Introduction of new medicines into practice

Dave Abbott
Medicines Information Pharmacist
Before we begin...

- Want to talk about what factors are considered about medicines as they are introduced into practice, but...
- Without knowing about how medicines are paid for, it's difficult to explain why things are done as they are, so...
  - 1. How are medicines funded?  
     **Commissioning**
  - 2. How do you know what medicines you’ll be using next year?  
     **Horizon Scanning**
  - 3. What do you need to think about when a new product comes into practice?  
     **Introduction of a new medicine**
Commissioning in Wales, Scotland and Northern Ireland

• Whoever holds the money gets to decide on the most appropriate way to spend that money.
• Money comes from tax revenue
• Local Health Boards agree contracts with secondary care providers
  – Funding provided within these contracts
The ‘new’ NHS commissioning landscape in England (the simple version)

• Whoever holds the money gets to decide on the most appropriate way to spend that money.
  – Money comes from tax revenue and goes to the DoH
  – DoH allocates money to NHS England
  – NHS England allocate a proportion of this to local Clinical Commissioning Groups to provide local services
    • Led by clinicians
    • Fund primary and secondary care services
    • Advised by Clinical Support Units (CSUs)
  – NHS England retain some money to fund specialised services
    • Led by clinicians in Clinical Reference Groups
    • Fund specialised services (renal, liver, cystic fibrosis, cancer etc)
  – NHS England allocate some money for public health services
What does PbR mean?

• Each episode of care is given a ‘tariff’ price, that a provider is paid to provide that care
  – For some patients, this will be more than their care costs the provider (‘profit’)
  – For some patients, this will be less than their care costs the provider (‘loss’)

• This incentivises providers to become more efficient, which makes the NHS more efficient
What is a High Cost Drug?

• Some drugs are so expensive, and unevenly used, that to include within a Tariff would be unfair
  – Some Trusts (low users) would have a much higher tariff than what it cost to treat their ‘easy’ patients
  – Some Trusts (high users) would have a much lower tariff than what it cost to treat their ‘difficult’ patients

• These are classed as High Cost / tariff excluded / non-tariff/ non-Payment By Results / pass-through drugs

• Every time a High Cost Drug is used, it can be charged to the commissioner who approves its use
  – If you’ve a mechanism to charge the commissioner
Horizon Scanning – Why?

- Manage budgets
  - In 2013/14, spend on medicines in secondary care increased by 15.1%
  - In 2014/15, funding for the NHS is expected to increase by around 1%
  - There is a need to plan ahead to allocate money from limited budgets to fund service developments
  - Commissioners are becoming less able to fund in-year developments outside of the commissioning cycle
  - Commissioners generally require information on potential developments 6 months before the start of the financial year
Horizon Scanning – Why?

• Manage entry of products into practice
  – Funding may need to be obtained
  – Pathways of care may need changing
  – Guidelines may need to be developed
  – ‘Shared care’ may need to be organised
  – May need to disinvest in another product to release funding
  – May need to manage patient expectations
Horizon Scanning – How?

• Resources
  – NICE workstreams
    • AWMSG / SMC published workstreams are usually too short to use in horizon scanning
  – New Drugs Online
  – Prescribing Outlook
  – Local intelligence
Introduction of a new product into practice

• What aspects other than ‘does it work?’ need to be considered before the introduction of a new product into practice?

  – Who pays, and how?
  – Who will provide the service?
    • Secondary care?
      – Development of existing service, or new service?
    • Primary care?
    • Both?
  – Are there associated costs and requirements?
    • Clinic / medical / nursing time?
    • Supportive medicines?

• Aseptic production?
  – ‘Opportunity costs’?
  – Do controls on use need to be implemented?
    • Is the product likely to be used outside of the intended indication?
    • Is the product targeted at a currently unmet need?
    • Is there likely to be significant pressure to prescribe (industry, patient groups)
Case Studies – Patient Access Schemes

• Dolutegravir
  – First in class HIV treatment
  – NHS England commissioned position due in 3-4 months time
  – Product has gained a license, but company will provide free of charge (via a patient access scheme) to eligible patients prior to the NHS England commissioned position
  – What would you focus on in an application to use within your Trust?

• Are considerations different for daclatasvir (hepatitis C treatment)? Olaparib (BRCA-mutation ovarian cancer maintenance)? Pembrolizumab (melanoma via EAMS)?
Case Studies – New product in a ‘new’ service

• Request for dapoxetine for premature ejaculation within secondary care – first licensed product for the indication
  – GPs have been referring patients to the urology service for some time and patients are being managed on unlicensed uses of antidepressants
  – Proposal is for initiation in secondary care, with maintenance in primary care (as the current use of antidepressants)
  – CCGs feel this is not a commissioned service and may not be a commissioning priority in this financial year
  – **What would need to be done before the use of dapoxetine could be considered?**
Case studies – New product in an ‘old’ service

• Capsaicin patches for neuropathic pain
  – Patients are already seen in secondary care for this indication
  – The clinical appropriateness of the product for a small niche of patients has been supported
  – Capsaicin patches are not a High Cost Drug
  – Cost of the patch (list price £210), is greater than the money received for the clinic visit
  – What potential solutions to this problem can you think of?