

SMC – Implications for Both Sides of the Border and Rare Cancers

Prof Ken Paterson
British Sarcoma Group
Glasgow – 19 March 2009

Scottish Medicines Consortium – Why?

▶ Situation pre-2002

- 15 Scottish Health Boards
- 15 Area Drug & Therapeutics Committees
- Different approaches to new drugs assessment
 - ▶ Variable coverage and rigour
 - ▶ Much duplication of effort
 - ▶ 'postcode prescribing' and issue
- "could do better"

▶ SMC formed 2002 as informal consortium of ADTCs

- Pool activities and resources
- Improve speed and quality of decisions

SMC Remit

- ▶ Comparative effectiveness and cost-effectiveness of ALL new drugs
 - ...and major new indications/formulations
- ▶ Advice at, or close to, product launch
 - ...shape practice rather than change practice
- ▶ Three possible outcomes of assessment
 - Accepted for use
 - Accepted for use with restriction(s)
 - Not recommended for use
- ▶ Estimated 80 assessments per year

SMC – Who are We?

- ▶ Doctors from 1ary and 2ary care
- ▶ Pharmacists from 1ary and 2ary care
- ▶ Public health doctor
- ▶ Health service managers (CEO/Finance)
- ▶ Patient and Public Partners
- ▶ Pharmaceutical Industry representatives

- ▶ Nominees rather than delegates
- ▶ All financial and other interests declared

SMC – How do We Work?

- ▶ Onus of proof is on the manufacturer
- ▶ Structured submission required for every drug
 - Efficacy/effectiveness
 - Safety
 - Cost-effectiveness
 - ▶ Detailed modelling relevant to the Scottish context
 - ▶ Full detail of modelling and sensitivity analysis
- ▶ Interactive approach during assessment and SMC process
- ▶ 16-18 weeks from submission to decision!

Assessment Timelines

- ▶ Initial review by pharmacist/economist – 6/8 weeks
 - Communication/clarification from manufacturer
- ▶ New Drugs Committee – last Tuesday of month
 - Detailed scientific review – draft decision shared with manufacturer – chance to respond
- ▶ SMC – first Tuesday of month (5 weeks later)
 - NDC advice, response from manufacturer, input from Patient Interest Groups
 - Final decision based on science + wider perspectives
 - Advice shared with manufacturer and NHS
- ▶ Advice in public domain – 4-5 weeks later

