one nucleus insights

Market Access Challenges

In collaboration with MAP Biopharma, a local (to Cambridge) market access consulting company, One Nucleus held a breakfast meeting to discuss market access strategy.

In a complex and changing environment it is becoming crucial to implement a market access strategy in the early stages of a product's lifecycle. Accurate information on countries to consider, pricing and legal leverage not only optimise time and budget at the implementation stage but also ensure a relevant collection of data in the upstream processes.

This breakfast meeting addressed the main topics to be considered in a market access strategy in the UK

- Topic selection by NICE: how to make sure you are considered by NICE and what might the alternatives be?
- NHS England - the evolution continues - how to plan for 2016 and beyond
- Challenging pricing and reimbursement decisions

And discussed key points raised were as follow:

- Timing and impact of NHSE strategy (and bear traps in the future), pricing
- Topic selection, for cell and gene therapies specifically
- Challenges – Black box – Clarity
- NICE - what determines price? Is NICE becoming tougher or less so? Are companies getting better or worse at liaising with NICE?
- UK versus the rest of the world and what changes can we expect if the UK exits the EU?

Below is a summary of the notes to accompany slides (here) together with relevant links (below):

Routes to reimbursement

There are six key routes to reimbursement for new products in England:

- National Institute for Health and Care Excellence (NICE)
- Commissioning policy
- Clinical Commissioning Group
- Individual funding requests (IFRs)
- Commissioning through evaluation
- Cancer Drugs Fund (CDF)

Role of NICE:

The role of NICE is becoming increasingly more diverse and now includes more than just evidence based guidance. It includes Guidelines, Guidance, Quality Standards, Information Services and Additional Services (including the new Office for Market Access from 2015).

Horizon Scanning, how to be NICE'd and how to gain NHS England commissioning:

- The most talked about route to reimbursement in England and Wales is via a NICE appraisal but many drugs do not fit the NICE agenda
- Suggestions for guidance on a new medicinal product (that has not yet received a marketing authorisation) should be made by the relevant company through UKPharmaScan
- Healthcare professionals, researchers and patients can also suggest potential technologies for NICE to appraise by contacting the National Institute for Health Research Horizon Scanning Centre
- NICE guidelines have a library based process for selecting their topics and the interventional procedures and medical technologies programmes have a notification system in place for their topic selection

NHS England Background and context

- NHS structure according to the King's fund click here for more information
- 2015/16 Planning Round: commissioners submitted a single-year operational plan as a refresh of '14/'15
- 2016/17: very different
- A Government at start of 5-year term: A new multi-year Mandate
- FYFV: system wide strategy for next 5 years click here for more information
- A Comprehensive Spending Review settlement to cover the next 5 years
- Government plan: 10-year cycle to reduce public sector spending to historic low levels (not just NHS)
- No plans to amend the Health & Social Care Act

The Decision Making Process in Specialised Commissioning

A long, tortuous and unpredictable journey based on several decision or recommendation-making organisations:

- 74 Clinical Reference Groups
- National Programme of Care Board
- Prescribed Specialised Services Advisory Group
- Rare Disease Advisory Group
- Clinical Priorities Advisory Group
- Directly Commissioned Services Committee

Appeals and Reviews of Pricing and Reimbursement Decisions

EU and UK Level Controls are Directive 89/105 – pricing/reimbursement transparency and National Health Service Act 2006. UK remedies include:

- PPRS disputes
- Statutory scheme appeals
- NICE appeals
- Cancer Drugs Fund reviews
- CCG commissioning
- Using Freedom of Information Act
- Judicial review by pharma companies or by patients

Accelerated Access Review – Key Points click here for more information

- Recommendations to Government on reforms to accelerate access for NHS patients to innovative medicines and medical technologies (including devices and diagnostics)
- A key aim is to demonstrate that the UK is the best place in the world to design, develop and deploy innovative products
- The scope includes
  - Regulation, reimbursement and uptake
  - Identification of key priorities for action – both strategic and operational – and suggest practical improvements
  - Consideration of the long term landscape for innovation adoption and how schemes like the CDF, PPRS and Value Based Pricing may fit into an integrated specialist commissioning system
  - Cost-effectiveness and affordability (BUT not the ICER threshold or methodology of NICE)
  - use of data and measurement to drive evidence based development and commissioning of effective innovative medicines
- Implementation steps becoming clear over Q1-2 2016 including success metrics

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