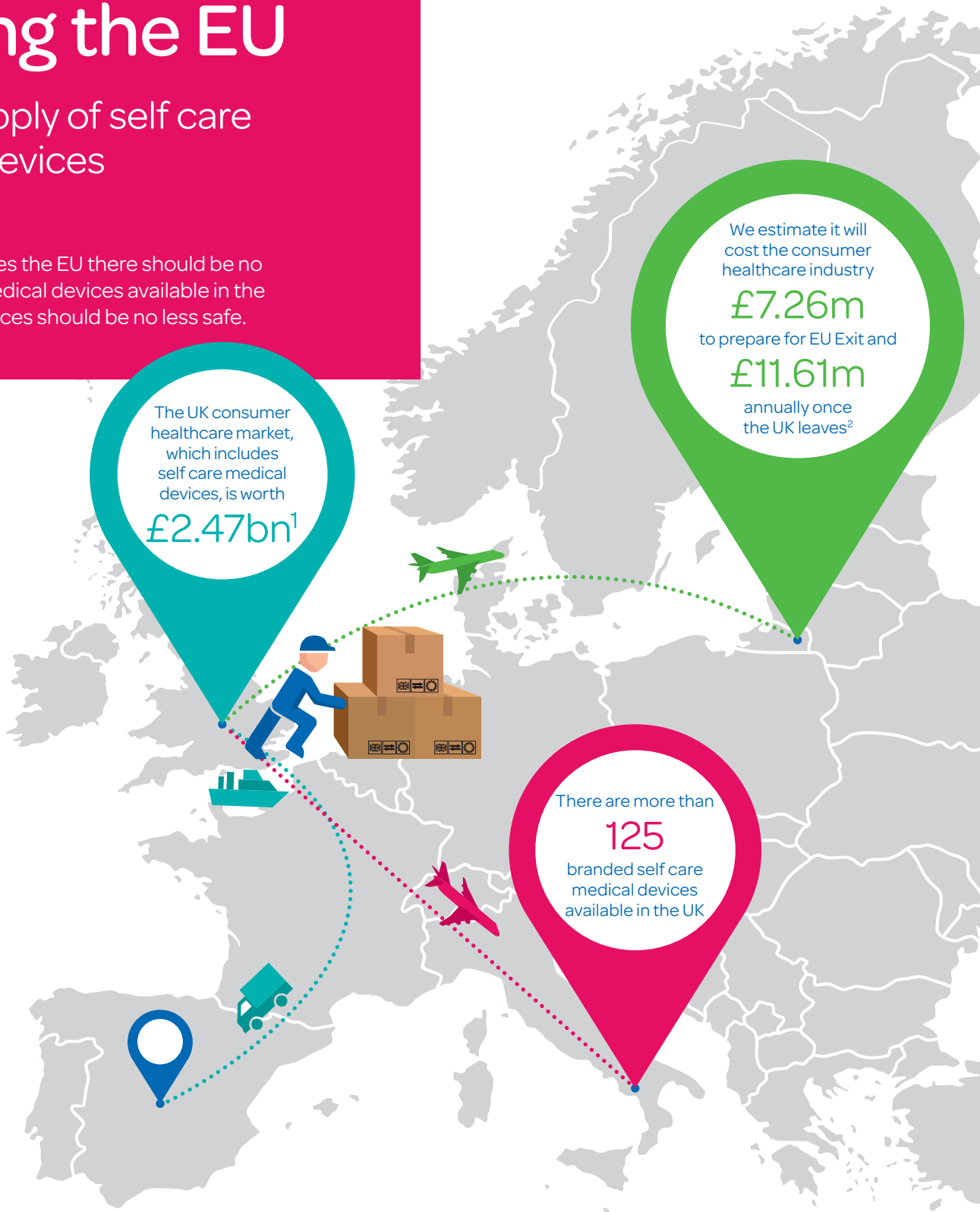
PAGB Representing the Consumer Healthcare Industry since 1919

