Thames Valley Chamber of Commerce Group
2 Brunel Way ▪ Slough
Berkshire ▪ SL1 1FQ
Executive Assistant: Alexandra Keane: +44 (0)1753 870 500
www.thamesvalleychamber.co.uk

House of Commons
Westminster Palace
London
SW1A 0AA

31st December 2025

For the attention of:

The Rt Hon Peter Kyle MP, Secretary of State for Business and Trade and President of the Board of Trade
The Rt Hon Liz Kendall MP, Secretary of State for Science, Innovation and Technology
The Rt Hon Wes Streeting MP, Secretary of State for Health, and Social Care

Dear Secretaries of State,

May we take this opportunity of wishing you all a Happy New Year and all the best for 2026. As one of the UK's largest Chamber's we look forward to continuing our work in supporting economic growth and championing the Thames Valley as a driver for wider UK prosperity.

UK-EU Mutual Recognition Agreement (MRA)

We are writing in regard the status and the case for agreeing quality checks for pharmaceutical batch release testing between the United Kingdom (UK) and European Union (EU) through the Mutual Recognition Agreement (MRA). We highlight the commercial opportunities and threats to UK plc.

The following comments are submitted on behalf of our membership. They have been prepared in consultation with several of the key representatives (including academia, business, professional bodies and research establishments) involved in our health and life sciences working group (see below).

The remainder of this letter outlines the context to our proposed recommendations:

Our Recommendations

1. Scope and implementation

The MRA should cover mutual recognition of GMP inspections, batch testing, and manufacturing site certification to avoid duplicative assessments. Clear operational procedures must be established for recognition, suspension, and notification between the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA).

2. Regulatory governance and autonomy

While supporting mutual recognition, it is essential that the MHRA retains its ability to set independent regulatory priorities that align with the UK's innovation agenda and public health objectives. The MRA should therefore be constructed as a framework of trusted equivalence rather than dependence, ensuring flexibility to update standards as scientific evidence evolves.

3. Economic impact and competitiveness

A well-designed MRA will directly improve the UK's competitiveness by reducing regulatory costs, enhancing manufacturing efficiency, and enabling faster access to EU markets. The current lack of mutual recognition imposes substantial economic costs; for instance, the ongoing annual costs of running dual testing systems are estimated (2025) to be between £127 million and £171 million.

Conservative estimates suggest that the annual business lost, and new costs incurred by the UK pharma sector's lab testing market due to Brexit are likely in the range of £250 million to £300 million, reflecting lost EU-facing contracts and relocated services. A MRA would directly address these substantial financial drains, counteract the deterrent effect of the current UK medicine levy, and restore investor confidence in the life sciences sector.

There are benefits for Europe of a Europe/UK MRA. Succinctly outlined, for example, by the European Medicines Agency, these include free market access and greater international harmonisation; a reduction in duplication and facilitation of trade.

Stakeholder engagement

We would welcome continued engagement with Government and the MHRA to inform the technical detail of any proposed MRA. This would include transitional arrangements, implementation timelines, and the management of sector-specific issues affecting R&D, innovation, and manufacturing.

Our Ask

For you, and colleagues within Government, to accept our invitation to meet with the Thames Valley Chamber of Commerce, and our members listed above, to discuss the content of this letter.

Background

When medicines are made, or tested, they be checked by the manufacturers for safety and quality in a process known as batch release testing. Countries with similar high standards and regulatory checks often agree a MRA on these batch tests, so that companies do not have to repeat the testing when a medicine/product crosses a border. Prior to BREXIT, batch release testing and Qualified Person (QP) certification performed in the UK was mutually recognised and accepted across the EU, and vice versa, allowing for seamless trade and preventing duplicative processes.

Currently, the UK unilaterally recognises batch testing and Qualified Person (QP) certification performed in the EU for most medicines imported, without requiring additional UK testing or QP certification. However, the EU treats the UK as a 'third country' post-Brexit, and mandates retesting and batch release for UK-manufactured medicines imported into the EU. This means that batch release for EU markets must occur within an EU or EEA country in accordance with EU law, despite the UK maintaining a list of approved countries (including EU/EEA states) for batch release import without repeated testing. The EU does not reciprocate this arrangement for UK products. This asymmetrical status creates a significant trade barrier for UK pharmaceutical exporters.

