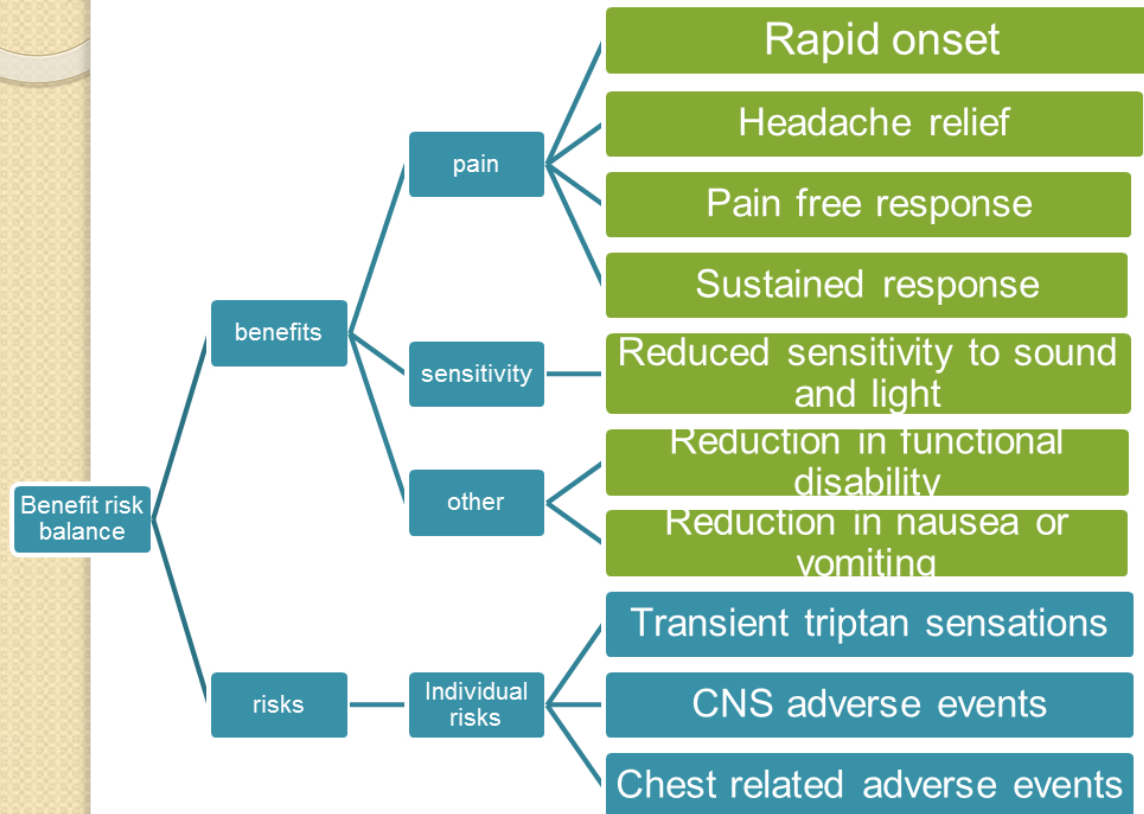
## Pre Review

### Example of value tree



Common Domains for  
Nonprescription Drugs

# Value tree for triptan for migraine



Key question is whether these domains change if a product is prescription or non prescription



# What are the valid concerns about allowing effective products to be OTC?

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## Can these concerns be managed or mitigated?

- Information, information, information
  - On pack, in leaflets, at point of sale, through test kits
- Pack size restrictions
- Inherent consumer caution
- Risk Management plans which include post marketing surveillance and reporting



# What information is needed with a switch product in a new category?

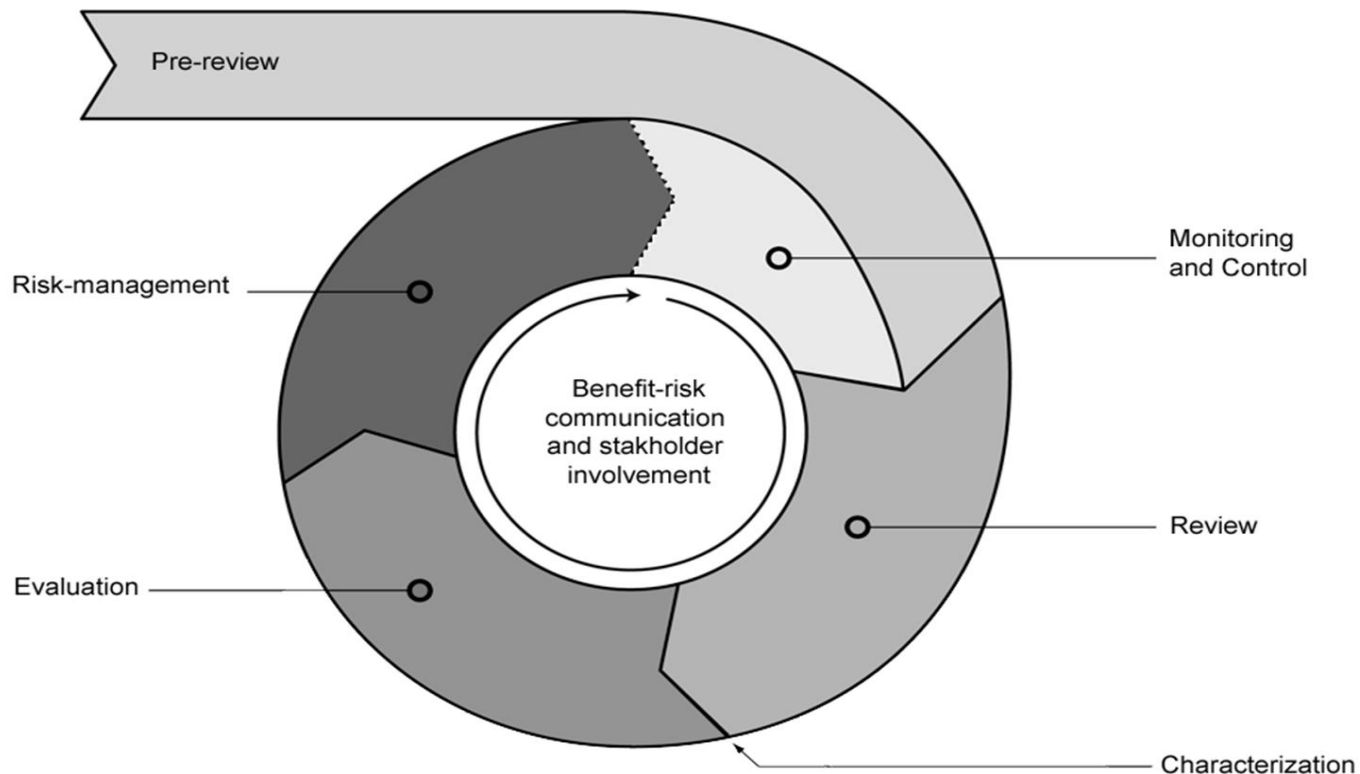
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- Education needs to be more than information about the product
- Information about the illness, when it is safe to treat and what are the red flags that mean you should see a doctor
- Collaborative care programmes with the support of medical professionals and pharmacists focusing on the education of patients can produce significantly positive clinical outcomes



