New Medicine Evaluation

Scottish Medicines Consortium

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Dir of Pharmacy NHS Lothian

AIM

- To describe the approach used in NHS Scotland to assess the clinical and cost-effectiveness of new medicines

How does a medicine get to a patient in NHS Scotland?

- License from European Medicines Agency / MHRA
- SMC provides advice on clinical and cost-effectiveness (HTA)
- ADTC -formulary
- Clinicians choose for patients

SMC

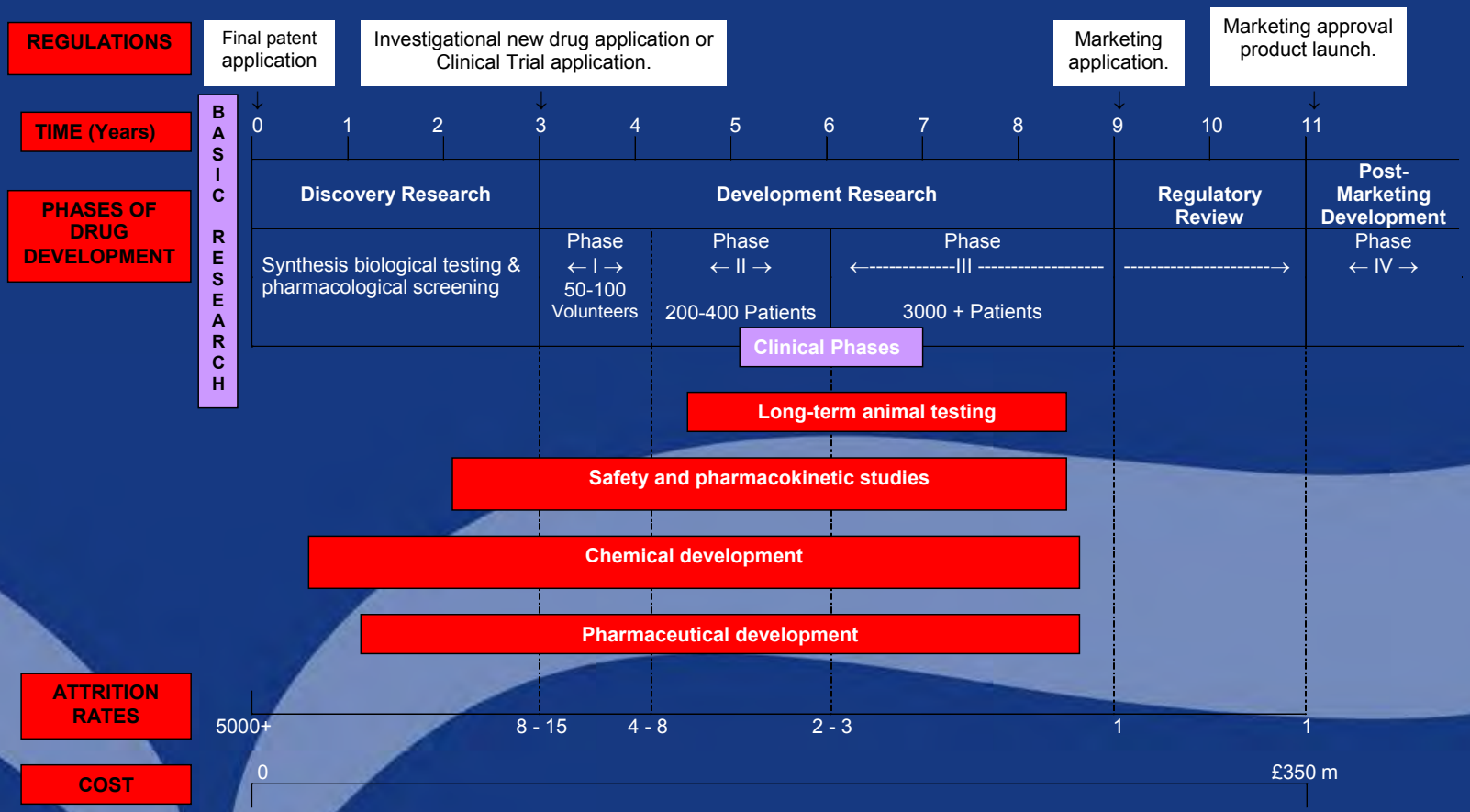
- Assesses clinical and cost-effectiveness of all new medicines
- Established October 2001
- Clinicians driving decisions with broad stakeholder engagement
- Provides advice to Health Boards
- Rapid assessment -18 week timeline
- Widely recognised as exemplar Health Technology Assessment (HTA) agency for medicines

SMC 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!"

