



NHS R&D Forum

15th May 2018

Leslie Galloway
Chairman

EMIG  Ethical Medicines
Industry Group

EMIG  Ethical Medicines
Industry Group

- 270+ Member companies & organisations
- 90% Members represented only by EMIG
- EMIG represents c. 50% of UK branded volume*
- 80% – Alliance, Ammiral, Dermal, EUSA
- 10% – Allergan, Astellas, Gilead, Takeda, Teva
- 10% – Dompé, Santhera, Shield Therapeutics, Zogenix

*(Ref: IMS BPI)

EMIG  Ethical Medicines
Industry Group

EMIG  Ethical Medicines Industry Group **Ecosystem**

Patient Charities

- AKU Society, Cancer52, Myeloma UK, National Voices

Research Policy

- AMRC, Society of Biology, The AMS, UUK

Universities/research institutes

- de Montfort, Imperial, ICR, King's, Manchester, Oxford, Plymouth, QMUL, Southampton, UCL

EU Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

'Ethical' in EMIG = One company, one vote

Equal say in shaping policy!



BREXIT

Accelerated Access
Review

Life Sciences
Industrial Strategy

PPRS

EMIG Ethical Medicines
Industry Group



EMIG Ethical Medicines
Industry Group

Brexit Transition Deal

- Draft 21-month transition deal with EU until 31 December 2020
- UK to remain in the single market and the customs union (EEA) – lose decision-making powers in the EU
- EU citizens arriving in UK during transition period – same rights as those arriving before March 2019
- Professional qualifications will continue to be mutually recognised
- UK able to negotiate and ratify international agreements with other countries
- UK to be consulted by the EU on draft acts to ensure proper implementation in the UK

Brexit Transition Deal

EMA Announcement April 2018

- Draft transition period – MHRA excluded from the EMA from March 2019
- Government to agree MHRA participation in the EMA in October 2018
- In the interim, EMA insistent companies must prepare for MHRA to be excluded

Future Trading Relationship with EU

UK Position

- Chequers cabinet agreement on 'three baskets' approach – 'managed divergence':

Complete Convergence

- Aerospace
- Automotive
- Chemicals
- Pharmaceuticals

Share Ideals

- Consumer Rights
- Animal Welfare
- Environmental Protection

Distance Sharply

- Agriculture
- Fisheries

Future Trading Relationship with EU

'Our Future Partnership' Speech March 2018

- Seek associate membership of the EMA post-Brexit – MHRA would maintain involvement in undertaking evaluations
- Science & Innovation pact to enable the UK to participate in future EU funding programmes
- Labour mobility framework to allow individuals to move freely across the EU for business
- Preserve integrated supply chains across the EU – UK to explore how the two options put forward in its [Future customs arrangements paper could be implemented](#)

Future Trading Relationship with EU Prime Minister's Five Key Tests

Guide for the negotiations and ultimately what the final Brexit deal will need to be judged against:

1. Taking back control of money, laws and borders
2. Finding an enduring solution that avoids future EU-UK disagreement and negotiation
3. Protecting jobs and security
4. Creating an outward looking Britain
5. Strengthening the union of the UK nations



Future Trading Relationship with EU

- EU leaders' summit June 2018 – withdrawal agreement to be finalised
- Final agreement on future relationship by October 2018
- European Parliament approval

Future Trading Relationship with EU Obstacles

- Border issues
 - Northern Ireland & The Republic of Ireland
 - Spain & Gibraltar
- “Nothing is agreed until everything is agreed”
- Parliamentary vote on final agreement



‘They can deliver our new passports when they come here to catch our fish’

Accelerated Access Review



- Accelerated Access Pathway (AAP)
 - Streamline methods of assessment for all new products
 - Simplify and accelerate access
 - Single clear decision point
- Value assessments – improved patient outcome measures – cost data extending beyond one-year
- Accelerated Access Collaborative (AAC)
 - Sir Andrew Witty (chair)
 - MHRA, NICE, NHS England, NHS Improvement and Govt
 - Patients, industry and clinicians

But....

