

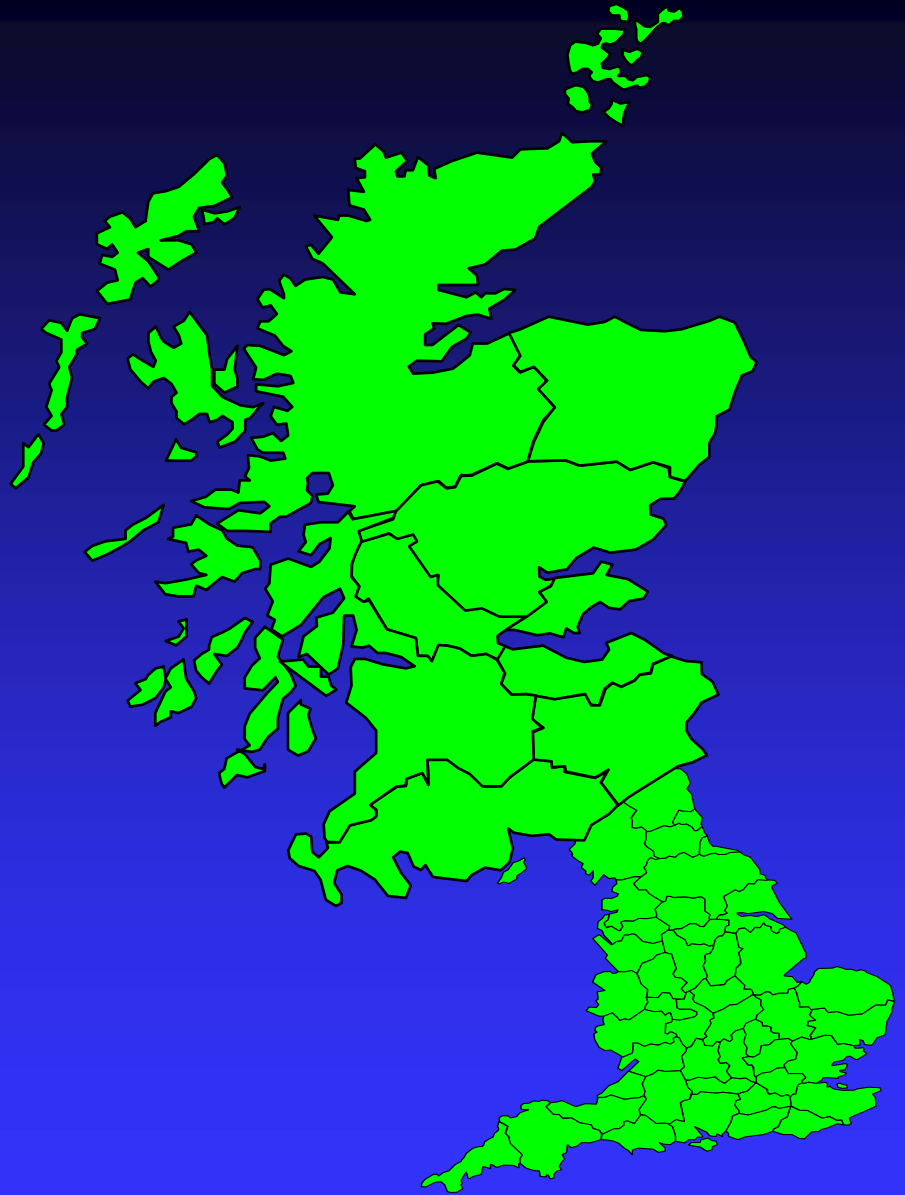
# Scottish Medicines Consortium

Rapid Health Technology Assessment of  
New Medicines

**Dr Ken Paterson**

**3<sup>rd</sup> International EBHC Symposium**

**Krakow – 24 November 2008**



# Scotland

- 5.5M inhabitants
- Separate Parliament since 1999
  - ◆ ...own Health Minister/Department
- All health issues devolved to Scotland
  - ◆ ...except training and drug licensing
- NICE advice does NOT apply in Scotland
  - ◆ ...though MTA usually accepted

# Situation pre-SMC

- 15 health boards
- Each with Area Drug & Therapeutics Committee (ADTC)
- Each making decisions on new drugs
  - ◆ Variable rigour/quality
  - ◆ Duplication of effort
  - ◆ Post-code prescribing
- “Could do better!”