This extra step, required by the EU, complicates the supply chain, adds unnecessary burden and costs, and can delay medicines/products reaching EU patients (by an average of six weeks), which must be accommodated within delivery scheduling.

Under the EU-UK trade deal, both sides agreed to recognise each other's site inspections of manufacturing site, but the deal did not go as far as agreeing to mutually recognise batch tests. However, we recognise that, to our knowledge, the EU declined to grant this during the TCA negotiations 5 years ago and that the 'climate' on industrial policy of this nature is perhaps a little tougher now to get an MRA.

The benefits of an MRA

The current duplication, on exports from the UK to the EU, has introduced a trade barrier for medicines / product supply. If both sides could agree to remove it, it would strengthen the supply chain resilience for medicines/products in Europe, and support the UK to become a more attractive destination for manufacturing investment by:

- **Saving time and money:** almost half (46%) of all medicines and pharmaceutical products, for example, exported from the UK go to the EU. Reducing the cost of duplicating a batch test on a product exported from the UK into the EU could save businesses £1,500 per batch and the broader economic impact is far greater. The ongoing annual costs of running dual testing systems are estimated (2025) to be between £127 million and £171 million. Furthermore, conservative estimates suggest that the annual business lost, and new costs incurred by the UK pharma sector's lab testing market due to Brexit are likely in the range of £250 million to £300 million due to lost EU-facing contracts and relocated services.
- **Supply chain security:** both the UK and EU have discussed the importance of safeguarding supply for critical goods such as medicines/agrifood products. They both have strategies which include working with international partners to find agreements that would make supply chains more resilient – in our opinion, this is one such area they should be prioritising.
- **Attracting investment into Europe:** since the UK already accepts EU batch testing without the need for repeated testing, agreeing to do the same for UK batch testing going to the EU would remove another cost/benefit consideration for future investment. Failure to agree may result in UK based companies moving operations, such as testing and research and development operations, to the EU rather than investing in the UK, leading to a long-term impact of reduced investment and a diminished role for the UK in the European pharmaceutical landscape.

General Comments

4. Addressing the Tariff Barrier

We reflect on the perspective from the EU. Given it has not moved to address this tariff barrier, is it because they consider this issue insufficiently important, relative to other matters, or it has no financial incentive to address it for wider reasons?

5. Support for the principle of a UK-EU MRA

We strongly support the continued negotiations of a MRA between the UK and the EU covering the manufacture, quality assurance, and regulatory oversight of medicines, health products, and testing. MRAs are an established international mechanism to remove unnecessary technical barriers to trade, reduce duplication of regulatory inspections and testing, and enable products to circulate efficiently between trusted

markets without compromising safety or public health standards. The value of mutual recognition agreements lies in preventing costly and time-consuming duplication of batch testing, a principle evident in MRAs the UK and EU have with other territories such as Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the USA.

The existing state of batch release testing recognition can be exemplified as follows with the USA as example:

Region	Accepts batch testing from UK?	Accepts batch testing from EU?	Accepts batch testing from USA?
UK	Yes	Yes (without formal MRA but policy acceptance)	Yes (formal MRA)
EU	No (no MRA for UK batch testing; requires retesting)	Yes (internal batch testing)	Yes (formal MRA)
USA	Yes (formal MRA)	Yes (formal MRA)	Internal batch testing

6. Strategic importance for the pharmaceutical, agrifood tech and life sciences sector(s)

The UK's pharmaceutical industry is a leading contributor to national R&D investment, manufacturing, and exports. The absence of mutual recognition, since the UK's departure from the EU, has increased costs, introduced delays in product release and batch testing, and created regulatory uncertainty. with duplication costs being substantial. An MRA would deliver tangible benefits by:

- Reducing duplication of inspections and testing requirements, shortening timelines for product availability, and accelerating patient access to new medicines and vaccines
- Enabling UK based R&D and manufacturing to remain fully integrated with EU supply chains.
- Protect the UK's attractiveness as a location for investment, clinical trials, and commercial R&D.
- Reinforce global confidence in UK regulatory standards, maintaining the country's position as a world-class life sciences hub.