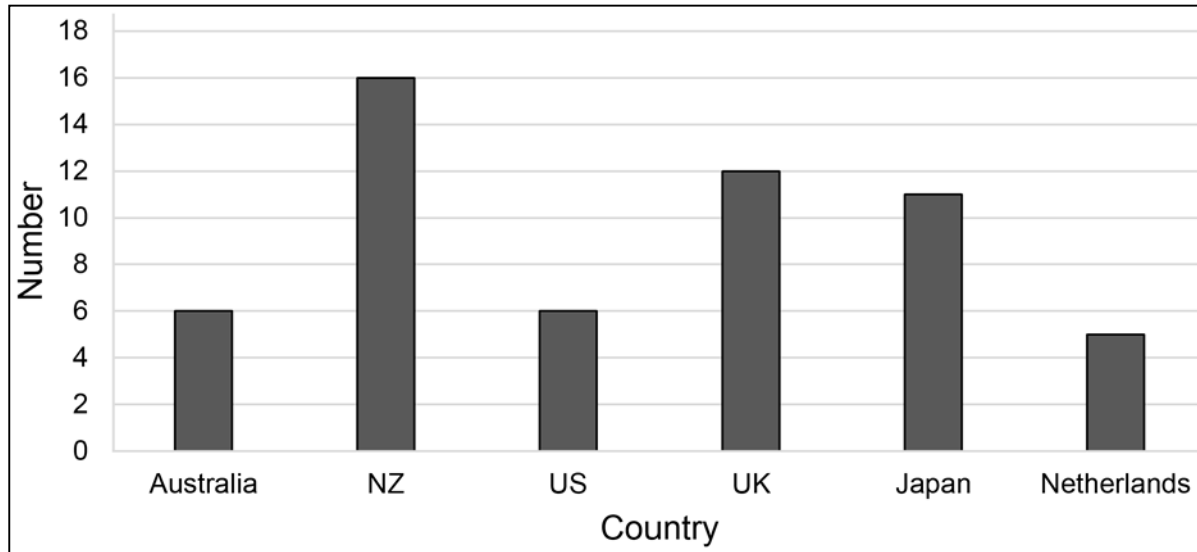
# Communication and stakeholder involvement

## Governance Institution



*Brass, Loftstedt and Renn: Clin Pharmacol Ther 90:791, 2011*

# Legislation and guidelines have to be flexible



Switching Medicines to Non-Prescription: A Six Country Comparison Natalie J. Gauld et al. 2014



# Self-care

European legal framework is established by the Classification Directive 92/26/EC

- 'Normal status' assigned to non-prescription medicines
- Criteria defined the prescription status.
- Non prescription is the classification for 50% of products on the EU market
- But new switches have to be decided by all the member states centrally

- when they are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision

- when they are frequently and to a very wide extent used incorrectly, and are likely to present a danger to human health.

- when they contain substances or preparations which require further investigation

- when they are normally prescribed by a doctor to be administered parenterally( for injection)

# Essentials for a switch framework

- Define the criteria to be met if a drug is to be restricted to prescription supply based on safety
- All other drugs are nonprescription
- Define the indications for which nonprescription medicine is to be used
- Publish lists of prescription and nonprescription medicines
- Set out the requirements for a submission for an application for change of legal classification
  - establish timelines and clear processes
  - Hold scientific advice meetings between regulatory agency and manufacturer on a case by case basis

# Essentials for a switch framework

- Set out the legal process that follows the scientific decision
- Establish a benefit: risk approach to evaluate applications for switches involving new indications and major new ingredients
- Build data protection and market exclusivity into the framework of legislation in support of a switch
- Allow the same brand names to be used for prescription and nonprescription medicines
- Encourage the use of up to date information sources to provide information to consumers to help extend the scope of responsible self-care