# Scottish Medicines Consortium

- Formed 2002 as a Consortium of ADTCs
- Current Chairman: Dr Ken Paterson
- Vice-Chairs: Ms Angela Timoney, Dr Jan Jones
- Secretariat and meetings held in Glasgow
  - ◆ Meets every month

# Remit

Provide advice to NHS Boards and ADTCs on comparative and cost-effectiveness of:

- New Medicines
- New Formulations of Medicines
- Major new indications for Medicines
  - ◆ 80 products (approx) per annum
- Provide advice as close to product launch as possible (within 3-6 months)
  - ◆ “shape practice, not change practice!”

# SMC Membership

Membership (30) - multi-disciplinary,  
geographically spread

- Physicians (1° and 2° care)
- Pharmacists
- Nurse, Economists
- Board and Hospital Executives,
- Lay & Patient Representatives
- Pharmaceutical industry representatives
- Full declarations of interest

# New Drugs Committee

- Membership: Total = 18  
Physicians, Pharmacists,  
Health Economists  
Nurse, Public Health Consultant
- Primarily an Evidence Review Committee
- Chairman: Dr Jan Jones (Tayside)

# SMC Advice to NHS Scotland

## 3 Categories of advice

- Accepted for use in NHS Scotland
- Accepted for restricted use in NHS Scotland
- Not recommended for use within NHS Scotland
- Some drugs may also be ‘unique!’

# The Aim of Product Assessments

- Efficacy – does the drug have an effect?
- Effectiveness – does it work in normal use?
- Cost-effectiveness – how much bang for the buck!

# Submission Content

- Standardised form
- Summaries of efficacy/effectiveness and safety
- Detailed health economic case
  - ◆ Cost-utility approach preferred (£ per QALY)
  - ◆ Budget impact for Scotland (or per 100,000)
  - ◆ Full explanation of model assumptions
    - ◆ Linked to Scottish (or UK) data
  - ◆ Full sensitivity analysis
    - ◆ Univariate  $\pm$  probabilistic analyses

# Submission data

- All referenced data to be included
  - ◆ May include unpublished data
    - ◆ ...including 'commercial in confidence'
- Economic data to be included
- Supplementary data – SPC, draft protocols, etc

# Review Process

- Efficacy/effectiveness/safety reviewed by critical appraisal pharmacist
- Health economic case reviewed by health economist
- Overall case reviewed by 'Lead Assessor' (from NDC)
- Interaction with sponsor during review
- Review lasts around 6 weeks

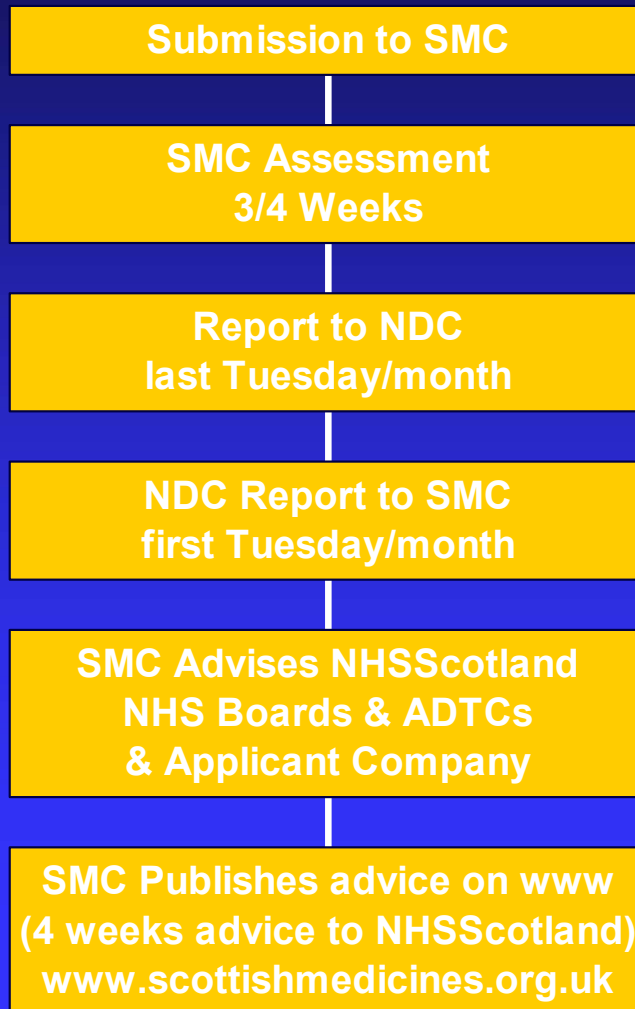
# Clinical Expert Panel

- Important to inform the SMC process
  - ◆ Impact of disease
  - ◆ Unmet therapeutic need
  - ◆ Current therapeutic strategies in Scotland
  - ◆ Test economic case assumptions
- NOT asked “do you want this drug?”
- All interests declared

