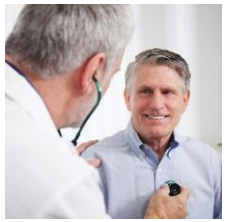
European Federation of Pharmaceutical Industries and Associations

BREXIT: Making Health a Priority in Brexit Negotiations

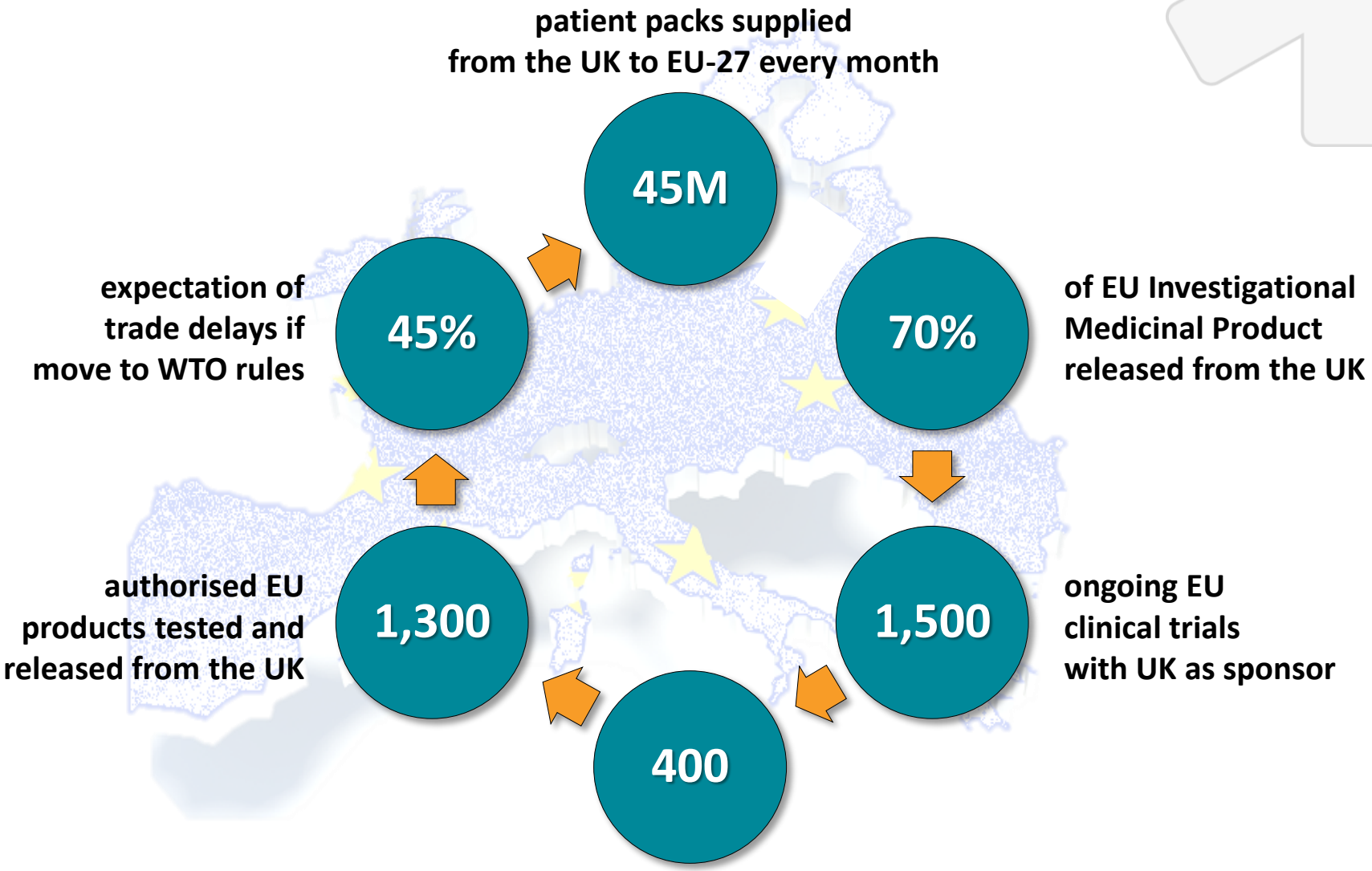
Dr Virginia Acha, Executive Director – Global Regulatory Policy, MSD