Stages in the Discovery and Development of a New Medicine.



The Fourth Hurdle

Market Authorisation (licensing) assesses a drug on the basis of:-

1. **Safety**
2. **Efficacy**
3. **Quality**

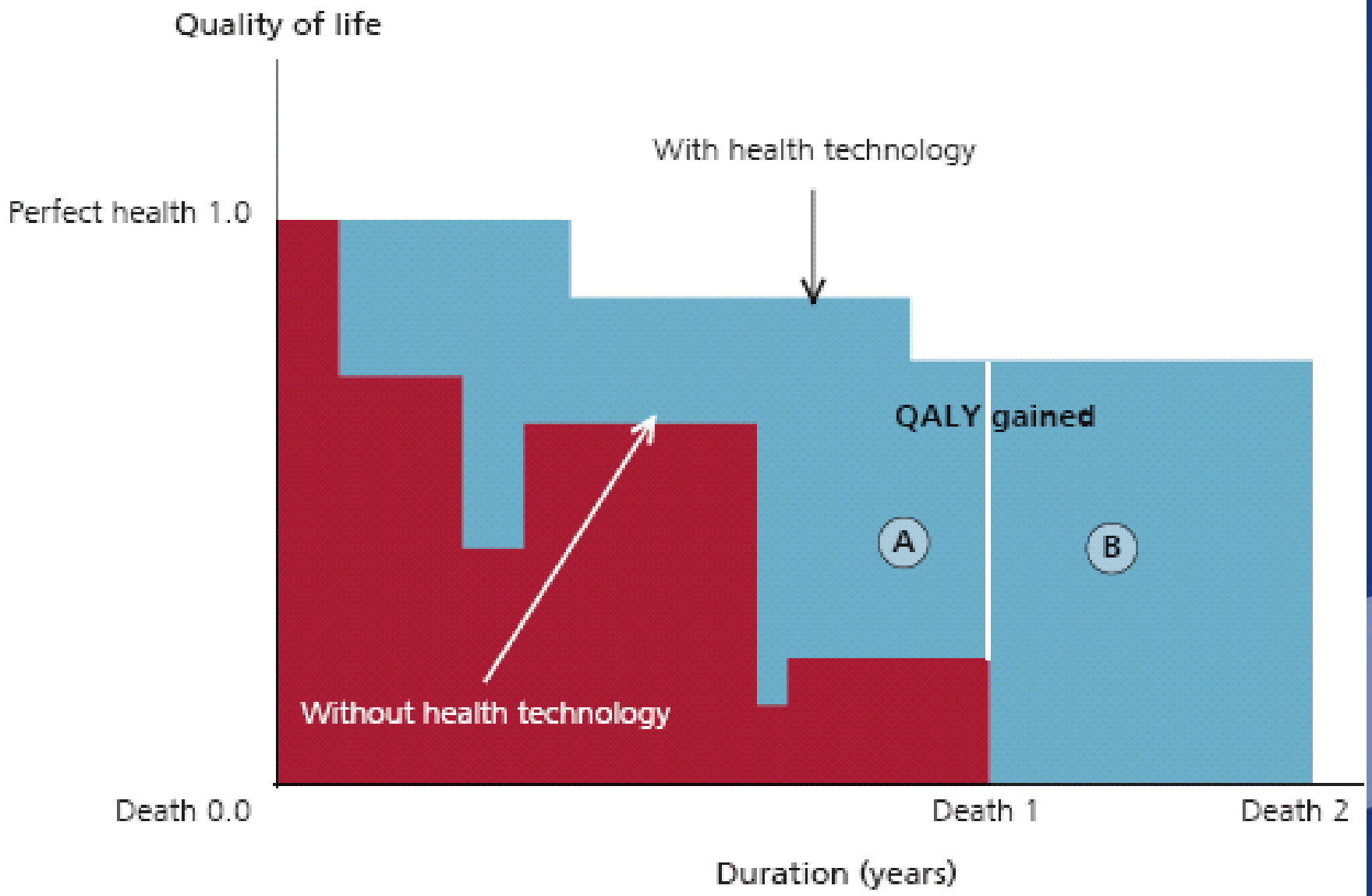
   But not:-

4. **Relative effectiveness/ cost effectiveness**

Health technology assessments

- Measure costs, benefits and disbenefits of new technologies
- SMC prefer cost utility analysis (QALYs)
- No QALY threshold but <£20k is usually acceptable to NHS, >£30k must be justified.

Figure. Diagram of the concept of QALY (quality-adjusted life years)



SMC Advice to NHSScotland

3 Categories of advice

- Accepted for use in NHS Scotland
- Accepted for restricted use in NHS Scotland
  - Restriction beyond anything in SmPC
    - Sub-group of patients
    - Sub-group of possible prescribers
- Not recommended for use within NHS Scotland

SMC Membership

Membership (40) - multi-disciplinary, geographically spread

- Physicians (1° and 2° care)
- Pharmacists
- Economists
- HB CEOs and Finance Dirs,
- ABPI
- Lay & Patient Representatives
- Full declarations of interest