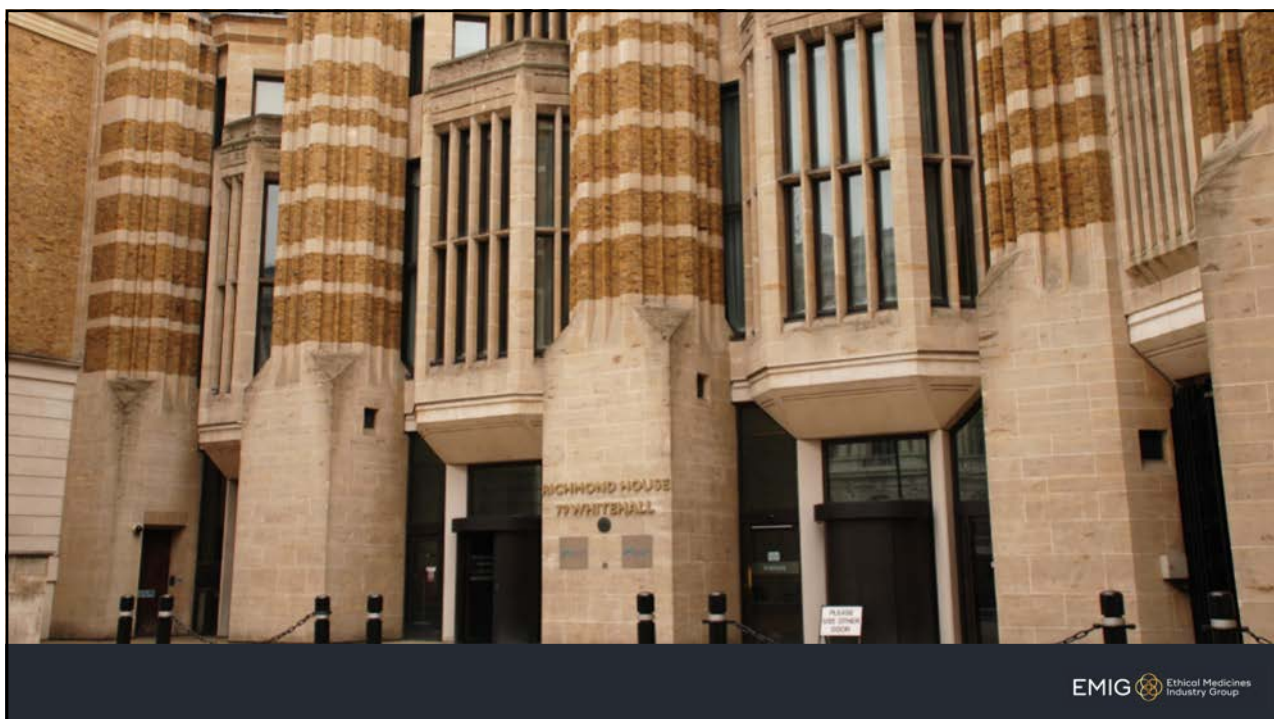
- Squeeze on NHS funding of medicines
- New 'breakthrough' status for transformative medicines
 - Cost Neutral
- £86m AAR funding mainly for small digital health start-ups
 - digital innovations less expensive
 - capable of delivering huge in-year efficiency savings
- £35 million of fund for accelerating access to digital products
 - only £6m will support Medtech, Diagnostics and Pharma
- Remaining £39m for "encouraging grassroots adoption and uptake of new medical technologies"

