

Understanding consumer healthcare

as the UK prepares for EU Exit

As the UK negotiates its withdrawal from the EU, PAGB has been working with our member companies to examine the implications of EU Exit on the consumer healthcare sector in the UK.

The UK consumer healthcare market is worth

£2.47bnⁱ

In 2015, we estimate the UK imported approximately

£1.5bn

in consumer healthcare products and exported approximately £1.5bnⁱⁱ



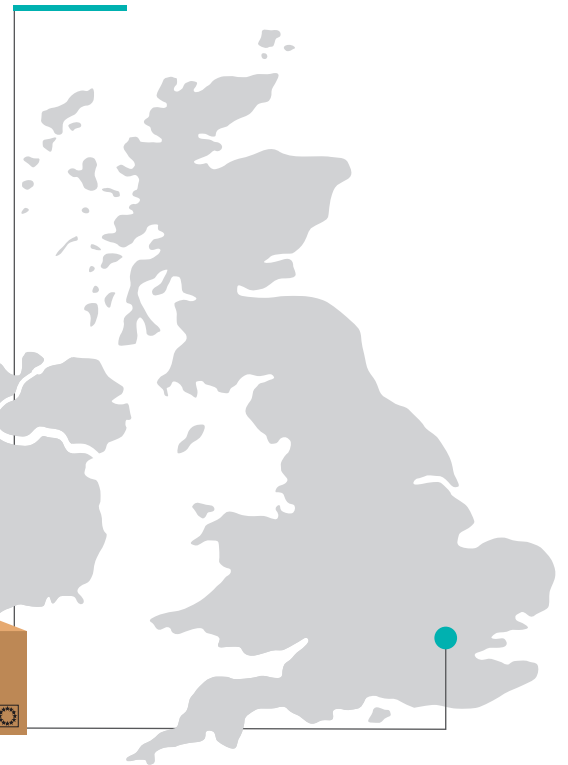
This includes over

650

branded medicines and over

125

medical devices that can be bought from a pharmacy or other retail outlet without a prescription



Consumer healthcare includes the over-the-counter medicines (OTC), self care medical devices and food supplements that people use on a daily basis – hay fever tablets, cold and flu treatments, and painkillers, to name just a few.

Keen to offer solutions as well as highlight challenges, we have identified two priority actions for the Government to take to ensure that when the UK leaves the EU there are no fewer OTC medicines or self care products available in the UK and that those products are no less safe than they are today:



Ensure appropriate mutual recognition agreements (MRAs) are in place to allow OTC medicines/self care products manufactured, tested and released in the UK to continue to be exported and vice versa



Should MRAs not be put in place ahead of the 29 March 2019 exit date, the Government must secure a simple transition process to any new arrangements, which is at least two years but ideally five and during which there is no divergence from EU regulation

The importance of the EU to the UK consumer healthcare market

On average

4

border crossings between the EU/UK may be required for ingredients in the manufacturing process^{iv}

20%

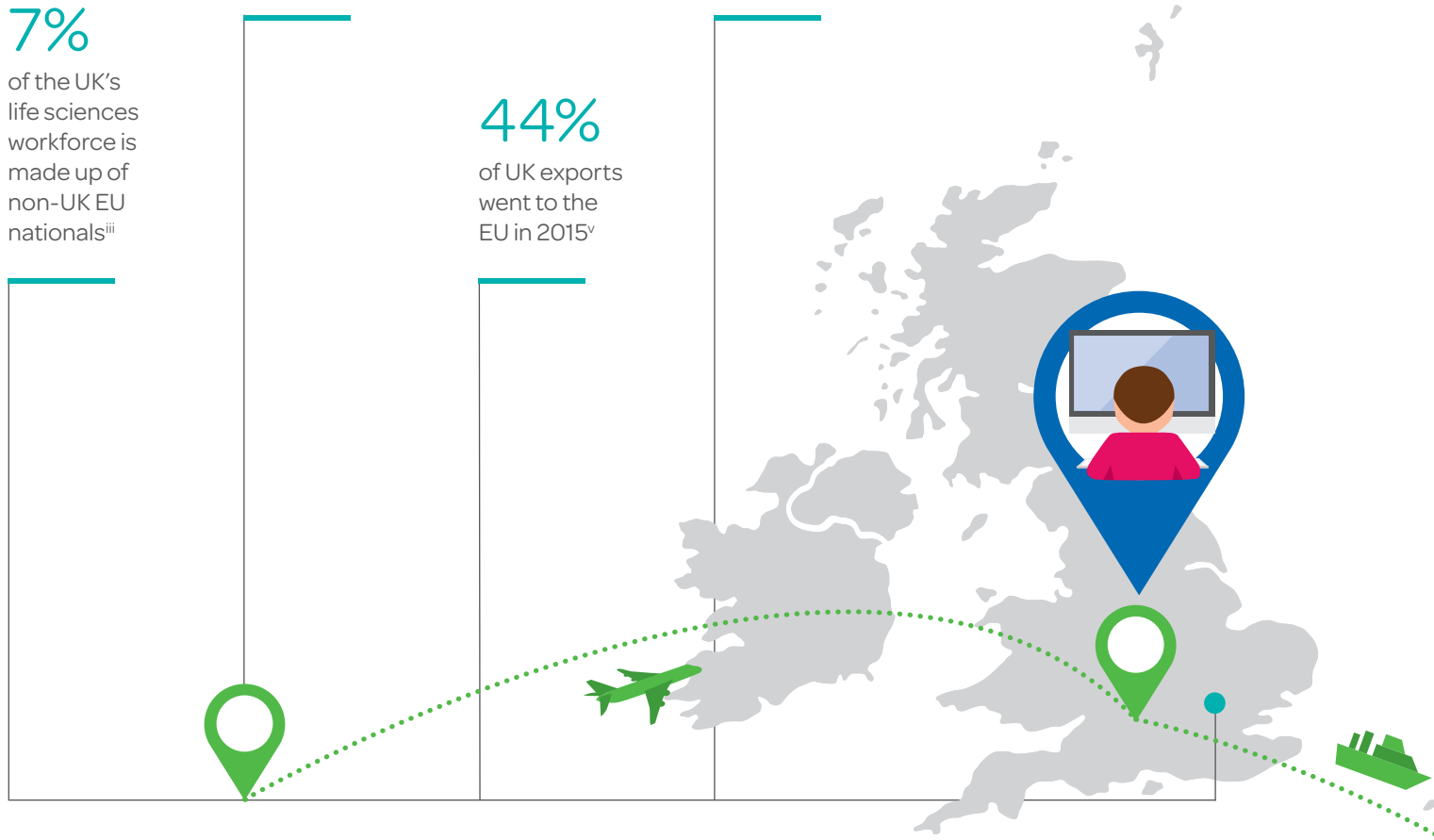
of the EU's pharmacovigilance is done by the UK^{vi}