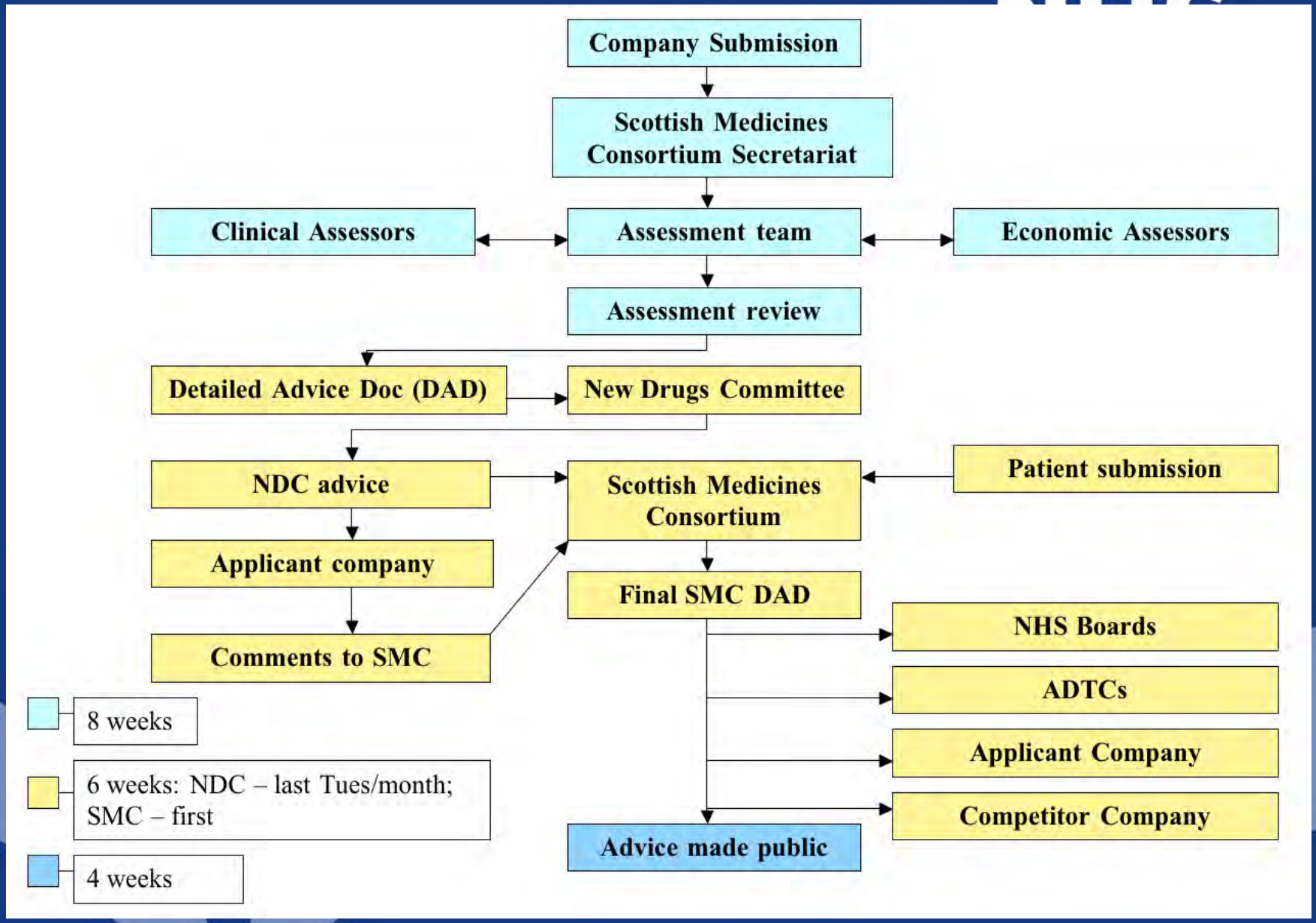
