

NHS Confederation submission to inquiry into the Windsor Framework

28 April 2023

The [NHS Confederation](#) is the membership organisation that brings together, supports, and speaks for the whole healthcare system in England, Wales, and Northern Ireland. The members we represent employ 1.5 million staff, care for more than 1 million patients a day and control £150 billion of public expenditure. We promote collaboration and partnership working as the key to improving population health, delivering high-quality care, and reducing health inequalities.

The [NHS European Office](#) - which is part of the NHS Confederation - is the conduit for the NHS to engage with the EU's health based initiatives. It covers a wide range of EU policy and legislative developments which have implications for the NHS.

What is your overall assessment of the Windsor Framework? How far does it go to resolve the problems that have arisen with the Protocol? Does it leave any issues unresolved?

1. Overall, the NHS Confederation welcomes the Framework and regards it as a very positive result following long and difficult negotiations. It enables access for patients in Northern Ireland (NI) to the same range of medicines and medical devices as patients in the rest of the UK, something the NHS Confederation have highlighted as a concern for a long time. We were pleased that the solutions embodied in the Windsor Framework were precisely those we advocated for, most recently in the oral evidence the NHS Confederation gave to the Committee on 25 January 2023.
2. The Framework goes a considerable way towards resolving the practical problems relating to health arising from the existence of a land border on the island of Ireland between the UK and EU. The introduction of "green" and "red" lanes and of streamlined, digital systems will enormously reduce the volume and complexity of checks on goods imported from GB into NI but cannot wholly eliminate the need for some checks (for goods "at risk" of entering the EU single market) or the associated physical and digital infrastructures.
3. The Framework embodies excellent solutions to practical problems for businesses and citizens in relation to health arising from implementation of the Protocol. We appreciate however that political difficulties remain. The Framework's provisions to create procedures and a governance system to deal with legislative or regulatory divergence with constitutional implications (the "Stormont Brake" and dispute mechanisms) represent, in our view, an honest attempt to resolve the democratic deficit arising from the Protocol in its pre-Framework form.

To what extent will the Windsor Framework protect both “Northern Ireland’s integral place in the United Kingdom’s internal market” and its “unique access” to the EU Single Market?

4. The Framework attempts to square the circle of avoiding a hard border on the island of Ireland whilst enabling UK regulatory and customs divergence, including pursuing an independent UK trade policy outside the EU.
5. The Framework tackles the practical problems arising from the trade and regulatory barriers engendered by Brexit with some success, by introducing “green” and “red” lanes and streamlined digital systems that will enormously reduce the volume and complexity of checks on goods imported from GB into NI, but cannot wholly eliminate the need for some checks (for goods “at risk” of entering the EU single market) or the associated physical and digital infrastructures.

What is your assessment of the Windsor Framework’s provisions in relation to customs procedures and the movement of goods between Great Britain and Northern Ireland, including the arrangements for ‘green’ and ‘red’ lanes, an enhanced Trusted Trader Scheme, handling of Tariff Rate Quotas and the system of commercial data-sharing?

6. All the Framework’s provisions in this respect are significant improvements on the pre-Framework protocol. We welcome them, though they will not wholly eliminate the need for customs checks and will require some physical checks. In addition, the UK will need to supply relevant data to the EU to demonstrate compliance with the Framework.
7. Suppliers will want information and guidance as soon as possible so they can take the necessary steps to comply, especially where stock control and warehousing necessitate long lead-in times and where products may need to be packaged/labelled as “for NI only”.
8. It is worth noting that in the event of UK non-compliance with the Framework’s rules the European Commission will be able to suspend these easements, though we hope that the co-operation and governance arrangements in the Framework will, in an atmosphere of mutual trust and goodwill, render such action superfluous.

What is your assessment of the Windsor Framework’s provisions on the supply of human medicines to Northern Ireland? Do they deal sufficiently with the issues previously raised by industry in relation to the Protocol?

