



Workshop Session



Scottish Medicine Consortium Requirements for Advanced Therapy Medicinal Product Provision

Dr Alan Macdonald

Chair of the Scottish Medicines Consortium



Scottish Medicine Consortium requirements for ATMP provision

Alan MacDonald
Consultant Rheumatologist, Aberdeen Royal Infirmary
Chairman, Scottish Medicines Consortium

NAATTC Meeting May 2019

Advising on new medicines for Scotland
www.scottishmedicines.org



SMC

Disclosures

None

SMC: ATMPs

Objectives

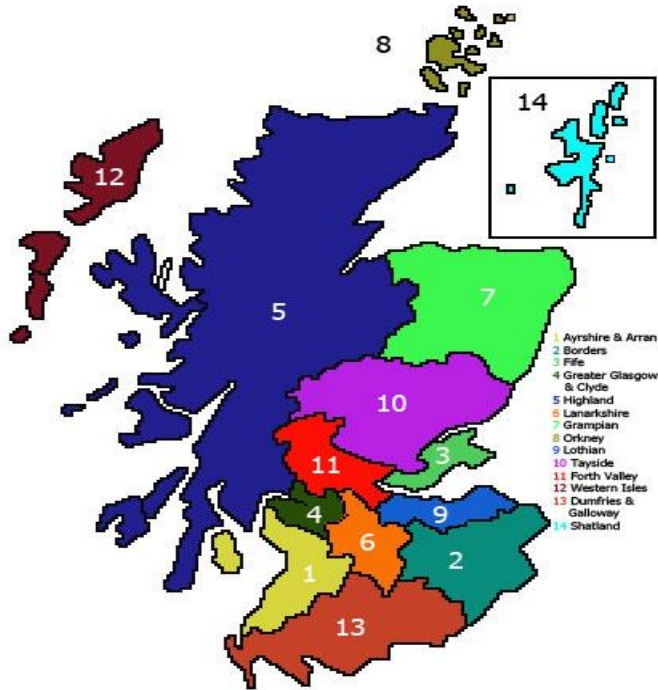
- How does SMC make its decisions?
- What are the specific challenges in assessing ATMPs?
- How can these challenges be met in the future?

SMC



We Are Not NICE

SMC



- part of Healthcare Improvement Scotland – Evidence Directorate
- SMC – early HTA of all new medicines
- 14 NHS Boards with ADTCs and Health Board Formularies (primary care and hospital medicines)
- 2015/16 £1.67 bn p.a. spend on prescribed medicines (increase outstrips rate of growth of healthcare spend)

SMC and NICE

NICE

Technology Appraisal

Cancer Drugs Fund

Highly Specialised Technology

SMC

Technology Appraisal

End of Life/Orphan

Ultra Orphan Pathway

SMC: Policy Background



The Scottish Parliament
Pàrlamaid na h-Alba

Health and Sport Committee
8th Report, 2013 (Session 4)
Access to New Medicines

Published by the Scottish Parliament on 3 July 2013

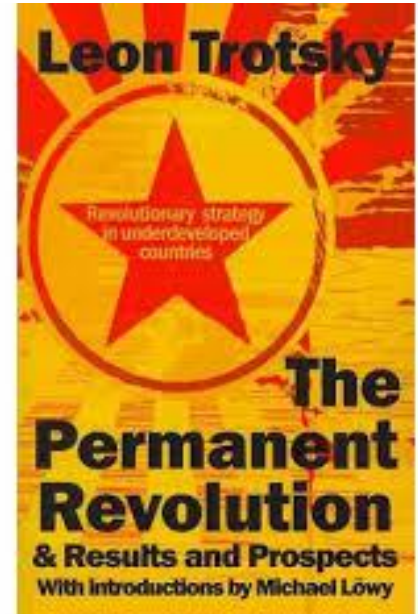
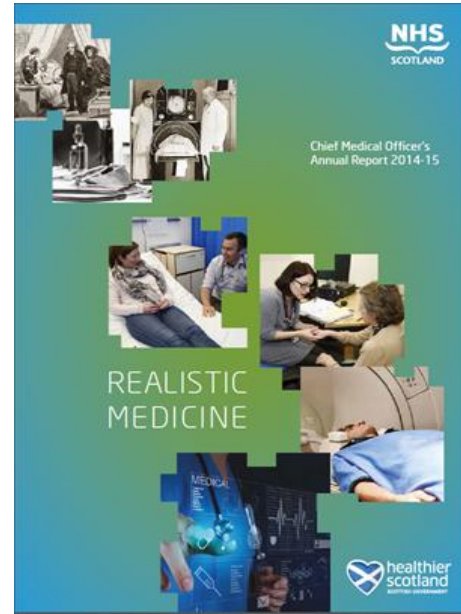
SP Paper 378

