

‘No Deal’



No deal: the default

Outside Single Market
(ends free movement of
goods and people)

Outside of Customs Union
(trade with EU on WTO rules
involving checks and tariffs)

Independent trade policy
can do trade deals around
the world

Scope for regulatory
divergence from the EMA
(and alignment with the
FDA?)

More restrictive visa regime
from EEA countries

No ECJ jurisdiction

Ends EU budget
contributions
(but do we keep the £39bn?)

Return to a hard border ???

No deal assumptions: Operation Yellowhammer

40% worst-case flow rate on Day 1
via the main Channel crossings

Significant disruption
lasting up to six months

Medicines/medical products
particularly vulnerable to delays
(75% of medicines come via this
route)

Reduced availability of products with
short shelf lives
- limits on transit times, or require
temperature-controlled conditions



Parliamentary intervention?

MPs have very few opportunities to legislate to stop no deal

A vote of no confidence would not necessarily stop no deal

There is little time to hold a general election before 31 October

A second referendum can only happen with government support



NICE Methods & Process Review

- Steering Group – NICE, NHS E, DHSC, Independent Advisor
- Working Group – NICE, NHS E, DHSC, Academia, Patient Charities & Industry
 - T&F Groups – from each stakeholder group
 - 12 EMIG nominees
- Working Group Meetings scheduled to mid 2020
- Bureaucratic exercise or meaningful review?

NICE Methods & Process Review

- Restrictions:
 - Voluntary Scheme – QALY thresholds will not change for duration of the Scheme
 - NHS Budget for medicines – ‘fixed’
- Political influence
- To date:
 - Discounting
 - HRQoL
 - Cost minimisation
 - Types of Evidence – sourcing
 - Types of Evidence – synthesis
 - Exploring uncertainty
 - Costs used in HTA
 - Modifiers considered in decision making
 - Equality considerations in guidance development



Department
of Health &
Social Care

NHS

England

NICE



Opportunities

- Horizon Scanning
- Improving engagement
- NICE Value Assessment
- Commercial arrangements
- Combination branded products
- Uptake support – five highest health gain categories

Voluntary Scheme

8-11%

Consultation Community Pharmacy Drug Reimbursement Reform

- all pharmacy contractors have equitable access to medicine margin
- reimbursement prices better reflect market prices
- Second stage – detail of how DHSC reimburse pharmacy contractors – formulae used to calculate reimbursement prices
- Consult with PSNC only
- Not an "all or nothing" set of proposals – no pre-conceived commitment to taking any forward
- 1st April 2020
- Impact Assessment – impact pharma & wholesalers at circa £250M pa, through reduced income on Cat A and C drugs

Consultation Community Pharmacy Drug Reimbursement Reform

- ... the determination of reimbursement prices of generic medicines in Category A
- ... the distribution of medicine margin added to generic medicines in Category M
- ... the determination of reimbursement prices of medicines in Category C which are prescribed generically but have multiple suppliers
- Inclusion of drugs (other than licensed and unlicensed medicines) with a reimbursement price in Part VIII
- ... the determination of reimbursement prices for non-part VIIIA drugs Current reimbursement arrangements
- ... the arrangements for reimbursing and procuring unlicensed medicines ('specials')
- ... the reimbursement of generically prescribed appliances and drugs dispensed as 'specials'
- ... the deduction scale to reflect different levels of discount for branded and generic medicines

Consultation Community Pharmacy Drug Reimbursement Reform

- Formula for determining Category A, C and M prices in the Drug Tariff (DT) to change:
- **Cat A will not be based on the List Price** of current (AAH, Alliance, Teva, Actavis) but on **actual ASP's** from new quarterly Information Requirements sourced from Pharma companies and wholesalers
- Implications:
 - Cat A DT prices will fall, often materially
 - Much of this information already collected in quarterly generics reports to NHS digital (under the Costs Act)
- **Cat C** products with multiple suppliers will no longer be based on the price of a single reference product (usually originator brand's list price), but on either:
 - Weighted average dm+d **list** prices of suppliers; or
 - Actual ASP's from new quarterly Information Requirements sourced from Pharma companies and wholesalers
- Implications:
 - Cat C DT prices will fall, often materially
 - The 'Cat C Model' – branded generics suppliers encourage CCG's to prescribe by brand name – all but dead

EAMS Strategy Group

- Anna Dijkstra, Senior Advisor NHS E – Chair Strategy Group
- T&F Groups:
 1. Process Improvement – administration of EAMS, internationally competitive
 2. Comms Process – articulate the value of EAMS :
 - a) Patients with unmet clinical needs
 - b) NHS and clinicians
 - c) Industry
 3. Industry Involvement – options for recognising the prescription of EAMS products from PIM to HTA
 4. Opportunities & Obstacles to Engagement – understand the enablers and barriers for engaging with EAMS
- EMIG nominees – 11

Credentialing

- Angela Douglas, Deputy Chief Scientific Officer (Prof Sue Hill)
- Minimal cost
- Janet Monkman, CEO, Academy for Healthcare Science
- MIA
- Competition

Special Interest Groups

EMIG Market Access Group 5th Sept 2019

EMIG HR Group 10th Sept 2019

EMIG-NICE NICE Webinar - Cell and Gene Therapy 24th Sept 2019

EMIG BD Group 17th Oct 2019

EMIG Patient Organisation Group 18th Oct 2019

EMIG Digital Health Group 22nd Oct 2019

EMIG Compliance Group

EMIG Finance Group



Devolved Nations

EMIG N. Ireland 11th Sept 2019

- Anne Marie Marley, Nurse Consultant, Belfast Trust

EMIG Wales 15th Oct 2019

- Kath Haines, Head of WAPSU AWTTTC and Tony Williams, AWTTTC – The Vault
- Martin Davies, NHS Direct Wales – ‘Your Health Your Medicine’

EMIG Scotland 28th Nov 2019

- Laura McIver, Chief Pharmacist, Healthcare Improvement Scotland – ADTC Collaborative, Electronic prescribing, PACS/National Review Body and the work of SIGN
- Speaker, National Procurement Scotland
- Dr David McDonald, Service Improvement Manager, Scottish Govt, Whole System Patient Flow Programme

EMIG Parliamentary Dinner 2019

- Monday 11th November, 6.45pm
- Etc Venues at the Old County Hall Westminster, London SW1P 3AA
- Guest Speaker: Broadcaster John Pienaar
- www.delegant.co.uk/emig





Agenda

Monday 11th November 2019

- **Industry Response to the Long Term Plan**
 - James Roach, Director, West Essex Integrated Care Partnership
- **AAC/EAMS**
 - Dr Sam Roberts, Director of Innovation, NHS E & Anna Dijkstra, Chair EAMS
- **Credentialing**
 - Angela Douglas, Deputy Chief Scientific Officer & Janet Monkman, CEO, AHS
- **Regulation Post Brexit**
 - Dr June Raine, Interim CEO & Director VRMM, MHRA