

SmartHealth

Healthcare Regulatory Affairs and the next stages of Brexit

On 22nd November 2018, London and Brussels announced the publication of a “declaration policy”, framing the rest of their post-Brexit negotiation. This declaration states the possibility of extending the transition period provided for the exit agreement, for a maximum of two years. Like the withdrawal agreement, this document consists of thirty pages that must be ratified by the British and European parliaments.

Brexit date pushed back to April 12 and then to October 31, 2019

On 29th January 2019, two weeks after the rejection of the exit agreement, and while their Prime Minister is out of "Plan B", the British deputies adopt two amendments through which they reject the principle of an exit without a deal. Theresa May then announces that she will "reopen" negotiations with Brussels to find an acceptable alternative. Talks between the Prime Minister and the European Parliament take place until March 11. But the next day, a vote in the House of Commons again rejected the exit agreement by a large majority.

On March 13, 2019, the parliamentarians also specify, for the second time, that they will refuse an exit without a deal, forcing the British government to submit to a third scenario: postponing the Brexit date to find a solution.

This option was approved by the European Council on March 21st and 22nd, meaning that Brexit was postponed till the 12th April.

July 2019: Boris Johnson replaces Theresa May and says he is ready to take on an exit without agreement

The day after the European elections, Theresa May announces her resignation on the 7th June 2019. Two weeks later, following an internal campaign in the Conservative Party, Brexiter Boris Johnson was elected leader of the Tories and therefore became Prime Minister.

Boris was therefore responsible for finding a solution to Brexit before the 31st October 2019. Eager to renegotiate the exit agreement - a prospect still refused by the EU - he says he is ready to assume a no deal if necessary.

October 2019: Europeans and British sign new exit agreement

On 17th October, Brussels and London agree on a new agreement for the UK to leave the EU that necessitates regulatory and customs checks to be carried out in the Irish Sea, between Northern Ireland and the rest of the United Kingdom. This agreement was adopted the same day by the European Council.

January 2020: the exit agreement is definitively adopted by the British and European deputies

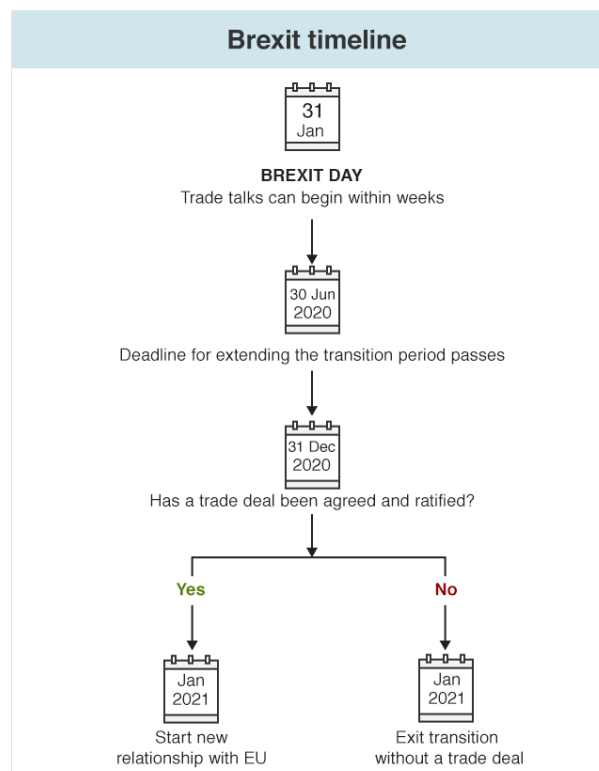
After several readings from the House of Commons and the House of Lords, the withdrawal agreement was finally validated by British MPs on January 22, 2020. The European Parliament in turn approved this agreement on 29th January 2020, by a very large majority (621 votes in favor, 49 against).

January 31, 2020: The United Kingdom leaves the European Union

At midnight on the 31st January 2020 the United Kingdom left the European Union. From 1 February begins the transition period, during which the European Union and its ex-member state must decide on their future relationship. This is scheduled to last until December 31, 2020, unless it is extended by mutual agreement. In the meantime, the United Kingdom loses its decision-making power in the European institutions, but most of the European rules and standards continue to apply in the country.

What will happen next?

On February 1st the “transition period” began. We are now experiencing a new period where uncertainty is still in the air. This transition period is due to end on 31st of December 2020. For example, *“during the transition period, **EU pharmaceutical law** as laid out in the ‘acquis Communautaire’ will be **applicable to the UK**. This means that pharmaceutical companies have **until 31 December 2020** to make the necessary changes to ensure that their centrally and nationally authorized medicines comply with EU law and can remain on the EU market.”*



Source: BBC

What is at risk in the case of a No Deal Brexit?

Research and innovation

The prospect of a no-deal is already having an impact on pharmaceutical research. Medical research firm Recardio has suspended all UK activities due to uncertainty about how new medicines will be approved after Brexit. The 114 NHS trusts currently involved in European Reference Networks, will be excluded.

Regulation

Patients in the UK could face additional delays in accessing new medicines, as the Swiss model has shown. It is estimated that as a smaller market, Switzerland gains access to new medicines 157 days later on average than the EU.

Medical supply chains

Trade between the UK and the EU is substantial, delivering medicines and medical devices to patients across Europe. For medicines, 45 million patient packs go to the EU from the UK every month, and 37 million patient packs go from the EU to the UK. Medical supply chains could be affected in the instance of a no-deal.

Reciprocal healthcare

Reciprocal healthcare agreements will end. 190,000 UK pensioners living in the EU currently have the right to receive healthcare in the member state in which they reside. In the event of a no-deal, there could be an impact on NHS services if some people decided to return to the UK for treatment.

Public health and disease prevention

If the UK no longer had a relationship with the European Centre for Disease Prevention and Control, both UK and European health protection will be weakened due to a reduction in information exchange.



Source: Brexit Health Alliance

How can I access more information?

To get more information on Brexit and how to get ready:

- ❖ British Government information on Brexit available at: [gov.uk/transition](https://www.gov.uk/transition)
- ❖ French Government Information available at: [brexit.gouv.fr](https://www.brexit.gouv.fr)