BREXIT EFPIA survey results
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SIGNIFICANT IMPACT OF A ‘NO DEAL’ SCENARIO ON SUPPLY OF MEDICINES FOR PATIENTS

- Patient packs supplied from the UK to EU every month
- Expectation of trade delays if move to WTO rules
- Authorised EU products tested and released from the UK
- Ongoing EU clinical trials with UK as sponsor
- Centrally authorised products with UK as license holder
- Of EU Investigational Medicinal Product released from the UK
MANUFACTURING AND SUPPLY ISSUES WILL GREATLY AFFECT PATIENTS ACCESS AND PUBLIC HEALTH IN EU AND UK

- **45%** of EFPIA members expect trade delays if move to WTO rules

- **37M** patient packs supplied from the UK to EU every month
- **45M** patient packs supplied from the EU to UK every month

**Exports and Imports**

- **UK Exports**
  - **2,900** products from UK to EU (90% final product)
  - **3,200** products from EU to UK (70% final product)

- **UK Imports**
  - **2,700** products from UK to EU
  - **3,100** products from EU to UK
MARKETING AUTHORISATIONS BOTH IN THE EU AND THE UK WILL BE DISRUPTED BY BREXIT

Centralised Procedure

centrally authorised products with UK legal entities as MAH
(45% of all centrally authorised products)

multiple MAs per product

centrally authorised MAs with UK legal entities and requiring transfer
(17% of all centrally authorised MAs)

MAH transfer

review months EFPIA members and EMA need to carve out of important product lifecycle management
(based on 60 day standard MAH Transfer timeline)

Decentralised and Mutual Recognition Procedure

DCP/MRP nationally authorised MAs with UK legal entities requiring transfer and new RMS
(9% of all DCP/MRP nationally authorised MAs)
Batch Release

60% EFPIA members having batch release from the UK

1,300 number of products for EU distribution from UK batch release / test sites

4,000 review months EFPIA members and EMA need to carve out of important product lifecycle management (based on 90 day standard Type II CMC variation timeline)

40% of EFPIA members believe QP / Laboratory capacity is insufficient for retesting product released from UK (shortages and supply disruption concerns)

110 Qualified Persons for authorised product release based in UK
TIME TO MARCH 2019 IS TOO SHORT TO MOVE MARKETING AUTHORISATIONS; MORE FLEXIBLE APPROACH NEEDED FROM REGULATORS

**BREXIT Regulatory Procedures**

- No clear 150 day filing window for many of the industry’s impacted CP-approved products
- MAH Transfer
- Type II CMC Variation for new Product Release and Test Site

**Ongoing Non-BREXIT Regulatory Procedures**

*for an active, illustrative CP-approved product*

- **Type IB variation** (30 days)
- **Type IB variation** (30 days)
- **Type IA variation** (30 days)
- **Type IB variation** (30 days)
- **Type IB variation** (30 days)
- **Type IB variation** (30 days)

*duration of regulatory procedures based on standard EMA timelines
other submissions such as Serialization and Falsified Medicines Directive not shown*
Clinical Trials Product Release

1,050 IMPs in ongoing EU trials QP-released from the UK

70% of all IMPs in ongoing EU trials QP-released from the UK

40 Qualified Persons for clinical trial product release based in UK

Clinical Trials Footprint

1,500 clinical trials ongoing in multiple EU member states with UK as sponsor

50% of those clinical trials that will be ongoing in March 2019