Impact of Brexit from an Industry Perspective

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Opening Remarks

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- Is Industry doing enough?
- What is MHRA's future role?
- Resources and Innovation
- Patient Centricity

Brexit

- Aligned Industry advocacy goals
- A challenge of 2 parts
- Regulatory oversight
  - EMA relocation to Amsterdam
- The most pressing concern
- Spotlight on Bayer

Aligned Industry Advocacy Goals

Flexibility and co-operation

Short term: solutions for obstacles to completing process in time

- // Flexibility to minimise supply disruption
- // Transition period to complete the volume of work

GOAL

Long term: co-operation agreement

- // MHRA involved as a member of EU-network
- // Alignment of regulatory requirements

A Challenge of 2 Parts

Impact on both EU-27 and UK

- Developing expertise following re-distribution of CP workload from UK
- Completing RMS transfers from UK
- EMA relocation
- Ensuring network functions during change

- Developing expertise for all CP/DCP products on UK market
- Developing UK role as sovereign Regulator or in future EU network?
- Maintaining functional Agency during change

Regulatory Oversight

Ensure continued functioning of Regulatory Networks in EU, UK and beyond

Regulatory oversight:

- Most issues can be overcome by a transition period
- Lack of future agreement will add to burden and risk future divergence

EU – 27

- 2400 CP need MAH transfer
- >1000 national MAs need MAH transfers
- New CP Rapporteur knowledge transfer
- 3216* DCP procedures with UK RMS to be transferred
- Associated CPP transfers needed affect rest of world

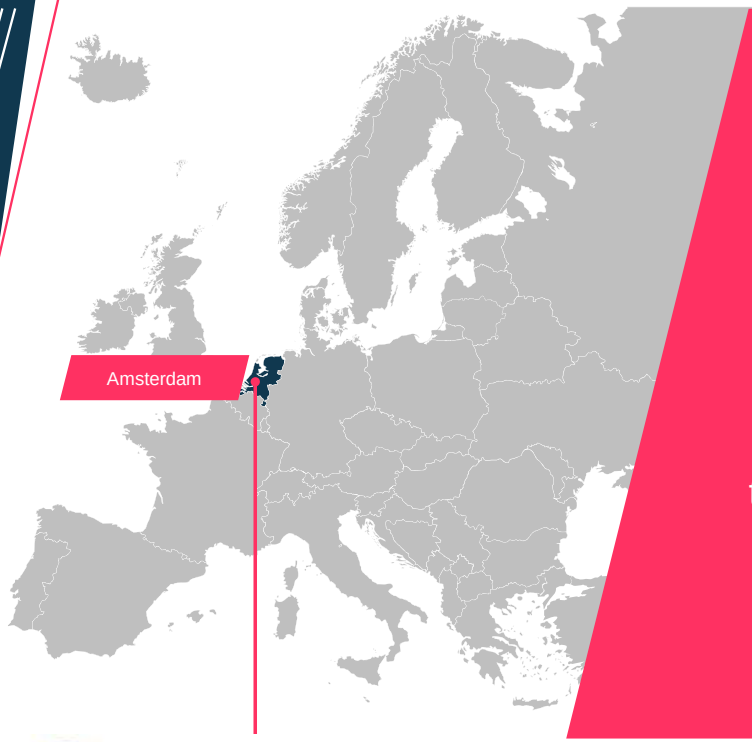
* April 2018

UK

- CP Marketing Authorisations to be grandfathered
- National system to be scaled up?
- Significant lifecycle work to manage change
- Adoption and integration of existing and new legislation
  - MDR, IVDR
  - CTR

EMA's Move to Amsterdam

Impact on EU Regulatory System



Relocation to New Site

- EMA move to temporary accommodation Q1 2019
- Vivaldi Building ready for all EMA staff Q4 2019
- Excellent transport links
- Staff losses
  - Submission of variations in Q1 2019
- Political challenges

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The Most Pressing Concern

Maintaining supply of medicines to patients in EU-27and UK…

37M patient packs from EU to UK | EVERY MONTH | 45M patient packs from UK to EU

- Most issues overcome by a transition period
- Cost of medicines may increase
- Smaller markets may lose some products

EU – 27

- **60% of EFPIA Member Companies test/batch release from UK (1,300 products)**
- QC testing transfers to EU
- QP release in EU (availability of EU QPs and OMCL testing capacity)
- Continuation of joint packs (UK/IR/MT)?

UK

- **MHRA flexible and pragmatic at point of Brexit**
- Border delays or importation/ exportation rules and certification
- Future duplicate testing and release?
- Continuation of joint packs (UK/IR/MT)?

Brexit

// Spotlight on Bayer

Spotlight on Bayer

Bayer in a good position to continue supplying patients with the medicines they need

Manufacturing and Supply

Good position:

- Bayer medicines manufactured in Germany
- 2 UK manufactured products not exported to EU
- Limited products with complex distribution route or needing refrigeration
- Risk - joint packs (UK/Ireland/Malta)?

Regulatory Oversight

Good position:

- No UK MAH to transfer
- Rapporteurs reassigned
- 2 RMS changes: 1 completed and 1 in planning
- Risk - potential delays in lifecycle work?

Major change for UK affiliate:

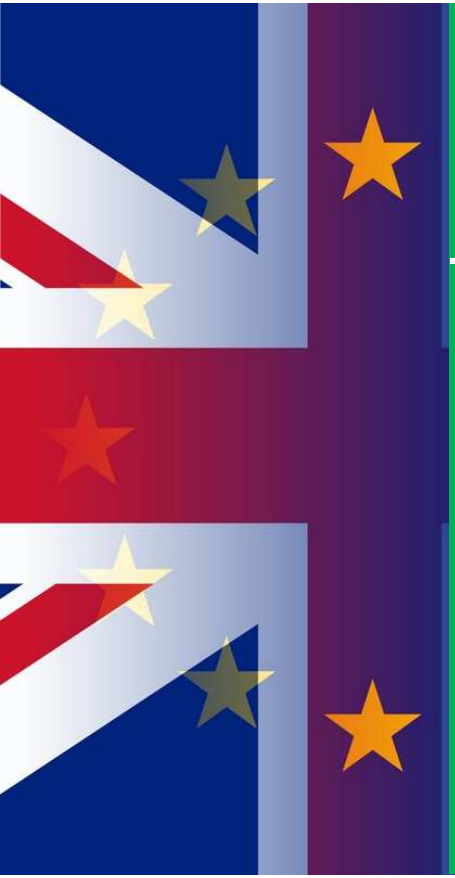
- CP grandfathering resulting in new UK MAs
- Need for baseline dossiers
- Major artwork changes and lifecycle work all products

Brexit

// Concluding remarks

Brexit

Concluding remarks



Is Industry doing enough?

- Industry is working hard to manage change and seeking regulatory co-operation to minimise disruption in supply of medicines to patients
- The scale of the changes and complexity of the system means all necessary work may not be completed prior to 30 March 2019

What is MHRA's future role?

- Industry wants MHRA included in the network with aligned processes and requirements
- Duplication of systems is not wanted or needed

Resources

- Huge amount of resource diverted to Brexit at EMA, Competent Authorities and Industry
- Brexit will bind and block resourcing in Europe for some years to come potentially slowing innovation and reducing EU competitiveness

Patient Centricity

- Maintaining EU and UK patient uninterrupted access to medicines is the key priority for all Stakeholders
- Patient's access to their medicines, this must not be jeopardised

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Thank you!