



EUROPEAN UNION
DELEGATION TO THE UNITED KINGDOM
OF GREAT BRITAIN AND NORTHERN IRELAND
Ambassador, Head of Delegation

London, 14 September 2021

Dear Michael,

Thank you for your letter of 13 September 2021. Allow me also to congratulate you on the unanimously approved report of the European Affairs Committee's Sub-Committee on the Protocol on Ireland/Northern Ireland that you chair, which I read with interest.

As you know the EU is particularly sensitive to public health issues. Our goal is clear: citizens in Northern Ireland must continue to have full access to all the medicines they need, as Commission Vice-President Šefčovič reiterated during his trip to northern Ireland last week. That is why I can confirm that the EU will table a legislative proposal in the coming weeks, suggesting a workable solution, within the Protocol.

In practice, the solution involves the EU changing its own rules, without changing the Protocol, so that regulatory compliance functions for medicines supplied to the Northern Ireland market only pursuant to authorisations issued by the UK in accordance with the Protocol may be permanently located in Great Britain, subject to specific conditions ensuring that the medicines concerned are not further distributed in the EU Internal Market. This will greatly facilitate the operations of pharmaceutical companies in Great Britain which will not need to relocate infrastructure or regulatory functions to Northern Ireland and will therefore be able continue to supply the whole UK market, including Northern Ireland, from where their infrastructure and regulatory functions are currently located.

Lord Jay of Ewelme
Chair of the Protocol on Ireland/Northern Ireland Sub-Committee
House of Lords London
SW1A 0PW

This demonstrates that the EU has an unshakeable commitment to the people of Northern Ireland. We will continue to seek practical solutions that facilitate the implementation of the Protocol, with the view of ensuring stability and predictability so that the people and businesses in Northern Ireland can benefit from the opportunities that the Protocol offers.

Yours sincerely,

A handwritten signature in black ink, consisting of a stylized 'J' followed by a long horizontal stroke that curves upwards at the end.

João Vale de Almeida
Ambassador