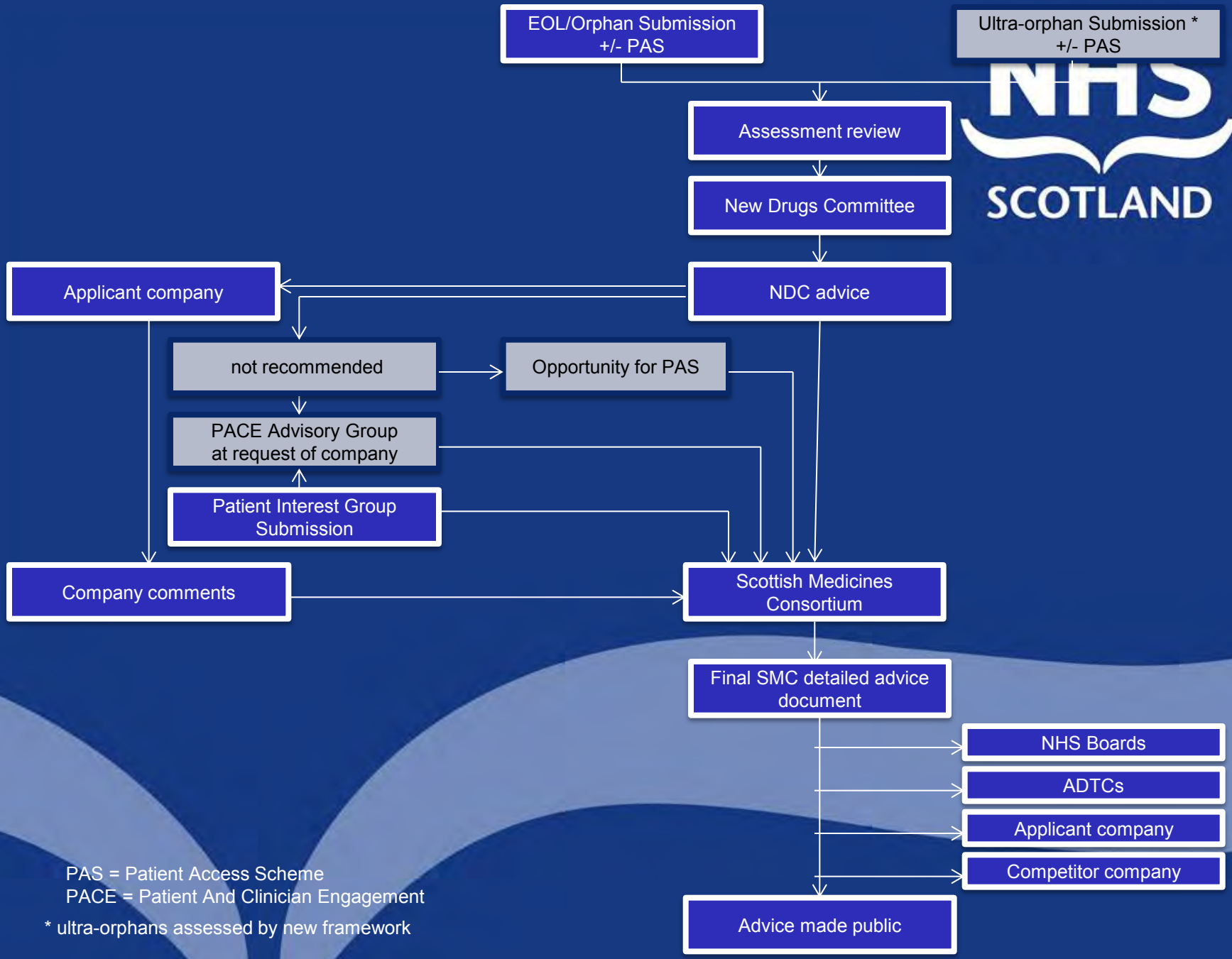

