Veterinary
Medicines
Directorate

EU Exit

Presented by: Sarah Norton, Project Lead
EU Exit and International Team

Overview of Presentation

- The EU Exit programme of work
- Day 1 issues
- ‘No deal’ statutory instruments (SIs)
- Implementation period
- IT
- Current work
- The future

What we know

- Article 50 was triggered on 29 March 2017
- There is a 2 year negotiation period
- Negotiations have started

- The actual date of exit will be 11 pm on 29th March 2019.
- There may be an implementation period.

What we don't know

- 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 ‘no-deal’ scenarios.

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

Today – VMD ensures quality, safety & efficacy of veterinary medications

The VMD:

- covers full range of veterinary medicines regulations and oversight
- authorises medicines for UK and EU use
- monitors use of these medicines in the UK
- VMD contributes to regulations on an EU and international level

After Exit - Ensure availability of veterinary medicines & UK remains attractive for investment

VMD needs to

- continue to deliver all our responsibilities
- Have a suitable legislation to enable primary powers post-exit
- Build alternatives to EMA's databases & systems & processes
- Secure Mutual Recognition Agreements (post exit)
- Ensure UK remains an attractive market for investment

The EU Exit Programme

- Workstreams:
  - Withdrawal agreement and implementation bill
  - Maintaining market access and availability
  - Negotiations
  - Contingency planning and building
  - Stakeholder Engagement

Withdrawal agreement and implementation bill

The Bill will:

- Repeal . . .
- Save . . .
- Give . . .
- Make . . .

‘No deal’ SIs

- The March 2019 deadline and ‘No deal’ planning
- This would mean no relationship with the EU
- Which requires change to the Veterinary Medicines Regulations

Exit SI ‘no-deal’

- Registration of Veterinary Medicines
- Regulation of Veterinary Medicines
- Post Surveillance Activities

Operational aspects affected, but not in specified SI

- Good Manufacturing Practice (GMP) Inspections
- Labelling
- Regulatory Networks

Both the ‘no deal’ SIs and the above operational aspects have directed our day 1 and high priority issues

Implementation Period

We now know what an implementation period looks like:

- Market access for medicines
- Batch release and testing
- Licensing and Packaging
- UK regulatory role
- MRLs

Maintaining Market Access

- 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

Contingency planning

- 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 any implementation period

Working with others in government

Not an exhaustive list!

- Defra
- DExEU
- MHRA
- FSA
- HSE
- DHSC
- Devolved Administrations
- IPO

IT

46 databases, systems, data exchanges with EMA

4 Considered priority IT systems:

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

Development, integration and user testing

The future

A thriving UK animal health industry