EMA Brexit Interested Parties Meeting
Joint Industry Presentation – BREXIT

Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products

March 23, 2018

This is a joint industry presentation on behalf of the trade associations shown

One year post Article 50 notice by UK – have we made enough agreement on progress to secure medicines?

Focus on Day 1 issues and Post-Brexit future

- Consistent call for continued regulatory collaboration and alignment EU-27 and UK

- Focus on Supply Chain challenges
  - Business Continuity Planning
  - EMA survey

- Post-Brexit:
  - Future arrangements and detailed Day 1 requirements

Recapping 2017: clarity on several practical issues, significant challenges remain – 'no-deal' scenario limitations

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Commission
Directorate-General for Health and Food Safety (DG SANTE)

- **Further discussions on practical/operational issues needed** in order to ensure a pragmatic approach and ways to simplify where possible to manage the significant impact on the regulatory framework

- Political agreement on **Transitional/implementation period** welcome in giving further time to implement (permanent) changes, with significant impact on resources and legal implications

- The importance of securing **ongoing cooperation** between the UK and EU on medicines as part of the negotiations to agree a new relationship between the UK and the EU

Life Science Industry Continuity Planning – ensuring business continuity in short term

- Trade associations are advising member companies to proceed with business continuity planning according to the published Q&A and practical guidance documents:
  - Regulatory
  - Trade and supply
  - Clinical trials
  - Workforce

- Companies are expending significant efforts and resources on Brexit-related continuity planning and implementation, which requires detailed planning with implications going beyond the EU and UK, impacting the global supply chains and patient access

- Company specific discussions with EMA, following the survey, to allow for understanding complexities and insights into products specific planning.

Life Science Industry Coalition Position paper

Joint trade association advocacy focused on ensuring draft guidelines for phase two negotiations reference the need to cooperate on medicine regulation and supply.

- **Transition/implementation period**. Transition critical to ensuring companies, national competent authorities and the EMA can deliver necessary changes so patients continue to access medicines
- **Regulatory cooperation**. Close cooperation in the regulation of medicines is essential.
- **People**. The life sciences workforce, should be protected by a solid citizens' rights agreement.
- **Trade**. Ensure that medicines can continue to move between both regions.

European Health Community support future UK-EU Cooperation

Priorities for European Health Community:

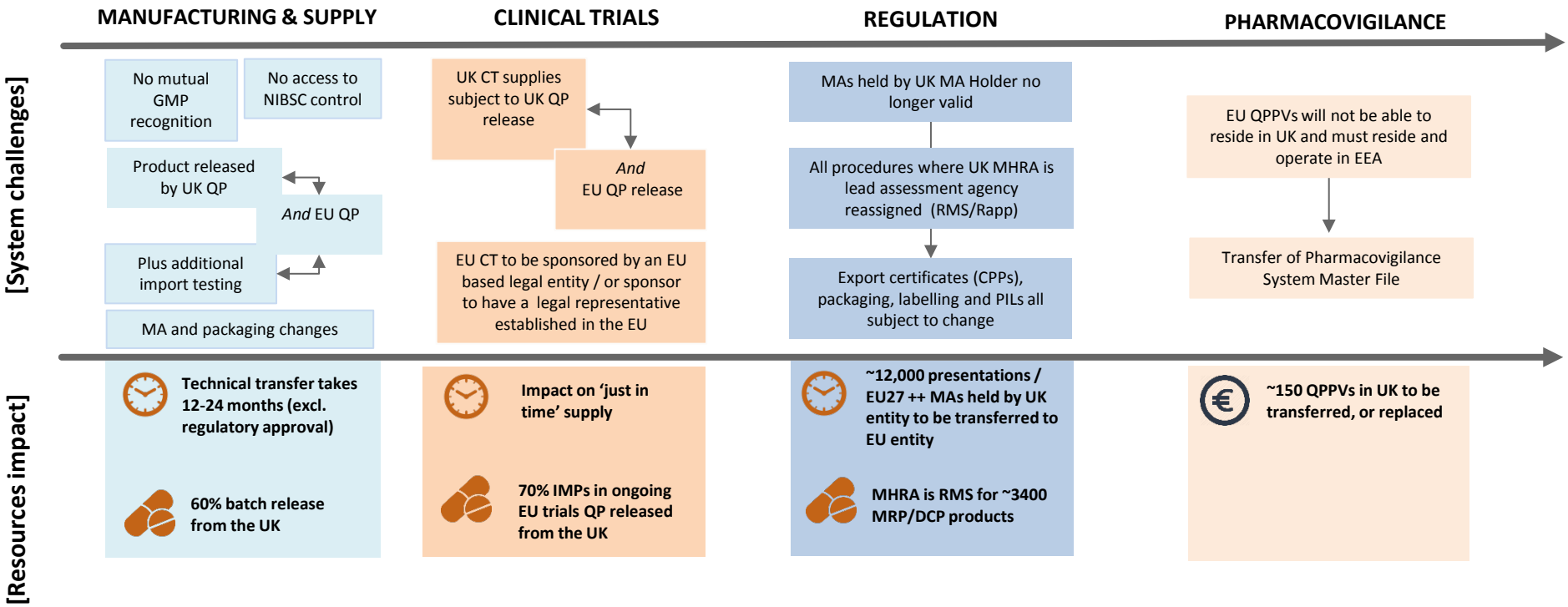
- ❑ Close cooperation between the EU and UK on the regulation of medicines and medical technologies
- ❑ Strong coordination on public health, including in pandemic preparation and disease prevention programmes
- ❑ A common framework for collaboration in research and information sharing
- ❑ Continued reciprocal healthcare arrangements between the EU and UK.
- ❑ Ensure EU and UK health professionals continue to benefit from mutually beneficial training and education opportunities, with automatic recognition of qualifications

Support future UK-EU Cooperation

Interventions from a range of coalitions and organisations including:

- ❑ Joint Health Stakeholders and patient groups outlining key questions of concern. Summit on 21 February (published on 8 March)
- ❑ Joint letter from 11 medical research charities calling on negotiators to ‘put patients first’ (published on 14 March)
- ❑ Ongoing joint trade association meetings with EU institutions.

Main challenges for EU Regulatory Framework: required changes in case of 'no-deal' scenario and related resources



OHE Consultants, commissioned by ABPI and BIA (Dec 12, 2017)
EFPIA BREXTI member companies survey (Nov 11, 2017)

A challenging year ahead – continue collaboration/dialogue to minimize resources impact

- Transition period: need for clear understanding of implications for EU regulatory system, role of UK, and MAHs

- Communication resources HMA/CMDh, EMA and MHRA: performance and delivery by the EU regulatory network

- Company specific product portfolio dialogue on BREXIT prepardness with EMA and CMDh/HMA

- Post-Brexit future arrangements :
  - Exploration of all options for future regulatory and trade relationship between the UK and EU
  - Exploration of (extended) Mutual Recognition Agreement (MRA) in the event of a Free Trade Deal

Questions…