Company Submission
Scottish Medicines Consortium Secretariat
Clinical Assessors
Assessment team
Economic Assessors
Assessment review
Detailed Advice Doc (DAD)
New Drugs Committee
NDC advice
Scottish Medicines Consortium
Patient submission
Applicant company
Final SMC DAD
Comments to SMC
NHS Boards
ADTCs
Applicant Company
Competitor Company
Advice made public
8 weeks
6 weeks: NDC – last Tues/month; SMC – first
4 weeks

Diagram 1 – Integration of PACE into SMC process for EoL, orphan/orphan-equivalent and ultra-orphan medicines



PAS = Patient Access Scheme
PACE = Patient And Clinician Engagement

* ultra-orphans assessed by new framework

Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
Delta House (8th floor) 50 West Nile Street Glasgow G1 2NP Tel 0141 225 6999 Chairman: Angela Timoney FRPharmS

NHS SCOTLAND

telaprevir, 375mg, film-coated tablets (Incivo®) SMC No. (742/11)
Janssen

04 November 2011

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following a full submission

telaprevir (Incivo®) is accepted for use within NHS Scotland.

Indication under review: In combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.

In the pivotal phase III randomised study, the addition of telaprevir to current standard therapy in patients with genotype 1 chronic hepatitis C virus, who had failed previous therapy, significantly increased the proportion of patients who achieved a sustained virologic response.

Overleaf is the detailed advice on this product.