The impact of leaving the EU

on the supply of self care medical devices

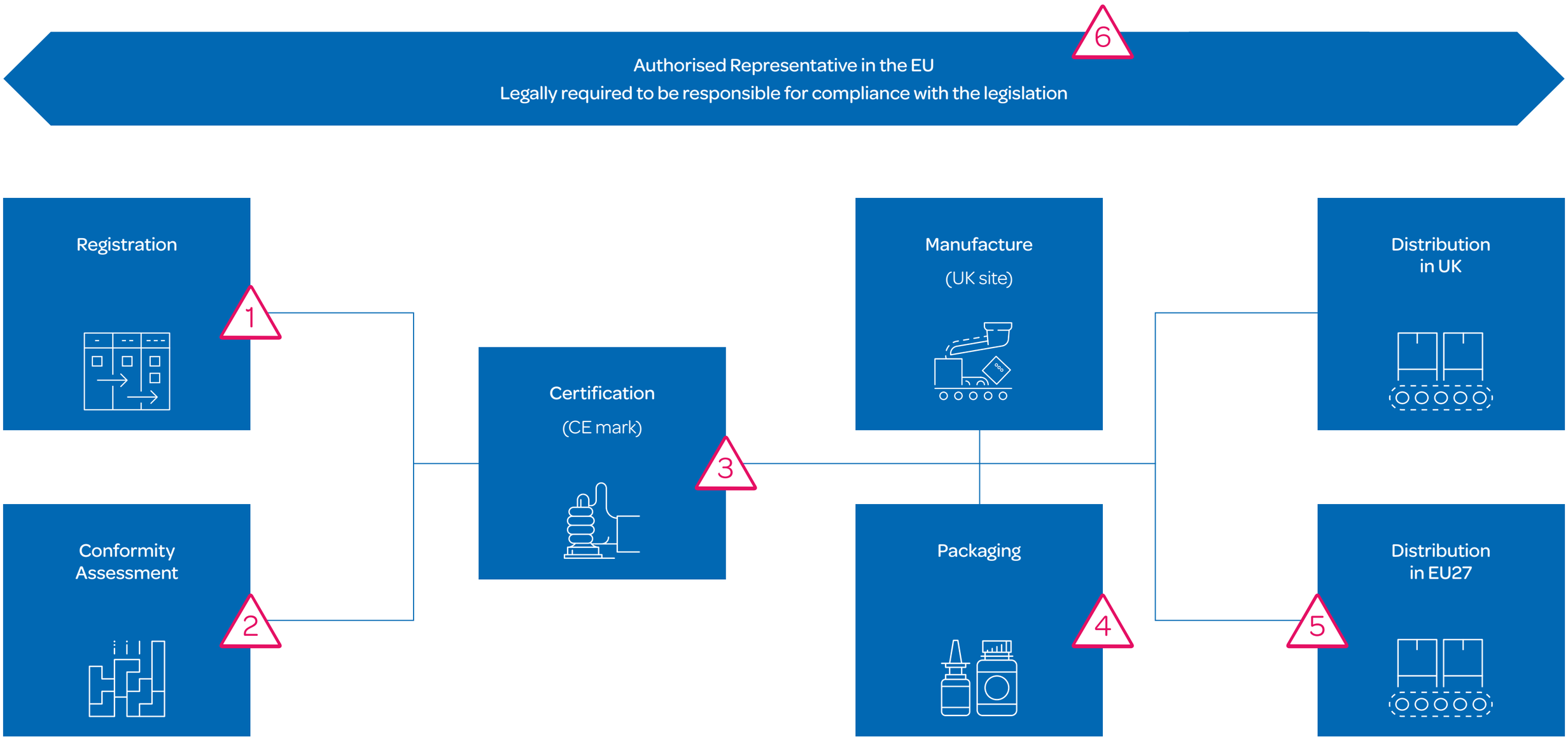
When the UK leaves the EU there should be no fewer self care medical devices available in the UK and those devices should be no less safe.



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 Europe.

If these agreements are not in place, the supply of self care medical devices designed, manufactured and certified in the UK to be distributed throughout the EU would face costly disruptions and potentially significant delays. To demonstrate this, we have mapped an example supply chain.

For distribution in the EU, many medical devices need to be assessed and certified by an EU based Notified Body (NB). In addition, an EU based economic operator and Authorised Representative need to be established. Without MRAs these activities and roles will need to be duplicated for medical devices manufactured and certified in the UK leading to delays throughout the process.



Potential points of duplication and delay

1 Class I medical devices will have to be registered in the UK and in the EU unless an MRA is in place.

2 For many medical devices a conformity assessment by an NB is needed. For use in the EU, currently only one assessment is required. However the assessment must be carried out by an NB established in the EU and designated by Member State. Without MRAs, an NB would need to be designated in both the EU and UK. Alternatively two conformity assessments would be required: one from an EU NB and one from a UK NB.

3 Each medical device must be placed on the market with a CE marking. Where a device has been assessed by an NB, the CE mark is followed by the NB number. Certificates issued by a UK NB before EU exit will not be recognised in the EU after the UK leaves and NB transfer will be required unless an MRA is in place.

4 Where a device has been assessed by an NB, the packaging must carry the NB number. Without MRAs or agreement to use the same NB number, packaging changes will be required.

5 To distribute within the EU, the 'economic operator' (manufacturer, importer, or Authorised Representative) needs to be established in the EU. Without MRAs, a UK manufacturer or importer will no longer be considered as an EU economic operator. To distribute in the EU27, they will need to establish an economic operator in the EU and comply with the obligations of an importer.

6 For manufacturers established outside the EU, an Authorised Representative established in the EU is required under the legislation and has a legal responsibility to ensure compliance with legislation for medical devices. This will need to be duplicated for UK-based Authorised Representatives, if the UK is considered as a third country.

How to prevent duplication and delays

- Ensure appropriate mutual recognition agreements are in place to allow medical devices manufactured, tested and released in the UK to continue to be exported to the EU and vice versa
- Secure a simple transition process to any new arrangements, which is at least two years but ideally five years, and during which there is no divergence from EU regulations, including the implementation of the Medical Device Regulation by 2020

Mutual recognition agreements will:

1

Allow UK NBs to be recognised in the EU so duplicate conformity assessment can be avoided and certifications issued by UK NBs remain valid

2

Enable manufacturers and importers established in the UK to be considered economic operators for purposes of distribution

3

Ensure EU recognition for UK-based Authorised Representatives and vice versa, preventing the need for duplicate roles in the UK and EU

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

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