9. The Framework resolves the issue of access for patients in Northern Ireland to the same range of medicines and medical devices as patients in the rest of the UK, an issue the Confederation has highlighted for a long time. We were delighted that the solutions embodied in the Windsor Agreement were precisely those we advocated, most recently in the oral evidence the Confederation gave to the Committee on 25th January.
10. Consequently, in future the MHRA will be able to license products for the whole of the UK including NI, and there will be no need for medicines packaging to incorporate the safety features required under the Falsified Medicines Directive, which will be permanently disapplied in NI. These changes have been warmly welcomed by patient organisations, industry and the NHS.

What is the significance of the Windsor Framework for regulatory divergence a) East-West, between Northern Ireland and Great Britain and b) North-South, on the island of Ireland? What is your assessment of the mechanisms to manage divergence, including the new Special Goods Body and the role of the Office of the Internal Market? Should a record be kept of such divergence, and if so, by who?

11. The Framework significantly reduces the possibility of East-West regulatory divergence by ensuring NI remains firmly within the UK internal market and reducing checks on goods deemed at risk of entering the EU single market to a minimum.
12. However, the UK explicitly envisages “significant [North-South] divergence” in future between the two distinct economies on the island of Ireland, to be managed by the mechanisms set out in the Framework.

In the context of the Government’s reference to the removal of 1,700 pages of EU law, what is your assessment of the Windsor Framework’s impact on the scale of the application of EU law to Northern Ireland? What are the political, constitutional and economic implications of this?

13. Clearly the Framework removes the need for some EU legislation to continue to apply in NI, for example the derogation from the Falsified Medicines Directive, but it is difficult at this stage to estimate the overall scale of disapplication from EU law. It is unclear how much EU legislation would need to remain on the UK statute book in order to continue the application of EU single market rules in NI, and what practical measures suppliers would need to take to ensure that goods intended for the NI market do not enter the EU.

What is your assessment of the proposed Stormont Brake and the conditions for its use, including that an EU act “would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist”? To what extent will this address the democratic deficit under the Protocol? What practical, political and legal factors need to be borne in mind in terms of its use and operation, including the Government’s commitment to bring forward legislation to give effect to the Stormont Brake, and the EU’s ability to take “appropriate remedial measures” in response to a UK veto?

14. The “Stormont Brake” goes a considerable way to addressing the “democratic deficit” but falls short of giving either the NI Assembly or the Westminster Parliament an absolute “veto” over upcoming EU legislation applicable to NI without risking damaging retaliatory action by the EU. The threshold for triggering the brake is relatively high, and the UK government is not obliged to agree to suspend application of the relevant law in NI once notified that a third or more of Assembly members object.
15. Nevertheless, we regard the Framework’s provisions as a significant and welcome improvement on the current situation. As is the case with the ‘Petition of Concern’ mechanism, we believe they could work if implemented in good faith and with a genuine commitment to finding a positive outcome for the people of NI, rather than being used to score points or stoke political tension.
16. The UK government could however find themselves the “piggy in the middle” between Stormont and the Commission, risking either domestic discord or confrontation with the EU, if the issue to which the Assembly members raise objections is not resolved through the mechanisms set out in the Framework. (These consist of discussion at the UK-EU joint committee followed by independent arbitration, with the ultimate possibility of the EU applying retaliatory sanctions should the UK disapply the EU rules in NI regardless of the outcome of arbitration).
17. There are tricky internal political obstacles for the government to navigate, to allay concerns by NI Assembly members that even if they object to a new EU rule, the Westminster government could disregard their concerns and agree with the EU to implement it. As the objections raised by Assembly members might well not command cross-community support, the government is suggesting legislating so that a rule could not be added to the Framework in the absence of a cross-community vote in support from the NI Assembly, unless the government could demonstrate that

“there were exceptional circumstances to justify it, or show that the measure would not lead to new regulatory borders between GB and NI”. They intend to discuss these proposals with all parties in NI.

18. In order to work, the Framework’s provisions need to be operated by all parties in good faith and with a genuine desire to seek workable solutions. This will require extensive and authentic involvement of NI stakeholders, allied with considerable political skill and effort, to arrive at domestic legislation that commands cross-community support and can provide a lasting basis for implementation.