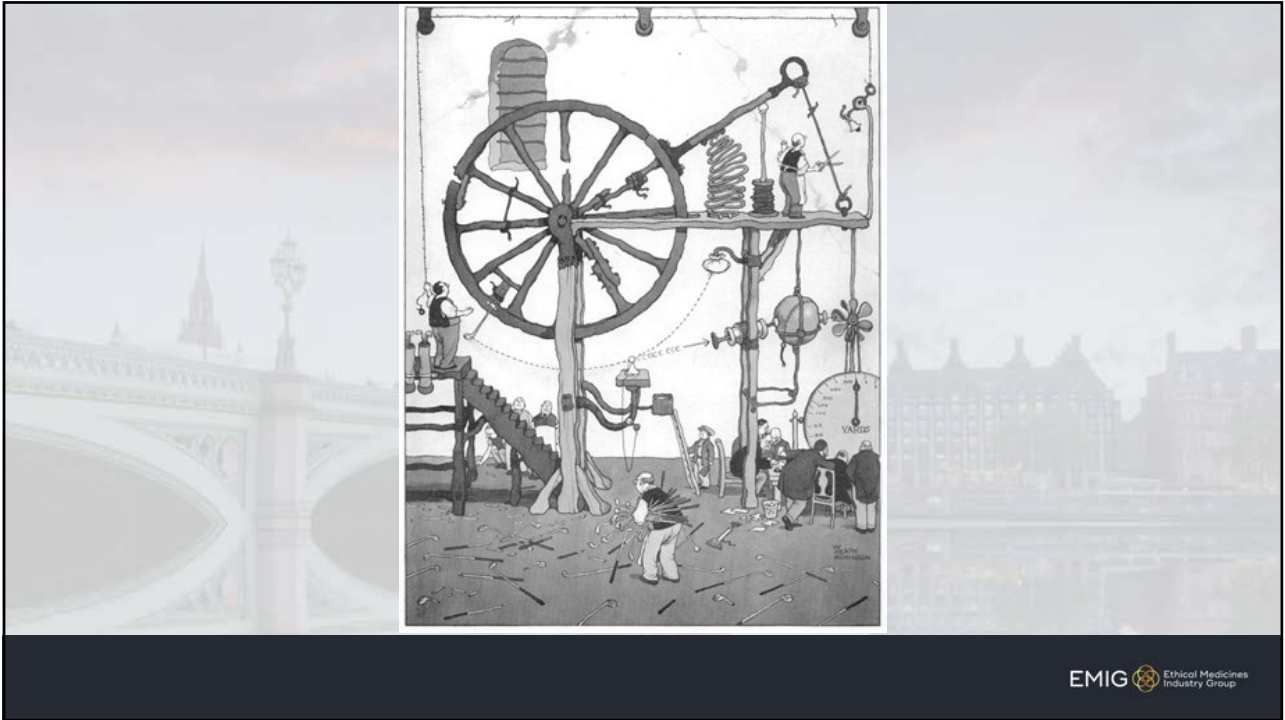
Life Science Strategy

- Raise total R&D investment to 2.4% of GDP by 2027 (1.68% in 2015)
- Increase the rate of R&D tax credit to 12 per cent
- Invest £725m in Industrial Strategy Challenge Fund programmes to capture value of innovation