Session 4 (2013)

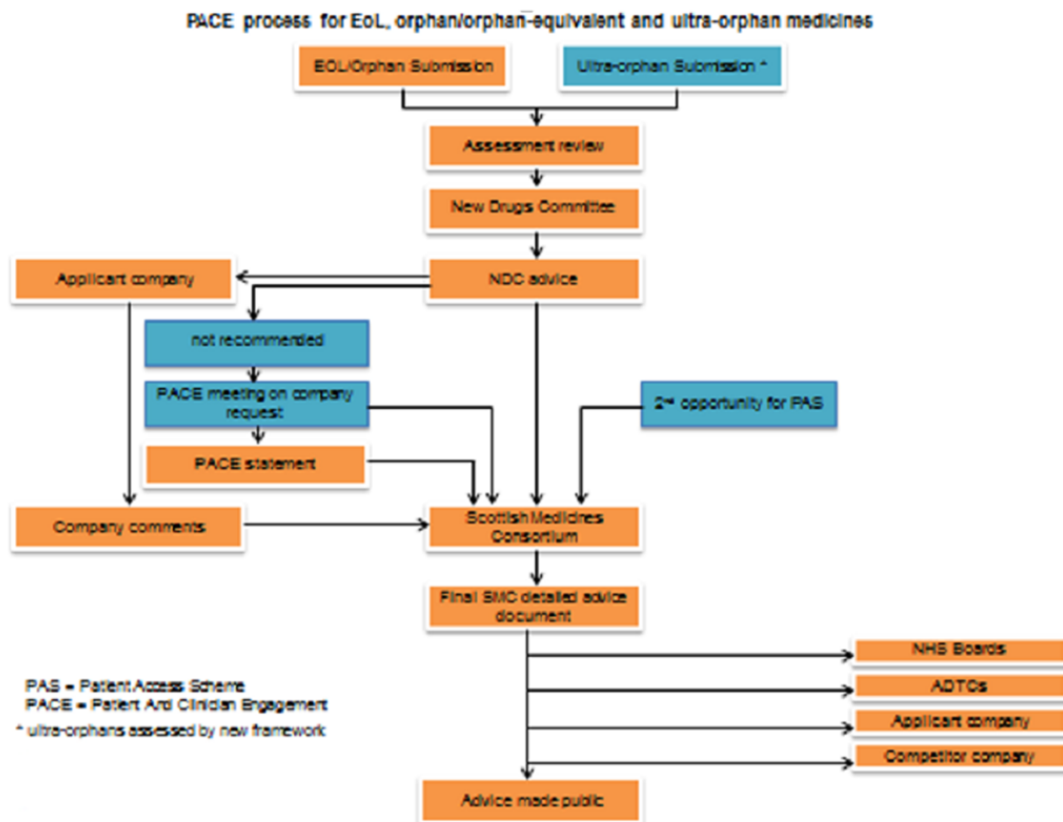
**Review of Access to
New Medicines**

**Independent review by
Dr Brian Montgomery**

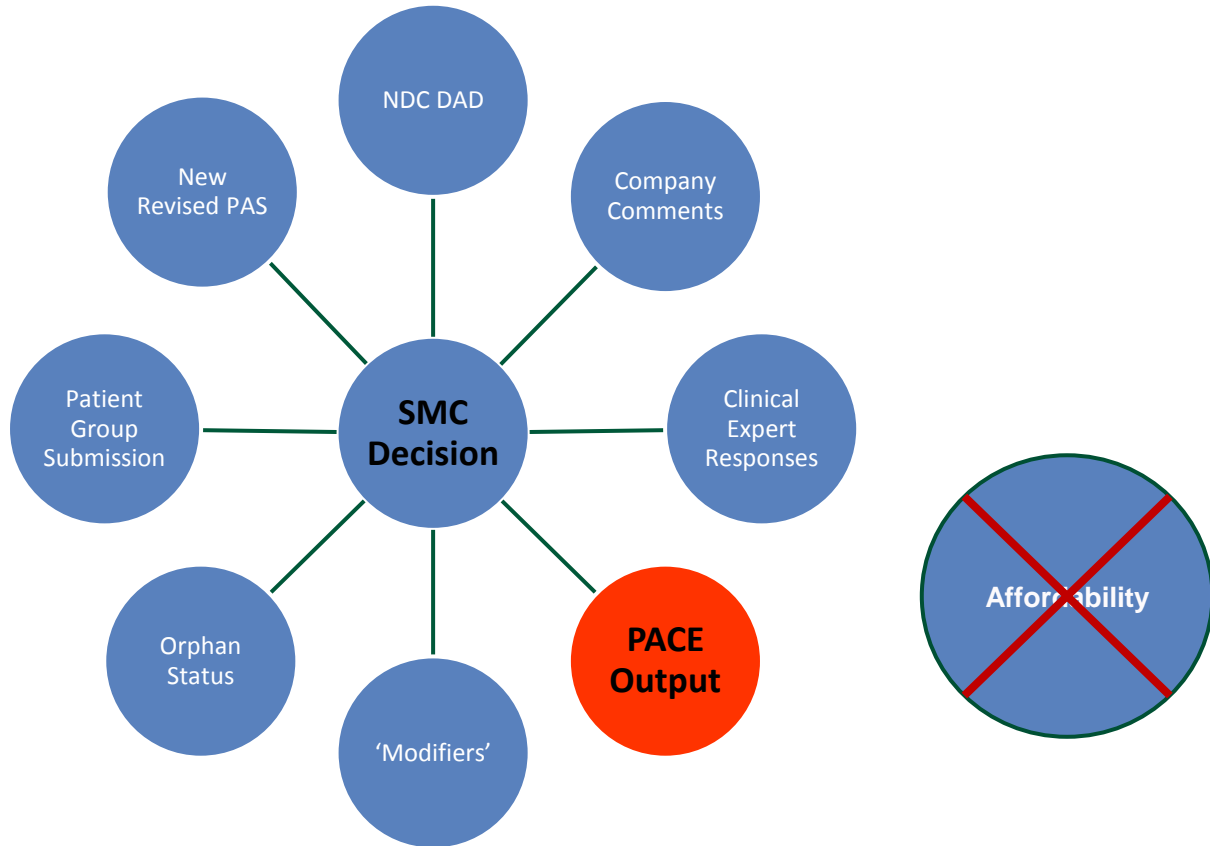
December 2016



SMC: What We Do



SMC decision making



SMC: Patient and Clinician Engagement (PACE)

- 'Added' benefit of a medicine that may not be fully captured within conventional assessment.
- Focus on added value:

For the patient

- impact on QoL
 - ability to work
 - psychological distress
 - ability to maintain self-care, independence, dignity
 - convenience of treatment
- out of pocket expenses

For the patient's family/carers

- impact on:
 - time for accompanied appointments
 - need for personal care/support
 - family life
 - carer's ability to work
- out of pocket expenses

- Completed PACE template has major impact on SMC decision

SMC: Cost Effectiveness

“The SMC does not have a formal threshold cost per QALY below which cost-effectiveness would be considered demonstrated. Nor does SMC have a fixed upper limit on willingness- to-pay for a QALY. The cost per QALY is only part of a wider judgement of the value of a new medicine. Where the cost per QALY is relatively high, other factors also play a role in SMC’s assessment and may modify the final decision (see below).”