Presentation to the ENVI Committee of the European Parliament, November 28, 2017

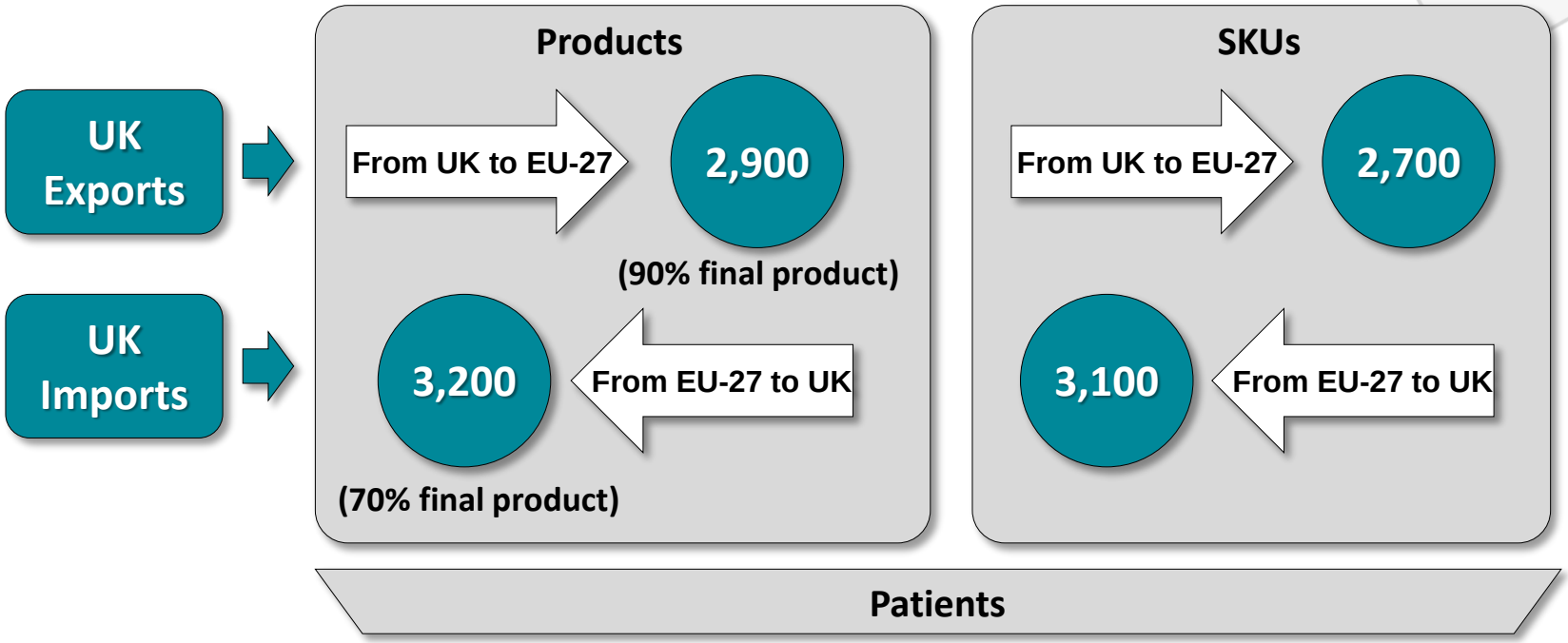
ACCESSING MEDICINES TODAY – AN INTEGRATED PROCESS ACROSS EUROPE



