Access to newly licensed medicines

Pfizer

This is an executive summary of a report from the Office of Health Economics commissioned by Pfizer on Trends in SMC Decisions on Drug Evaluation.

- A recent analysis of SMC decisions by the OHE has found that that 29% of medicines are accepted for use in NHS Scotland, 24% are restricted and 46% not recommended in 2011. (1)
- A further breakdown of decisions by therapy area outlined that medicines in cancer are as follows: accepted 17%, restricted 31% and not recommended 53%. This means that half of medicines in malignant disease are not recommended for use in NHS Scotland. (1.)
- Medicines in orphan diseases are not recommended by SMC in 49% of cases. (6)
- Medicines for the central nervous system showed an acceptance rate of 23%, restricted 32% and not recommended 46%. (1.)
- Cardiovascular medicines are accepted at a rate of 34%, restricted 32% and not recommended 34% (1.)
- SMC uses ‘QALY’ (5) health economic methodology which has a number of recognised problems. A review of SMC decisions over the last ten years reveals that medicines for common conditions such as Asthma and Diabetes tend to get positive recommendations while medicines for rarer conditions or diseases such as cancer or the central nervous system systematically tend to do less well. Evidence of this is demonstrated in the figures stated above. In England the limitations of QALY methodology have led to the establishment of the Cancer Drugs Fund (to fund medicines not approved as cost effective by NICE) and also the AGNSS process for the assessment of medicines for very rare conditions. NICE will assume responsibility for assessment of very rare medicines from April 2013 and have confirmed they will build on the wider framework developed by AGNSS.
- The QALY assesses quantity of life (how long you live for) and the quality of the remaining years of life for the medicine being assessed. The QALY combines these factors into a single measurement and gives a figure. Medicines for common medical condition tend to have lower QALY estimates than medicines for rare conditions since the price the manufacturer can afford to charge is lower due to the higher number of potential patients. Furthermore, the current SMC methodology does not include all of the benefits and costs associated with a medicine: it does not include costs and savings outside of the NHS budgets or benefit to the patient beyond quality of life or survival, such as convenience and dignity.
The SMC health technology assessment process relies on the QALY (1) measure of value for the evaluation of new medicines. Explicit and comprehensive guidelines exist for the estimation of the cost per QALY, and the goal is to maximise the number of QALY’s from a fixed budget. There have been very few deviations from the QALY based system however, there has been one notable evolution to the process where decision modifiers have been introduced to allow a QALY to be adjusted to reflect some additional value on some treatments. Despite the introduction of these modifiers many specialist treatments in cancer and rarer diseases are still not recommended.

The “modifier” approach does not resolve the issues as has been noted by the increase in medicines available elsewhere in the UK.

The current SMC framework aims to maximise the QALY’s generated (lower the QALY the better the value) but takes no account of who benefits and who loses out. While decisions result in an efficient allocation of resource the decisions can seem to conflict with the objectives of the NHS to reduce inequity and improve health outcomes. Medicines evaluation is one of the very few areas of the NHS subject to cost effectiveness thresholds.

The Innovation, Health and Wealth review on the dissemination of innovation in the NHS has been warmly welcomed by industry and contains a number of positive measures to improve the uptake of NICE approved medicines. The report recognises that use of new medicines, approved by NICE, can play a role in improving quality outcomes for patients. (2)

We welcome the Statement of Intent announced in June by the Deputy First Minister to make Scotland a leading centre for Innovation through collaboration between industry, NHS and Scottish government.

In terms of budget impact to NHS Scotland an analysis done in 2010 demonstrated that for the 22 cancer medicines not recommended for use in Scotland 2005 – Feb 2009 = Year 1 budget £14.9 million and year 5 £28.3 million (3)

14 cancer medicines not recommended for use in Scotland 2008 – Oct 2010 = Year 1 budget £4.9 million and year 5 £12.9 million (4)

Whilst there is a need to improve the current Individual Patient Treatment Request (IPTR) system, the issues around access to medicines in cancer and rare diseases could be resolved by the use of a wider decision making framework by SMC which is co created by industry and SMC.
• A wider assessment of value should be introduced in order to address the key issues which have arisen as a result of the use of the dominance QALY based framework
• Pfizer would propose that SMC adapt their decision making framework to allow a wider assessment of value. This framework should be co created by industry and SMC
• SMC is well respected. It is a great example of joint working between the NHS and industry. We are pleased to note its rapid, independent and robust decision making.

2. Innovation, Health and Wealth, Accelerating Adoption and Diffusion in the NHS, December 2011
3. Analysis of NHS Scotland budget impact by ABPI Scotland
4. ABPI Scotland budget impact analysis of Cancer Medicines Not recommended by SMC
5. www.scottishmedicines.org/About_SMC/Policy_Statements/A_Guide_to_Quality_Adjusted_Life_Years
6. Updated OHE Report August 2012

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