

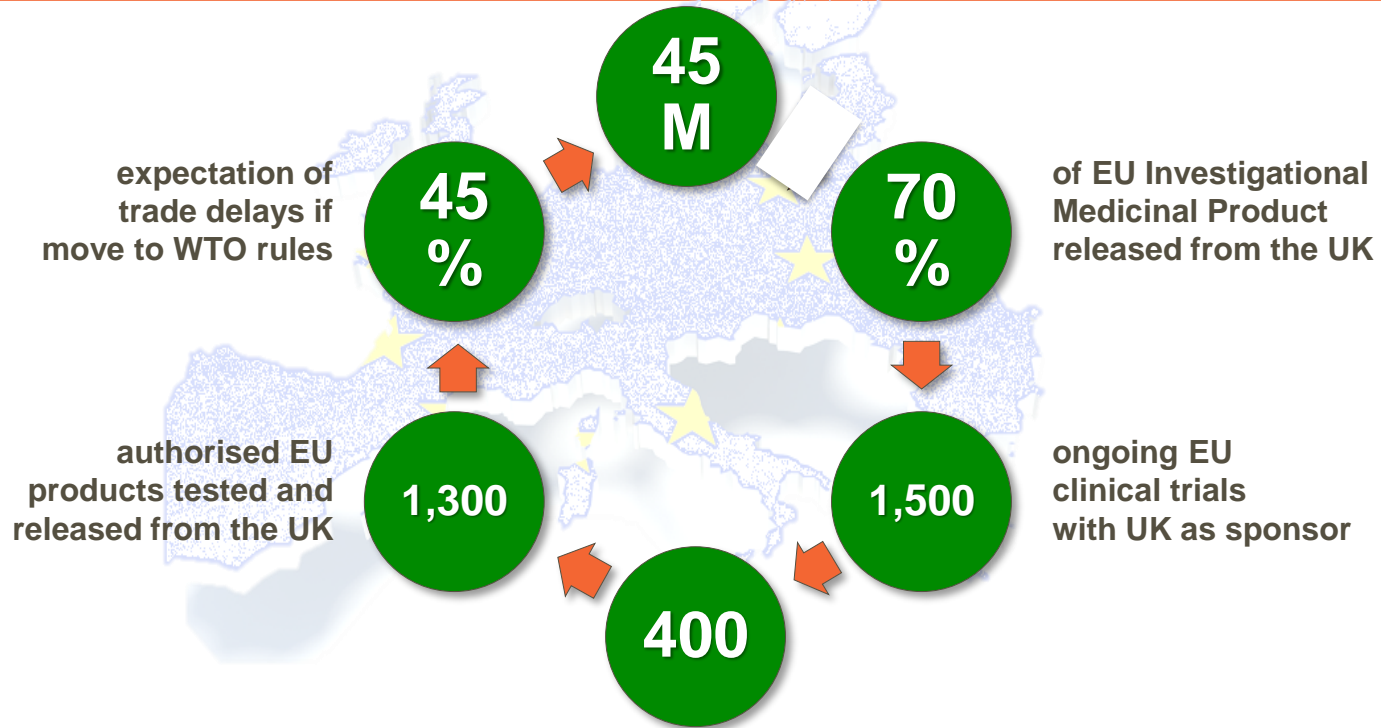
Brexit Implications for Pharma

PMI Seminar, Feb 1st, 2018

ACCESSING MEDICINES TODAY – AN INTEGRATED PROCESS ACROSS EUROPE



patient packs supplied
from the UK to EU-27 every month



EFPIA Member Survey
November 2017

centrally authorised products
with UK as license holder

Local Concerns



- Supply Chain Disruption - Delays
- Real fear of shortages of medicinal products - HPRA CEO, Dr Lorraine Nolan
- Transport and Customs Infrastructure
- VAT Implications – terms of payment

Imports liable to VAT at either 23% or 0%

0%

Medicine used for oral consumption, certain medical equipment

23%

Other, e.g., creams, injectables

- Impact on COGs – Who Pays?

Integrated supply at risk from no regulatory cooperation and renewed borders



- ✓ Single approval for centrally approved medicines for all EU/EEA
- ✓ Single supply checks for medicines used across EU/EEA
- ✓ Single safety monitoring system across EU/EEA

Example: HIV medicine



Supplying this approved medicine begins with active ingredients

Borders and regulatory divergence break these supply chains

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- **A status quo transition period of at least 2-years starting from March 2019 secured before April 2018 with a meaningful level of certainty**
 - **A negotiation category focused on 'Safety'** that includes health and patient safety, to ensure the continuing supply of medically critical products is prioritised in the talks.
 - **Mutual Recognition Agreements (MRAs)** between the UK and EU to avoid duplication of procedures and processes. The priority is an MRA on testing and release of medicines and healthcare products.
 - **The most comprehensive cooperation possible** between the EU/European Medicines Agency (EMA) and the UK/Medicines and Healthcare Products Regulatory Agency on regulatory systems and processes.
 - **Maintaining zero tariffs on healthcare goods with minimal customs procedures, duty and VAT on cross-border trade.**
 - **Systems that allow us to continue to attract the best, diverse talent in both the EU and UK.**
 - **Continued R&D collaboration between the UK and EU**
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