European Federation of Pharmaceutical Industries and Associations

BREXIT EFPIA survey results

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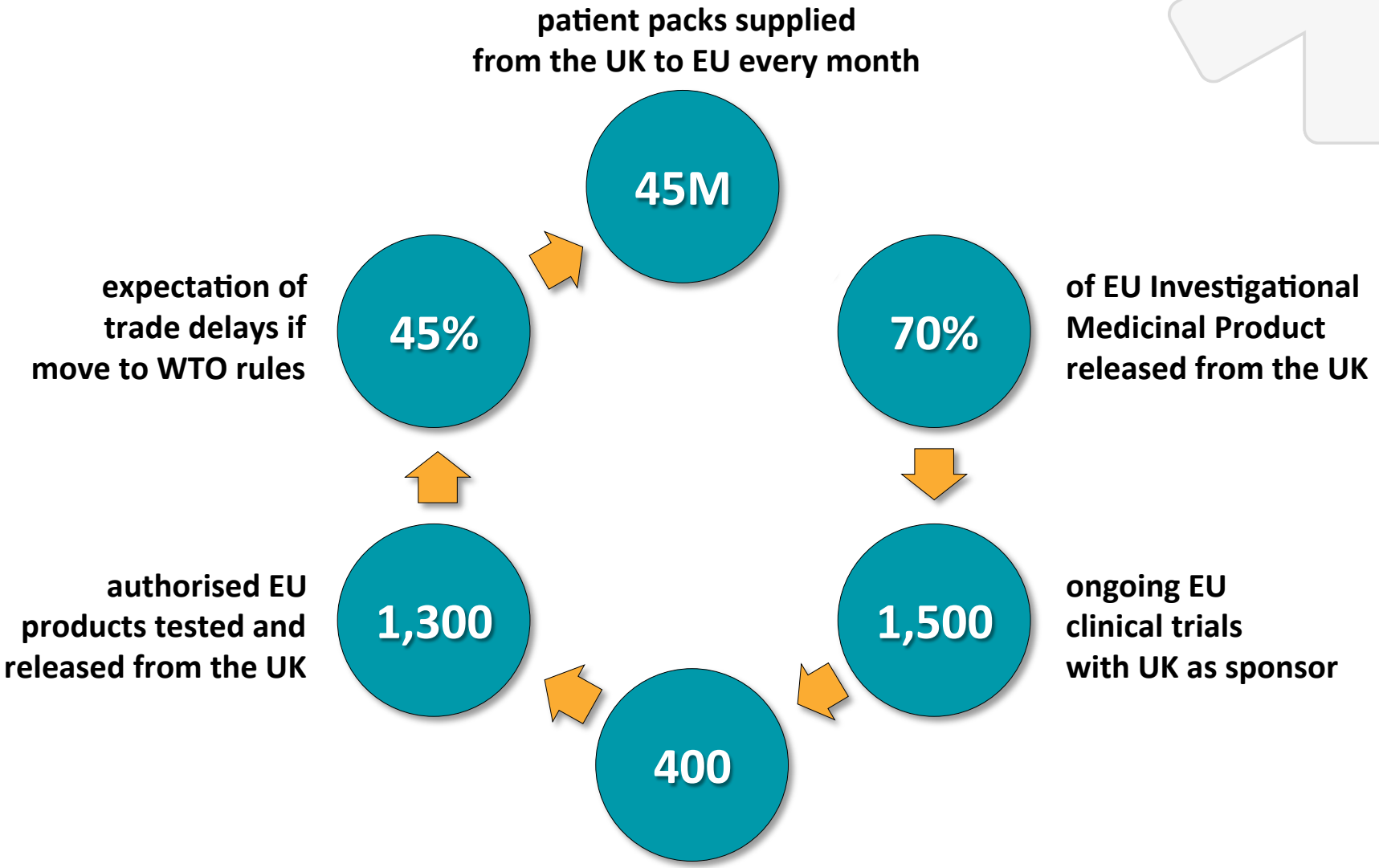
Presentation

SIGNIFICANT IMPACT OF A 'NO DEAL' SCENARIO ON SUPPLY OF MEDICINES FOR PATIENTS



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

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

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

Exports and Imports

	Products	Stock Keeping Units
UK Exports → From UK to EU	2,900 (90% final product)	2,700
UK Imports ← From EU to UK	3,200 (70% final product)	3,100

MARKETING AUTHORISATIONS BOTH IN THE EU AND THE UK WILL BE DISRUPTED BY BREXIT

Centralised Procedure

400

centrally authorised products with UK legal entities as MAH

(45% of all centrally authorised products)

multiple MAs per product

2,400

centrally authorised MAs with UK legal entities and requiring transfer

(17% of all centrally authorised MAs)

