Agenda

Monday 10th February 2020

- **The Task Ahead for UK-EU Future Negotiations**
  - Alex Stojanovic, Institute for Government
- **Integrated Care Systems**
  - Steve How, NHS Partnerships, Wilmington Healthcare
- **NHS England Commercial Framework**
  - Nina Pinwill, Head of Commercial Operations, NHS England & Improvement

NHS E&I/NICE – EMIG Meetings

- 9.6% - 5.9% rebate decline
- Innovation adoption?
- NHS spent more on medicines in 2019
- In last 3 Qtrs 2019 - Truvada, Adalimumab, HEP C
- CDF continues to grow
- Uptake mechanisms
- Assisting NHSE/company engagement – workshop
- Shortages

NICE Methods & Process Review

- QALY thresholds will not change for duration of Scheme
- 2% growth in medicines bill
- Voluntary Scheme – implementation
- Task & Finish Groups – meeting 12.2.20
    - Cost minimisation
    - Costs used in HTA
    - Decision Making
    - Discounting
    - Equality considerations in guidance development
    - HRQoL
    - Modifiers considered in decision making
    - Prescribing Pathways
    - Technology specific issues
    - Types of Evidence – sourcing & synthesis
    - Uncertainty

Voluntary Scheme (VPAS)

- Allowed growth of 2% in VPAS
- All growth above 2% funded by industry
- Any growth will lead a higher negotiation threshold at end 2023
- 2024 negotiations
- Statutory Regulations

Statutory Scheme Consultation – Monday 17th February 2020

- SS benefit is the mitigation of rebate for pre 31.12.18 FAs – progressively expiring
- Higher rebate levels in SS – VS more attractive
- 12 companies left SS to join VS on 1.1.2019 – only 10 companies remain
- All 10 may leave the SS at end 2020 – SS less relevant
- Legal 'backstop' for DHSC if future VS renegotiations fail

N. Ireland (N.I.) Protocol Group

- Specialised Committee on the Protocol
  - Official lead
  - Facilitates implementation of the protocol
  - Recommendations to UK-EU Joint Committee on funding the Protocol
  - No specific powers to enforce any solutions – escalate matters to the UK-EU Joint Committee for action
- UK-EU Joint Committee – 1st meeting March 2020
  - Responsible for the implementation of the Withdrawal Agreement
- Joint Consultative Working Group
  - Forum for sharing information and mutual consultation
  - Meets monthly & co-chaired by UK & EU
- BEIS lead on N.I. – OLS engage with sectors re concerns
  - Operationalisation of Protocol
  - Placing goods on the market
  - Access to databases

N. Ireland Protocol Group

- GB to N.I. – No tariffs on goods unless ‘at risk’ of going to EU
- ‘Risk’ determined by UK-EU Joint Committee
- UK licensed product valid in N.I. 2021 onwards
- Centralised licensed product in N.I. 2021 onwards?
- Role of MHRA in N.I. – UK has N.I. oversight
- Checkpoint in June 2020 – Transition period could be extended for 2 years
- https://www.gov.uk/transition
- Batch release mutual recognition – default position is that it will continue
- Feed concerns to OLS
- ‘No Deal’ = ‘Non-negotiated outcome’

Clinical Trials

Marketing Authorisations

Manufacturing

Importing

Distribution

Pharmacovigilance

Clinical Trials

- RWE to support regulatory decision-making
- Novel trial designs

MAs

- Target EU CHMP
- Conditional approvals – EAMS

PV

- UK's world-class system pooled with other global regulators

EMIG 5-Point Plan

1. Vibrant R&D Community
   - Publicly-funded research better align with global research priorities
2. Highly Skilled Manufacturing Sector
   - Competitive capital investment allowances and tax credits
3. Concentration of Commercial Expertise
   - Immigration regime to attract the best
4. Supportive Licensing & Reimbursement
   - Early licensing means early reimbursement
5. Life Sciences Support Services Sector
   - Capitalise on global interest in HTA and UK expertise

Credentialing

- Professor Sir Bruce Keogh Review – life sciences industry is authorised to access the NHS – ‘credentialing”
- Work with industry – identify a single set of policies that could be nationally adopted
- Remove barriers to collaborative working at a local level
- Avoid increase in cost or bureaucracy
- System of industry-led implementation across the NHS

Credentialing

- Life Science Industry (LSI) National Credentialing Register https://lifescienceindustry.co.uk/
- Janet Monkman, as Registrar, responsible for placing people on the Register – no-one else
- Training providers must not give impression of 'accrediting' people to the Register
- Medical Industry Accreditation (MIA) – an appointment system, not an accreditation
- MIA:
  - Set up by ABHI
  - Administered by Medical Industry Ltd (MIL)
  - 'Administered' = 'Fills in a form'
- The appointment system should not be administered by a training provider
- AHCS working with NHS E
- EMIG may be appointed to the Registration Council
- Change ……for the better

Special Interest Groups

EMIG Compliance Group 13th January 2020

EMIG Finance Group 21st January 2020

EMIG BD Group 20th February 2020

EMIG HR Group 10th March 2020

EMIG Market Access Group 12th March 2020

EMIG Digital Health Group 17th March 2020

EMIG Medical Directors' Forum

EMIG/NICE Face-to-Face with EMIG companies (40+ in 2019) + EMIG/NICE webinars

EMIG Patient Engagement Group

EMIG Women in Healthcare

Devolved Nations

EMIG N. Ireland 4th March 2020

- Dr Ruth Miller, Medicines Optimisation Project Lead, N. Ireland
- Terry McErlane, Resolute Public Affairs

EMIG Wales 10th March 2020

- Jonathan Morgan, Insight Wales
- Jonathan Lloyd Jones, RPS Wales

EMIG Scotland 19th March 2020

- Alison Strath, Principal Pharmacist, Scottish Government
- Irene Oldfather, Director of Strategy and Engagement, Health & Social Care Alliance, Scotland

EMIG Ethical Medicines Industry Group

Agenda

Monday 4th May 2020

- **Accelerated Access Collaborative**
  - Dr Sam Roberts, CEO AAC, Director of Innovation & Life Sciences, NHS E & I
- **EAMS**
  - Anna Dijkstra, Chair EAMS Strategy Group, Senior Advisor to NHSE&I
- **Credentialing**
  - Janet Monkman, CEO, Academy for Healthcare Science
  - Angela Douglas, Deputy Chief Scientific Officer, NHS England

EMIG Quarterly Meeting
10th February 2020

EMIG Ethical Medicines Industry Group