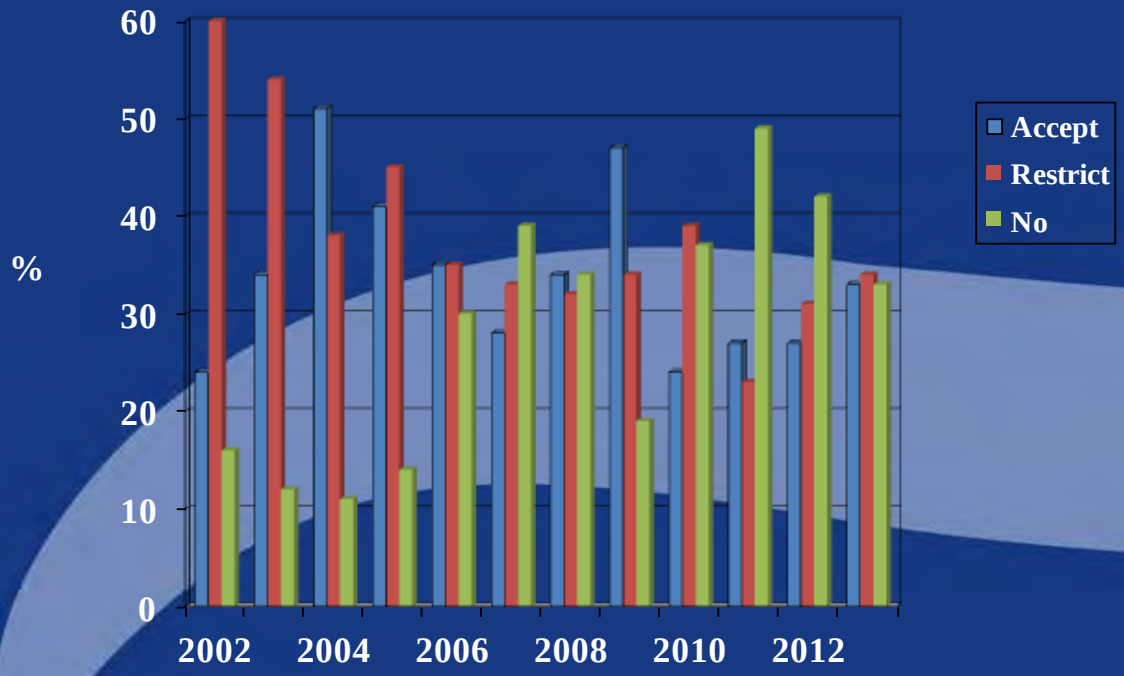
Chairman,
Scottish Medicines Consortium

Published 12 December 2011

Outcome of SMC Assessments

(Sep 2013)

- Accepted for Use – 35%
- Accepted for Restricted Use – 36%
- Not Recommended – 30%



Oncology Medicines (2005)

- Cancer medicines may be licensed with little phase 3 trial data
- Complex regimens involving poly-pharmacy and the use of many different regimens may make it difficult to identify suitable comparators for HTA
- There may be political and societal pressure to make products available

What did SMC decide?

2005

- 39/201 oncology medicines
- 11 accepted (28%)
- 15 accepted with restrictions (38%)
- 13 not recommended (33%)

2013

- 108/554 oncology medicines (full subs/resubs)
- 22 accepted (20%)
- 45 accepted with restrictions (42%)
- 41 not recommended (38%)

How did this compare with all other submissions?

	2005	2013
• Fewer RCTs for oncology		
– Median for cancer	1 (0-4)	mean 1.2 (0-3) med= 1
– Median for non-cancer	2 (0-17)	mean 2.3 (0-17)med= 2
• Cancer trials -longer follow-up		
– Mean	52 weeks(0-272)	105 weeks (0-272)
– Mean	12 weeks (0-208)	51 weeks (0-417)
• Higher cost/QALY		
–	£15k (dom-£67k)	£30k (dom-£109k)
–	£8.5k (dom-£105K)	£20k (dom-£565k)
• Acceptance rates		
– Cancer	66.7%	62%
– Non-cancer	66.4%	74%

Analysis and Interpretation

- Cancer medicines have fewer RCTs and a higher mean cost/QALY.
- ICERS are increasing
- Acceptance rates have changed a little
- Cancer medicines now have slightly lower acceptance rates

Technology advances

- **The continuing evolution of new technologies, such as 3-D biological printing, ultra-high-resolution analytical instruments, next-generation sequencing, desktop electron microscopy, gene therapy, translational research, stem cell therapies and microbiomics are changing the traditional rules for drug development, as well as the FDA (Food and Drug Administration) changing its own rules.**

New technologies drive pace of drug development July 2014

Targeted therapy at SMC

- Imatinib (CML, GIST) (philadephia chromosome)
- Trastuzumab (Breast Ca) (Her2 +ve)
- Irinotecan (Colon Ca) (UGT1A1 gene)
- Lapatinib (Breast Ca) (Her2+ve)
- Cetuximab (Colon Ca) (KRAS mutations)
- Busulfan (CML) (Ph chromosome)
- Erlotinib (Lung Ca) (EGFR expression)
- Rituximab (various) (CD20 variant predicts response)
- Crizotinib (ALK +ve NSCLC)
- Nintedanib- triple angiokinase inhibitor
- Ponatanib (CML and T315I mutation)

Regulatory changes

- Orphan medicines
- Biosimilar medicines
- Conditional licensing
- Early access progamme

Conclusion

- Technology advances can benefit drug development
- In HTA recognition of “innovation” as a benefit is controversial
- Health systems require to develop “fair rules” to aportion resources
- SMC has demonstrated a robust evidence based timely approach for Scotland

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pressdata

Drug approval system overhauled amid rows over new treatments

Move comes just hours after new therapy for advanced breast cancer rejected by scrutiny body

HELEN PUTTICK
HEALTH CORRESPONDENT

MORE drugs for patients with killer diseases should become available on the NHS in Scotland under a major shake-up of the system for screening new treatments.