Assessment Timelines



10-12 weeks

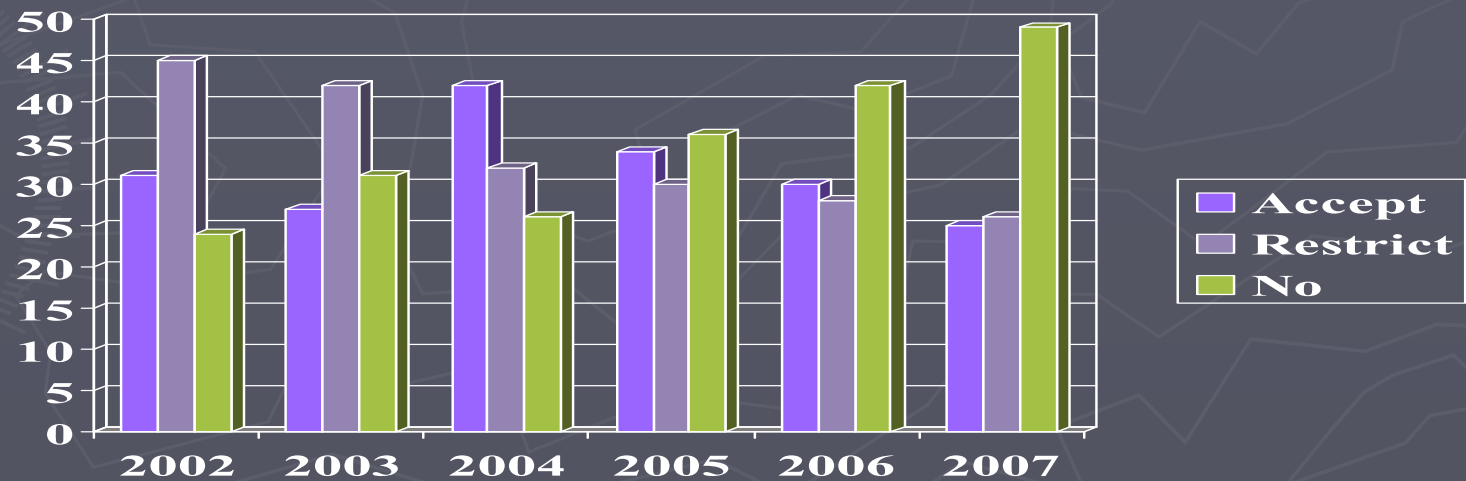
4 weeks

2002 – 2007

- ▶ 458 submissions considered
 - 2002 – 29
 - 2003 – 62
 - 2004 – 74
 - 2005 – 87
 - 2006 – 130 (111)
 - 2007 – 110 (95)
- ▶ ~20% 'abbreviated' submissions
- ▶ Up to 7 full submissions per month!

Outcome of SMC Assessments

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



Benchmarking of SMC

- ▶ NICE – 87% same decision (48/55)
- ▶ Wales – 84% same decision (16/19)
- ▶ Canada – 71% same decision
- ▶ Australia – 74% same decision

- ▶ Some reassurance that decisions are based on reasonable grounds

Implications of SMC for Scotland

- ▶ Single, transparent, robust process
- ▶ Rapid decision-making
 - Rapid access to drug if 'Yes'
 - Rapid move to re-assessment if 'No'
- ▶ Early decision impacts on actual practice
- ▶ Recognition that advice does always apply
 - Need for consideration of 'exceptional circumstances'
- ▶ Clinical ownership of process with wide stakeholder involvement

Implications of SMC for England

- ▶ Evidence-based advice available on website
 - May be useful pending NICE (or other) assessment
 - May avoid 'NICE blight' for patients
- ▶ May stimulate more rapid STA by NICE
 - Plans to expand STA workload by 2011
 - Not clear whether proposed process can meet timelines
- ▶ Has shown possible roles in new initiatives –
 - Value-based pricing
 - Patient access schemes

SMC and Cancer Drugs

- ▶ Fewer RCTs per drug (median 1 v 2)
- ▶ Longer follow-up (52 wks v 12 wks)
- ▶ Acceptance rate - 67%
 - About half with some restriction, usually to specialist use
- ▶ Higher cost per QALY (£15K v £8.5K)

Special Cancer Issues – 1

- ▶ Often scanty phase 3 clinical data
- ▶ Complex regimens with poly-pharmacy make comparators hard to define
- ▶ RCTs use different comparators from current practice in Scotland
- ▶ May require complex indirect comparisons
- ▶ Survival benefits unclear
 - Overall v 'progression-free' survival
 - Extrapolation not clear-cut

Special Cancer Issues – 2

- ▶ Quality of life assessment difficult
 - Impact of adverse events a problem
 - ? reevaluation of QoL near life's end
 - ▶ Note new NICE approach to 'end-of-life' drugs
 - ? special benefit with low expectancy
- ▶ Increased niching by indication
 - ...more (ultra-)orphan drugs
 - ▶ ...with expectations of "special case"
- ▶ Rule of Rescue - a rule??

Issues for Rarer Cancers - 1

- ▶ Drug may be expensive to re-coup R & D
 - ...but with a high cost per QALY
 - Not clear that rarity *per se* justifies high costs
 - Low overall cost not a justification ethically
- ▶ Efficacy data limited and less certain
 - ...making QALY estimate less certain
 - Rarity does explain uncertainty
 - Low overall cost permits more uncertainty

Issues for Rarer Cancers – 2

- ▶ SMC approach allows flexibility
 - Big impact on survival
 - Big impact on quality of life
 - Possible bridge to a definitive therapy
- ▶ We can say ‘Yes’ to good drug if QALY high
 - 29% of Cost per QALY >£30K – Yes
- ▶ We won’t reward modest progress by substantial price increase

Conclusions

- ▶ Early HTA of new drugs is possible
 - ...and maybe essential
- ▶ HTA is the 'least worst' way we know
 - ...but not perfect and needs to be flexible
- ▶ Rarer cancers do not “get out of jail free”
 - ...but can expect some level of ‘special review’
- ▶ Really good drugs can cost quite a lot
 - ...most cancer drugs are not very expensive, but regrettably also not very good

Scottish Medicines Consortium

www.scottishmedicines.org.uk

