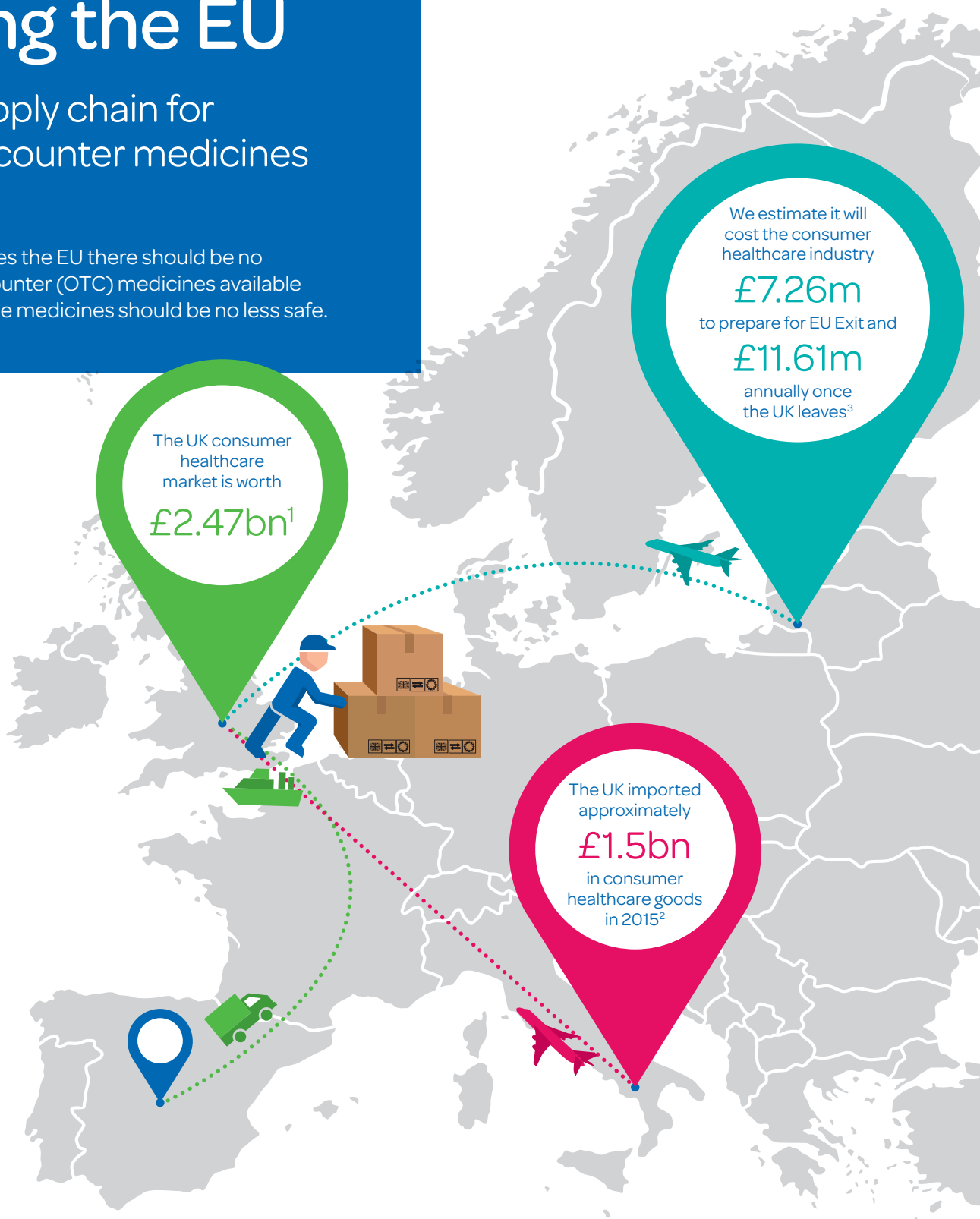
PAGB Representing the Consumer Healthcare Industry since 1919