Health Secretary Alex Neil announced a series of fundamental changes to improve access to new medicines just hours after scrutiny body the Scottish Medicines Consortium (SMC) rejected a new therapy for patients with advanced breast cancer.

Charities hope patients with rare or terminal illnesses will be more likely to get the latest drugs once the new measures are in place early next year.

The changes include revising the criteria the SMC uses to decide if expensive drugs for treating rare conditions or extending life are value for money.

The Individual Patient Treatment Requests (IPTR) system patients currently use to apply for medicines blocked by SMC will also be scrapped and replaced with one led by medical consultants.

It has also been decided that the SMC must also become more transparent, opening its meetings to the public and enabling patients to share their views.

The overhaul follows years of concern that access to new medicines in Scotland was falling behind other countries including England, culminating in a hard-hitting inquiry by the health and sport committee of the Scottish Parliament last year.

Doctors from across the country gave evidence to MSPs, describing the situation as a tragedy which was not only affecting the sick but also risking Scotland's reputation as a centre of excellence for cancer care.

Cancer charities were among the first to welcome the new approach, although some questions remained about how patients' voices would be heard.

Mark Flannagan, chief executive of Beating Bowel Cancer, said: "We welcome the government's announcement that it is to take decisive action to improve access to new drugs and treatments for Scottish patients.

"In particular, that it has listened to our concerns that the current system is failing patients. The death of the IPTR should lift the barriers to doctors wanting to prescribe the latest cancer drugs they believe will benefit their patients."

Breakthrough Breast Cancer said it hoped treatments like Perjeta, a drug shown to extend the life of people with advanced disease which was blocked by SMC on Monday, would be approved under the new regime.

James Jopling, Scotland Director at Breakthrough Breast Cancer, said: "At present women with secondary breast cancer have limited treatment options for what is an incurable form of the disease."

Mr Neil said he thought the new system would save lives but denied the old regime was failing patients. He said: "We are world leaders in this area and thes changes we are making will mak further improvements and wi make the system even more wor renowned."

"We welcome the announcement ... the Government has listened to our concerns that the system is failing patients

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END TO DRUG 'APARTHEID'

MORE Scots patients could get the drugs they need in an overhaul of the way new treatments are approved.

Health Secretary Alex Neil has ordered a shake-up of the Scottish Medicines Consortium after warnings of a 'medical apartheid' system, with Scots often refused drugs that are available in England. Mr Neil wants to make the system more transparent, with more public involvement in the process.

A £20million Rare Medicines Fund, launched earlier this year, will also be extended to 2016 to help fund treatments for rare conditions.

THE SCOTTISH Sun

FAST-TRACK DRUG HOPE ON CANCER

By ANDREW NICOLL, Scottish Political Editor

CANCER patients could get easier access to new drugs under new plans unveiled yesterday by Health Secretary Alex Neil.

The SNP minister has ordered the Scottish Medicines Consortium watchdog to become more "flexible" in approving treatments for terminally-ill patients and those with rare diseases.

It comes after Holyrood's Health Committee heard evidence from cancer sufferers denied drugs which could prolong their lives.

Fair

Mr Neil said: "We've put in place measures which will increase access to new medicines and make the system more open for patients."

Among the initiatives are extending the £20million rare drugs fund to 2016 and scrapping Individual Patient Treatment Request hearings.

SMC chief Prof Angela Timoney said: "We support access to medicines at a price that's fair for all."

Shake-up . . . Mr Neil

Tory health spokesman Jackson Carlaw said: "I'm encouraged progress is finally being made."

SMC changes

- New approach for medicines for end of life care and very rare conditions
- End of life – 3 years
- Very rare conditions – orphan or orphan equivalent

Rule of Rescue and rarity

- Opportunity cost – do we want all medicines to be available or do we want a "good death"
- Changing demographics
  - £34/yr age 5-9 £504/yr age 85-89
- Rarity is extremely common – more than 50% of people with cancer have a "rare" cancer
- With increasing targeted therapies- more rarity

Are “end of life” and “rare conditions” the right priorities? What else…

- Diseases of aging
- Chronic diseases
- Public Health priorities

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