



Veterinary
Medicines
Directorate

EU Exit

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Outline

- The EU Exit programme of work
- Day 1 issues
- IT
- Workshops
- The future

What we know

- Article 50 triggered 29 March 2017
- 2 year negotiation period
- Negotiations have started
- Prime Minister's Florence speech



What we don't know

- If it will be as a hard an exit as originally thought.
- If it will be 'deal or no deal'
- How the negotiations will end up
- Exactly what the 'New State' will look like
- How we might end up working with the EU and EMA



So...



There's lots we don't know
but

we can't sit back and wait for the answers,
so we are planning for a range of negotiated and
non-negotiated outcomes.

The EU Exit Programme

- Workstreams:
 - EU Withdrawal Bill
 - Market Access and Customs Union
 - Withdrawal Agreement and negotiations
 - Contingency planning and building
 - Stakeholder Engagement

European Union (Withdrawal) Bill

The Bill will:

- Repeal the European Communities Act 1972 and section 2(2) equivalent powers
- Save all secondary legislation made using section 2(2) ECA 1972 and equivalent powers
- Save all directly applicable EU law (i.e. Regulations and Decisions) – ie freeze the ‘Acquis’ – with some modifications
- Give a power to make consequential amendments to remove legal inoperability
- Give a power to make subordinate legislation to give effect to obligations/arrangements in the Withdrawal Agreement
- Make provision on devolution settlements

Market Access and Customs Union

- Trade is a top priority
- Identifying barriers to trade
- Need to ensure continued trade on Day 1
- Different trade models
- Residues surveillance programme
- MRLs
- Border control issues
- Imports and Exports



Withdrawal Agreement & negotiations

- Aim for a smooth transition
- Aim to ensure business continuity
- Aim to ensure continued availability of veterinary medicines
- Aim to ensure UK is attractive and viable for MAHs

Contingency planning & building

- Addressing Day 1 issues and longer term 'slow burn' issues
- Planning for a range of potential outcomes
 - Scenario A - sliding scale of EMA interaction
 - Scenario B - no relationship with EU
- Opportunities may come to be realised after transition state

Working with others in government

- Defra
- DExEU
- MHRA
- FSA
- HSE



Stakeholder engagement

- Original plans for UK wide engagement
- Now local level
- Consultation on legislation
- Workshops on issues and process changes



Day 1 & high priority issues

- Centralised MAs
- Maintenance of mutually recognised MAs
- Locations - MAH, QP, batch release
- Joint labelling
- On-going applications
- On-going referrals
- Pharmacovigilance and Rapid Alerts
- MAPIs
- Access to IT
- Special Imports Scheme
- GMP inspections
- MRLs
- Generics

34 databases, systems, data exchanges with EMA

Considered priority IT systems:

- Submission portal
- Pharmacovigilance systems
- Rapid Alerts
- Secure correspondence system

Scoping build/buy options

Development, integration, user testing and decision points

Workshops

- By the end of the year
- Invitation to register interest
 - Gov.uk
 - Mavis
 - Vet record
- Indication of topic preferences
- On the day
 - Work through scenarios or step through processes
 - Aim to gather views, record issues and identify opportunities

Risks

- Resources
- Primary Powers
- EMA exclusion

Current work

- Legislate, Negotiate and Build
- Devolved Administrations
- Stakeholder engagement

The future



A thriving UK animal health industry