# Patient & Public Input

- Patient & Public Involvement Group
- Patient group submissions considered at SMC
  - ◆ Only ~30% of medicines have a patient group submission
  - ◆ Can say things which pharma company cannot say!
- Now actively seeking patient group submissions

# Process timelines



10-12 weeks

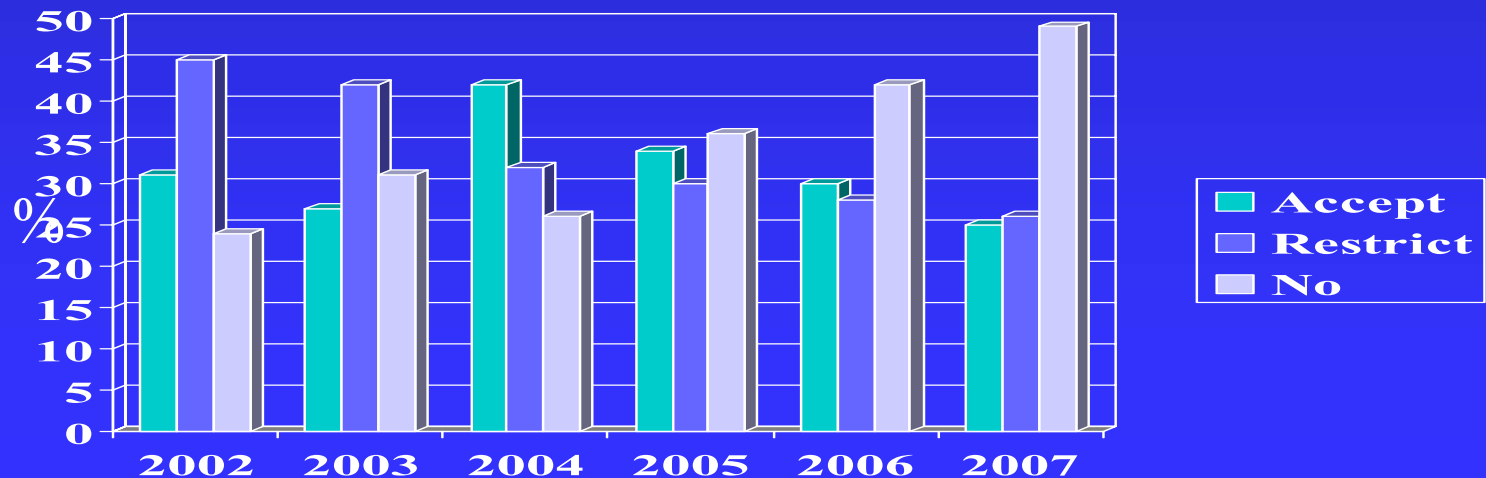
4 weeks

# 2002 - 2007

- 458 submissions considered
  - ◆ 2002 – 29
  - ◆ 2003 – 62
  - ◆ 2004 – 74
  - ◆ 2005 – 87
  - ◆ 2006 – 130 (111)
  - ◆ 2007 – 110 (95)
- ~20% are 'abbreviated' subs
- Rising proportion of re-submissions

# Outcome of Assessments

- Accepted for Use – 30%
- Accepted for Restricted Use – 33%
- Not Recommended – 37%
- No real evidence of change over time



# Driven by Budget Impact?

- Accept                    £388K            (207-569K)
  - Restrict                   £549K            (324-777K)
  - No                         £460K            (229-692K)
- 
- Large overlap suggests budget impact is not driving SMC decision-making

# Obsessed by QALYs?

- Cost per QALY < £10K – 79% ‘yes’
  - Cost per QALY £10-20K – 74% ‘yes’
  - Cost per QALY £20-30K – 55% ‘yes’
  - Cost per QALY > £30K – 29% ‘yes’
- 
- Cost per QALY plays (appropriately?) a large role – but not the only consideration!

# Benchmarking

- NICE
  - ◆ 83% same decision (52/63)
- Wales
  - ◆ 84% same decision (16/19)
- Canada
  - ◆ 71% same decision
- Australia
  - ◆ 74% same decision

# Early Technology Appraisal of Drugs

- ...is possible
- ...is the worst option apart from the others!
- ...allows real breakthroughs even at considerable cost
- ...does not reward small incremental change at substantial cost
- ...can avoid 'decision blight' and meet the timelines of specialists and patients

## ...to consider?

- Is speed the enemy of rigour?
- How much does consultation add?
- How can clinicians and patients be engaged/involved?
- Should industry be 'in' or 'out'?
- Should politicians be 'in' or 'out'?
- What happens when a drug fails to be accepted as cost-effective?
- How transparent should the process be?

# Scottish Medicines Consortium

[www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)