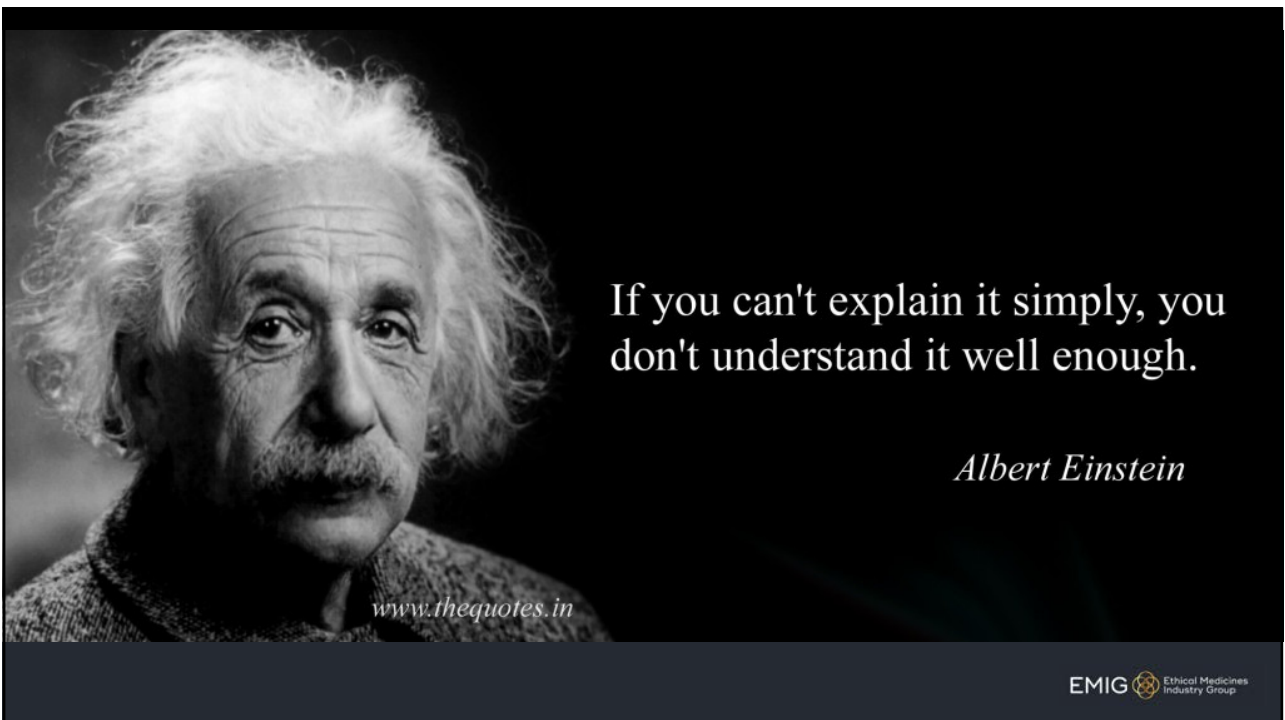
Reality for Pharma

- Most complex market access in EU
- Brexit
- NICE charging for Technology Appraisals
- NHS E Affordability Criteria
- FYFV Next Steps
- Regional Medicine Optimisation Committees
- NHS Specialised Commissioning Prioritisation





EMIG  Ethical Medicines Industry Group



If you can't explain it simply, you don't understand it well enough.

Albert Einstein

www.thequotes.in

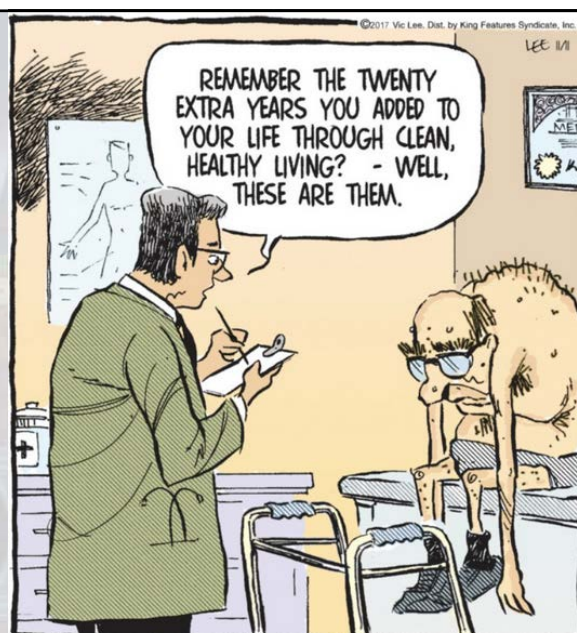
EMIG  Ethical Medicines Industry Group

Pharmaceutical Price Regulation Scheme (PPRS)

- 5 Year agreement between Govt and industry
- Stability and predictability to the Government and the industry
- Ensure NHS branded medicines bill stays within affordable limits
- Improve access ... ensure NICE approved medicines available widely in the NHS
- Quarterly rebates to DHSC
- Treasury 'allows' for rebates in NHS budgets
- Est. £3bn by end 2018

PPRS Workshops

- No 10, Treasury, DH, NHS E, Devolved Nations, trade bodies
- Challenges for Govt & industry over next 5 years
- 2014 PPRS – reflections on what worked well and what did not



PPRS Workshops

- Barriers to uptake
- Free pricing
- Cost effectiveness thresholds
- Adoption & uptake
- Multiple challenges faced:
 - Value
 - Mitigate risk
 - Budget impact
 - PPRS
 - Competition (tenders)

New Medicines Fund

- £3bn
- Separate from NHS budgets
- Independent administration Board
- NICE approved – Specialised Commissioning – RMOCs
- Budget holders/clinicians

You can't go back and change the beginning, but
you can start where are and change the ending.

C.S. Lewis

NHS R&D Forum

leslie.galloway@emig.org.uk
www.emig.org.uk