EFPIA Member Survey
November 2017

MANUFACTURING AND SUPPLY: BI-DIRECTIONAL TRADE FLOWS UNDERPINNING UK AND EU-27 PUBLIC HEALTH AND PATIENT ACCESS

Exports and Imports



45%

of EFPIA members expect trade delays if move to WTO rules

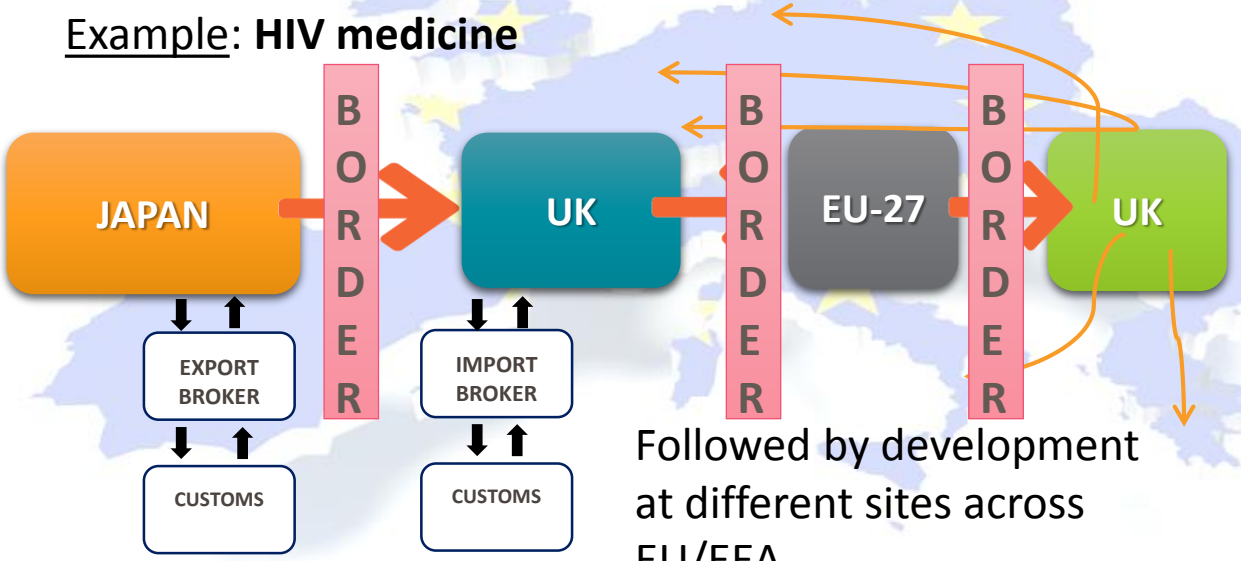
45M patient packs supplied from the UK to EU-27 every month

37M patient packs supplied from the EU-27 to UK every month

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

Followed by development at different sites across EU/EEA

When completed, the medicine is then distributed across the EU/EEA

Borders and regulatory divergence break these supply chains

Collaboration Pharmaceutical and Life Sciences Industry

Mr. Michel BARNIER
Chief Negotiator
Task Force for the Preparation and
Conduct of the Negotiations with
the United Kingdom under Article 50 TEU
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels, Belgium

Rt. Hon David DAVIS MP
Secretary of State
Department for Exiting the European Union
9 Downing Street
SW1A 2AG
London

Brussels and London, 13 July 2017

Dear Mr Barnier and Dear Secretary of State,

We are writing to you as the associations representing the European and British pharmaceutical and life science industry (AESGP, EFPIA, EuropaBio, Medicines for Europe, ABPI, BGMA, BIA and PAGB) to underline 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.

Securing such an agreement is the best way of ensuring that patients across Europe and the UK are able to continue to access safe and effective medicines and to ensure that there is no adverse impact on public health.

We take note of the phased approach of the negotiations as agreed at your first meeting. However, we feel that it is important to set out our position at this early stage given the significant time pressure to ensure that the necessary arrangements are in place to secure patient access to medicines, and avoid any adverse impact on public health and patient safety in both the EU-27 and UK after the UK leaves the EU.

EU-UK partnership on the regulation of medicines

As you will be aware, our industry is highly integrated across Europe, and regulated under EU law through a sophisticated system of legal and regulatory arrangements between EU institutions, Member States and national competent authorities. It is important that there is as much certainty as possible, as early as possible, to enable the pharmaceutical and life science industry to transition smoothly into the new framework, ensuring there is no disruption to patient access to medicines.

*"The importance of **securing ongoing cooperation between the UK and EU-27** on medicines as part of the negotiations to agree a new relationship between the UK and the EU-27."*

*"Securing such an agreement is the best way of ensuring that patients across Europe and the UK are able to continue to access **safe and effective medicines and to ensure that there is no adverse impact on public health.**"*

***An implementation period** that adequately reflects the time needed by pharmaceutical and biotech companies to transition to a new framework should be agreed on by negotiators. This will allow companies time to make the necessary arrangements to avoid any unintended consequences on the availability of the medicines that patient rely on, both in the UK and the EU-27.*

Continued cooperation on regulation and safety is critical for medicines

- **Importance of a future cooperation model between the UK and EU-27** for medicines as part of the negotiations to agree a new relationship
- Complexity of our supply chains and research infrastructure would require an **implementation period beyond 2019 to ensure continuity and to limit impact to patients**
- **Shared European regulatory network** is a robust regulatory system established over decades which benefits from consistency and scale
    - Ongoing cooperation is best means to ensure that continues
    - Avoids divergent requirements and safety assessment, and duplication of processes
- Uncertainty of the negotiations and the lack of sufficient progress so far: need to move to second phase **as soon as possible** in order to start sector specific negotiations.