MAH transfer

5,000

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

5,800

DCP/MRP nationally authorised MAs with UK legal entities requiring transfer and new RMS

(9% of all DCP/MRP nationally authorised MAs)

MOVING BATCH RELEASES BRINGS DISRUPTION AND ADDITIONAL COSTS TO INDUSTRY

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**

move 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)

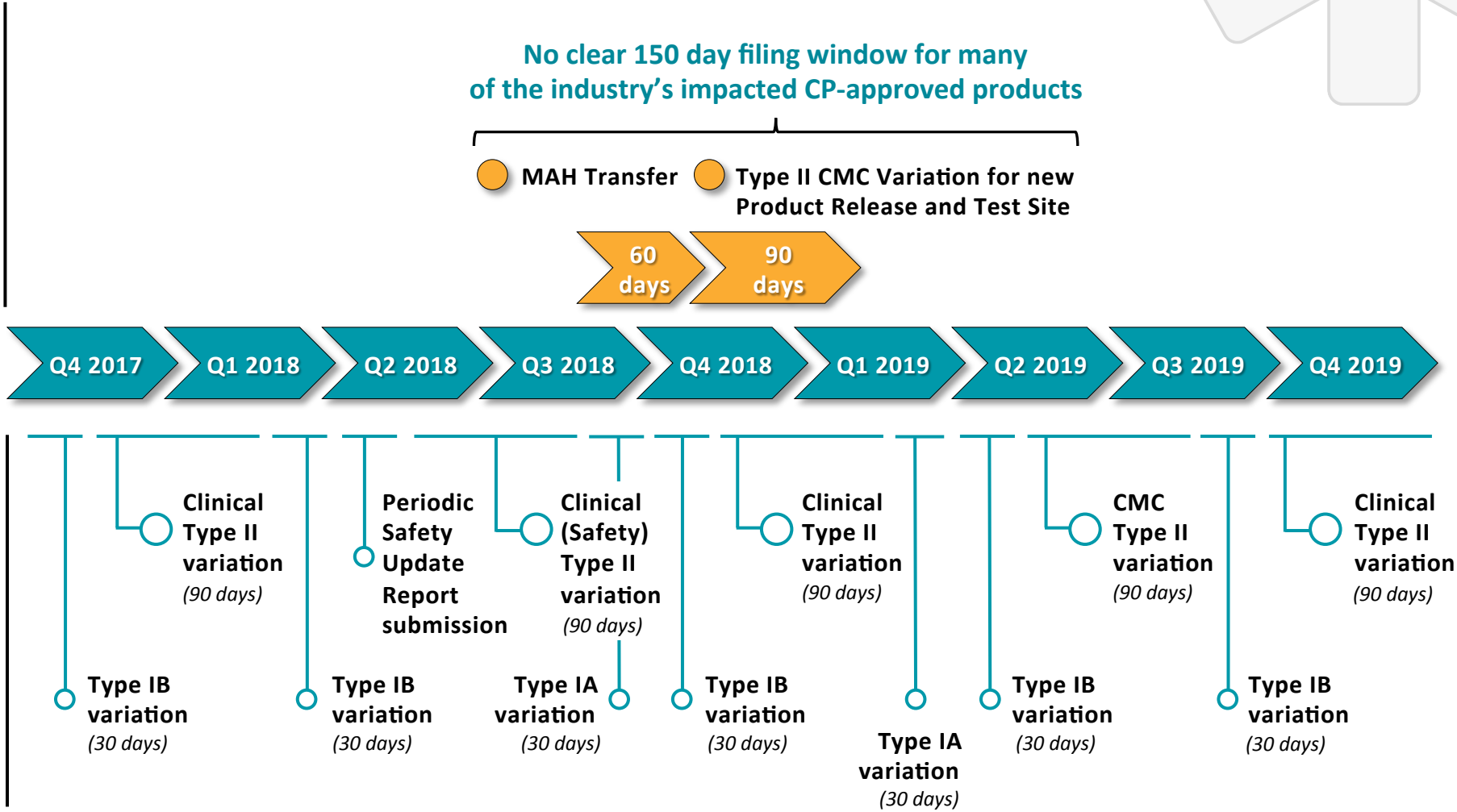
duplicate testing

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



Ongoing Non-BREXIT Regulatory Procedures

for an active, illustrative CP-approved product

duration of regulatory procedures based on standard EMA timelines

other submissions such as Serialization and Falsified Medicines Directive not shown

CLINICAL RESEARCH: UK ROLE IN EU INVESTIGATIONAL MEDICINAL PRODUCT RELEASE AND ONGOING CLINICAL TRIALS

Clinical Trials Product Release

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

40 Qualified Persons for clinical trial product release based in UK

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

More than half of EFPIA members who have 100% of their IMPs in ongoing EU trials QP-released from 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