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## WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

# Switching around the world: United Kingdom

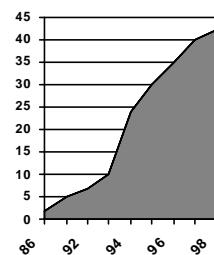
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### UK Switch Guideline

- Started life as industry paper
- MCA turned it to a UK guideline with industry and pharmacy input
- Pharmaceutical Society drew up a list of 54 potential switch candidates

### Switch guidelines - impact

- Establish Data and safety requirements
- Timetable for change
- Guideline 1993



### Switch Guidelines

- Case by case decision
- Dossier requirements clearly set out
- Information to consumers defined
- Process
  - Review of data
  - Decision and public consultation
  - Regulations are changed

### What have we achieved ? - Ingredients

- NSAIDs oral and topical
- antihistamines
- H2 antagonists
- antifungals
- antivirals
- steroids
- Nicotine

## What have we achieved ? - New Indications

- Arthritic pain
- Sleep problems
- Eczema and Baldness
- Vaginal thrush
- Smoking cessation
- Irritable bowel syndrome
- Prevention of illnesses

## Key Issues



Safety

Information

## Safety Issues

- Experience with the product as a POM
  - 5 years or 'enough' prescriptions?
- Ability to recognise condition
  - Diagnosis needed?

## Safety Issues

- Comparative Safety
  - Review of ingredients already available
  - Does new ingredient offer better safety profile?
  - Is it more effective?

## Information - Issues

- Packaging information
  - information about the product
  - information about illness
  - Readability and research

## Information - Issues

- Packaging Information
- Advertising and other media
  - Telephone helplines
  - Internet

## Information - Issues

- Packaging Information
- Advertising and other media
- Role of health advisors
  - Pharmacists
  - Doctors and Nurses
  - Others?

## Switch guidelines - impact

- P to GSL guideline 1995
  - Ibuprofen
  - Loperamide
  - Nicotine
  - (Ranitidine)