The impact of leaving the EU

on the supply chain for over-the-counter medicines

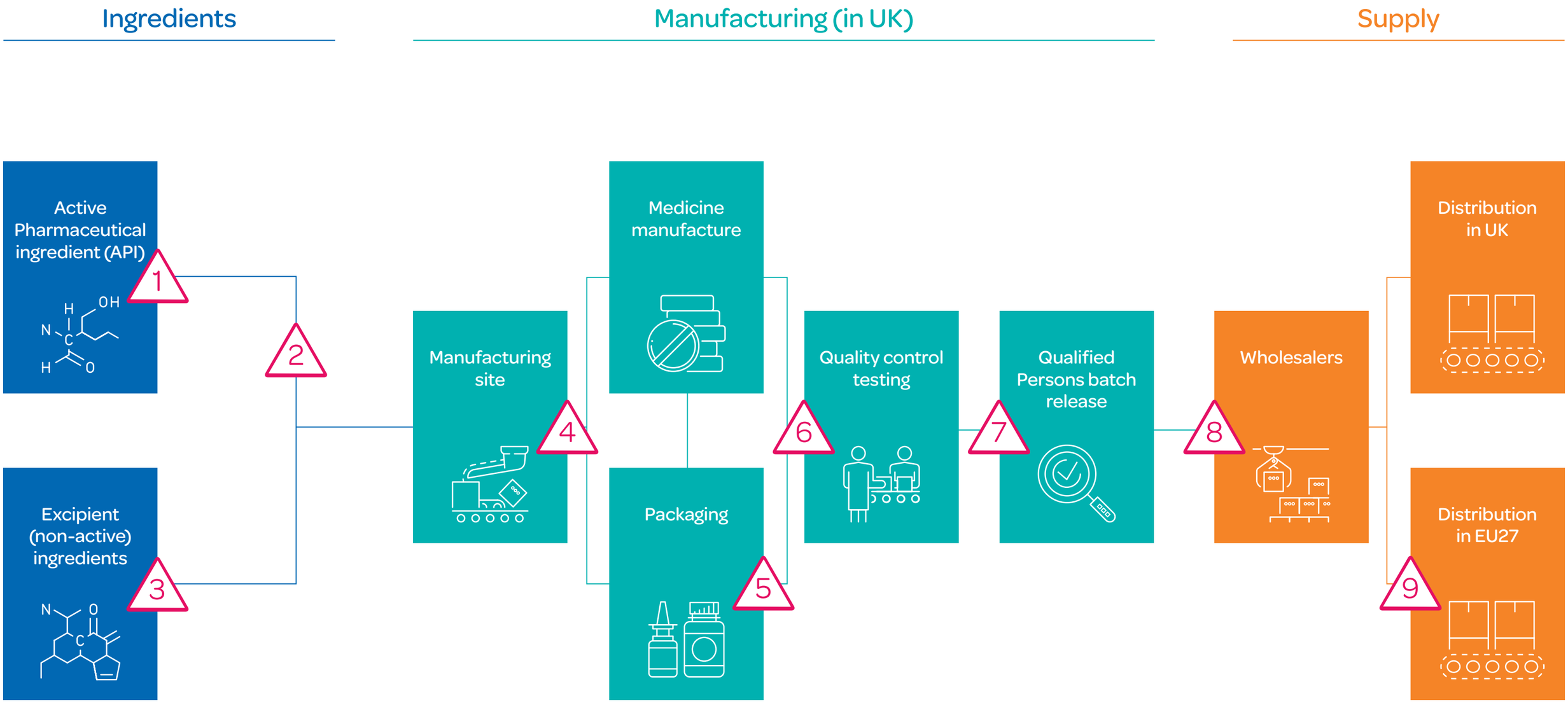
When the UK leaves the EU there should be no fewer over-the-counter (OTC) medicines available in the UK and those medicines should be no less safe.



In order to ensure this, PAGB is calling for mutual recognition agreements (MRAs) to be put in place as a priority between the UK and European regulators.

If these agreements are not put in place, the supply chain for OTC medicines, such as Anadin, Beechams, Calpol and Gaviscon would face costly duplications and potentially significant delays in both the UK and the EU.

To demonstrate these duplications and delays we have mapped an example supply chain. Throughout the development and distribution process, medicines need to be inspected by competent authorities and tested by Qualified Persons in line with European standards and regulations. Without MRAs, these inspections and tests must be done in the EU leading to duplication and potential delays throughout the process.



Potential points of duplication and delay

1 Inspection must be carried out by a competent authority based in the EU, so MHRA inspections and Good Manufacturing Practice certificates will not be recognised in the EU unless there is an MRA

2 A Qualified Person must be based in the EU for supply to the EU, so a UK Qualified Person's declaration for active material GMP status will not be recognised in the EU unless there is an MRA

3 To supply or manufacture a product containing a chemical excipient it must be registered under the REACH regulations. A company must be based in the EU, or have a representative in the EU, to do this

4 Inspection must be carried out by a competent authority based in the EU, so MHRA inspections and Good Manufacturing Practice certificates will not be recognised in the EU unless there is an MRA

5 Patient Information Leaflets and packs which mention the site of batch release will need to be changed when the UK is no longer in the EU

6 Quality control (QC) testing has to be done in the EU for a medicine being sold in the EU, so QC testing carried out in the UK will not be recognised in the EU and will need to be repeated in the EU, unless there is an MRA

7 Qualified Persons must reside in an EU country; therefore Qualified Persons batch release in the UK will not be recognised in the EU and will have to be repeated, unless there is an MRA

8 Inspection must be carried out by a competent authority based in the EU, so MHRA inspection will not be recognised in the EU unless there is an MRA

9 If the UK leaves the EU without a trade deal, tariffs may apply to some exports

How to prevent duplication and delays

- Ensure appropriate mutual recognition agreements are in place to allow OTC medicines manufactured, tested and released in the UK to continue to be exported to the EU and vice versa
- Secure a simple, five year transition process to any new arrangements, during which there is no divergence from EU regulations

Mutual recognition agreements will:

1

Allow MHRA inspections to be recognised in the EU so duplicate inspections by an EU based competent authority will not be required and vice versa

2

Enable EU recognition of UK based Qualified Person declarations, quality control testing and Qualified Person batch release, and vice versa

3

Ensure ingredients and products can cross borders during manufacturing and distribution without the need for additional checks and tariffs

1 PAGB. About our industry. July 2017 Available at: https://www.pagb.co.uk/about-us/about-our-industry/

2 PAGB estimates consumer healthcare will be 5% of total imported Life Sciences Goods. Source: UK EU Life Sciences Transition Programme Report. Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU. Sept 2016. Available at: https://www.bioindustry.org/resource-listing/maintaining-and-growing-the-uk-s-world-leading-life-sciences-sector-in-the-context-of-leaving-the-eu.html

3 PAGB estimate based on members' anticipated one off and ongoing running costs