7%

of the UK's life sciences workforce is made up of non-UK EU nationalsⁱⁱⁱ

44%

of UK exports went to the EU in 2015^v



What this will mean for the public

Without MRAs for the consumer healthcare industry, members worry the UK and EU public may face delays in access to OTC medicines, self care devices and food supplements, putting increasing pressure on healthcare systems, such as the NHS^{ix}.



The costs of leaving the EU

We estimate the UK's departure from the EU will cost the consumer healthcare industry

£7.26m

in one-off preparations alone^{vii}

A quarter of member companies anticipate the ongoing costs to their consumer healthcare business of leaving EU will exceed

£1m

per year^{viii}



What this will mean for industry and how the Government can help

The timeframes for the development and manufacturing of OTC medicines and self care products are such that companies are making decisions now about how to license and where to manufacture products that will be on the market when the UK has left the EU. As such, we need the Government to provide clarity and certainty on the future relationship with the EU **as soon as possible**.

While PAGB members are taking steps to try and mitigate this impact, uncertainty hinders their efforts.

PAGB is therefore calling for the Government to ensure appropriate mutual recognition agreements are in place to allow OTC medicines/ self care products manufactured, tested and released in the UK to continue to be exported and vice versa.

Why MRAs are important

MRAs allow:



Inspections and assessments conducted in the UK to be recognised in the EU so duplicate activities will not be required in the EU and vice versa



EU recognition of UK personnel involved in the testing, release and compliance of OTC medicines and self care products and vice versa



Ingredients and products to cross borders during manufacturing and distribution without the need for additional checks, representatives, or tariffs








PAGB (Proprietary Association of Great Britain) is the UK trade association representing the manufacturers of branded over-the-counter (OTC) medicines, self care medical devices and food supplements.

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Why time is needed

While our preferred option is regulatory harmonisation with the EU, should MRAs not be put in place ahead of the 29 March 2019 exit date, the Government **must secure a simple transition process to any new arrangements, which is at least two years but ideally five and during which there is no divergence from EU regulations.**

This will allow time for both regulators and industry to take the necessary steps to ensure compliance and maintain supply, which may include:

-  Transferring licences and the Reference Member State (RMS) from UK to EU
-  Preparing to reactivate dormant entities or find new business locations elsewhere in the EU, as required
-  Developing supply chain assurance
-  Implement packaging updates to reflect new supply arrangements (e.g. Made in UK/EU)
-  Planning for pharmacovigilance contingencies

Notes

- PAGB. About our industry. July 2017 Available at: <https://www.pagb.co.uk/about-us/about-our-industry/>
- 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>
- Hobson Prior. Global mobility in life sciences. 2015. Available at: <http://careers.abpi.org.uk/your-career/Documents/Global%20mobility%20life%20sciences%20-%20Hobson%20Prior%20V2.pdf>
- PAGB. PAGB Position on EU Exit. June 2017 Available at: <https://www.pagb.co.uk/content/uploads/2017/06/PAGB-position-on-EU-Exit-June-2017.pdf>
- 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>
- House of Commons, Health and Social Care Committee. Brexit: medicines, medical devices and substances of human origin. 13 March 2018. Available at: <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/392/392.pdf>
- PAGB estimate based on members' anticipated one off costs
- PAGB. Members survey. March 2018
- More information on how MRAs will prevent delays and duplications in the supply chain of OTC medicines and self care products can be found here [Insert links to PAGB infographics]