SMC: Assessment of ATMP

'Existing HTA methods and decision-making frameworks are applicable'

NICE CAR-T mock technology appraisal 2016

Clinical

- Immature data
 - High uncertainty re clinical outcomes and long-term safety
- Small patient numbers
 - ultra-orphan?
- Single arm studies (ethics of withholding therapy)
- Surrogate outcomes
- Less conventional or no comparator treatments

Payment

- High prices per patient
- Pay upfront
- Significant non-drug costs
- Innovative payment mechanisms (managed access)
 - 'Buy now, pay later'
 - 'No cure, no pay'
 - Lifetime leasing
 - Data collection/monitoring?

Other

- Input from highly specialised clinical experts
- SMEs

SMC

Improving the Value Proposition

- SMC doesn't do price negotiation
- Approx 80% of cancer medicines have PAS
- Role of Patient Access Scheme Assessment Group (PASAG)
- Traditional preference for simple discounts

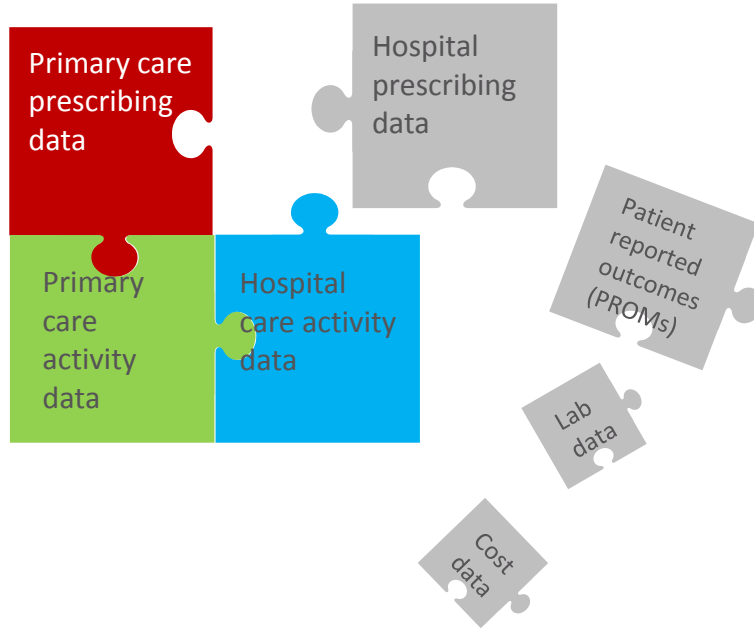
SMC

Complex PAS for ATMP (inc “lifetime leasing” models)

- May be more attractive for manufacturers
- May be appropriate when structured to address uncertainty and share risk
- May improve short term affordability
- Needs robust data collection infrastructure

Available datasets in NHS Scotland

Unique patient identifier - Community Health Index (CHI)



National disease registries/databases e.g.

- Renal
- Cancer
- Multiple sclerosis
- Hepatitis C
- Diabetes

Ongoing initiatives

- Development of a Scottish Cancer Intelligence Framework

SMC

Conclusions

- 1) HTA processes can support the efficient introduction of innovative therapeutics that lead to significant health gain.
- 2) Novel payment mechanisms and outcomes based schemes may be appropriate when they can address clinical uncertainty and improve affordability
- 3) When allocating resource, opportunity costs must always be considered
- 4) Improved data infrastructure remains a priority
- 5) NHS has good track record in handling introduction of disruptive therapeutics



**Healthcare
Improvement
Scotland**

The Scottish Medicines Consortium is part of Healthcare Improvement Scotland

Thank you

Web: **scottishmedicines.org.uk**