7. Concerns regarding the UK's investment climate

Recent commentary from the Association of the British Pharmaceutical Industry (ABPI) and major industry leaders highlights that the UK has become less attractive for pharmaceutical investment, in part due to the current medicines levy (VPAG), which stands at around 27%-35% of sales revenues for 2025- markedly higher than comparative EU countries such as Germany (7%), France (5.7%), and Ireland (9%). This, combined with regulatory fragmentation and the absence of recognition agreements, risks making the UK 'un-investable.'

Establishing a UK-EU MRA would help to offset these disadvantages, reduce compliance costs, and send a strong international signal of regulatory stability and collaboration. We commend the ABPI Framework, 'Creating the Conditions for Investment and Growth,' outlines the key factors that drive international competitiveness.

8. R&D and innovation considerations (RSSL input)

RSSL, as a leading analytical and regulatory science organisation, notes that MRAs can significantly reduce duplicative laboratory testing and regulatory oversight without compromising scientific rigour. This would free UK-based scientific capacity for innovation and R&D development, while retaining high-quality standards.

The UK should therefore ensure that the scope of any MRA includes the mutual recognition of Good Manufacturing Practice (GMP) inspections, batch release testing, and quality system audits.

9. Manufacturing and regulatory operations (Bayer input)

For companies operating complex cross-border supply chains, the lack of regulatory alignment adds considerable operational cost and uncertainty. Bayer and Syngenta have emphasised that the current divergence between UK and EU regulatory frameworks undermines efficiency in product release, labelling and manufacturing compliance. A UK-EU MRA would allow businesses to base manufacturing and R&D strategically in the UK while continuing to release products to EU markets without the need for redundant regulatory processes. This would also encourage reinvestment in UK production and strengthen resilience in global supply chains, countering the trend of manufacturing and testing operations relocating to the EU.

Our offer of help and support

We would expect that there are ongoing conversations with the EU on this, and wider industrial policy issues of mutual benefit. Equally there may be issues yet unresolved or considered in sufficient detail to progress. Most likely questions yet to be fully answered. For example, engaging with the equivalent of the industry bodies, such as the ABPI/ABHI, to whom we can/are speaking to champion in Brussels and to get some real traction within the Commission. Understanding, more fully, what EU-based companies and consumers get out of an MRA? Are there particular supply chains of medicines where continuity of supply from the UK is conclusively in the EU's interests? How might an approach of dynamic alignment enable progression (which might have greater chance of success in the long term with the EU rather than an MoU and mutual recognition proposal)?

Conclusion

The conclusion of a UK-EU Mutual Recognition Agreement represents a vital strategic opportunity to restore confidence, enhance trade efficiency, and secure the UK's position as a global leader in pharmaceutical innovation and manufacturing. It would reduce regulatory duplication, strengthen supply chain resilience, and signal that the UK remains a collaborative and trusted partner in global health regulation.

We therefore urge Government to prioritise this agreement as a central element of its life sciences and trade strategy, ensuring that its design delivers lasting benefits for patients, business, and the wider UK economy.

Background Information

By invitation, TVCC were asked to provide:

- A detailed submission to inform the Industrial Strategy – see HERE[1] from March 2025.
- An immediate response to the Industrial Strategy – see HERE[2] from June 2025.

Published a Manifesto for investment, health and growth in the Thames Valley and champion the sector / wider growth ambitions for the Thames Valley through, inter alia, our annual Business Manifesto 2026.

From a health and life sciences perspective, we're very pleased to be focused on women's health for our next working group meeting in February. Our discussion will include helping to shape a submission to the

[1] https://www.thamesvalleychamber.co.uk/wp-content/uploads/2025/03/14-03-2025_Invest-2035_TVCC_response_HLS_FINAL-1.pdf

[2] https://www.thamesvalleychamber.co.uk/wp-content/uploads/2025/07/TVCC-Feedback-on-the-Governments-Industrial-Strategy-26.06.2025.pdf

Women's Health Strategy. We welcome any guidance and continued support in our work and confirmation as to who, when prepared, we should be speaking in regard our submission.

We trust these comments are received with consideration to inform the Government's continuing discussions and to assist in shaping a proportionate, transparent, and effective MRA framework that supports the UK's global life sciences competitiveness.

We look forward to hearing from you shortly.

Yours sincerely,

Paul Britton
Chief Executive Officer