Title: Windsor Framework arrangements for the supply of medicines into Northern Ireland **IA No:** DHSCIA9641 **RPC Reference No:** N/A **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:** Medicines and Healthcare products Regulatory Agency, Cabinet Office	**Impact Assessment (IA)** **Date:** 15/02/2024 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:**

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2024 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£13m	£13m	£2.2m	Qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

Under the terms of the original Northern Ireland Protocol, the application of EU rules to medicines licensed for and supplied to Northern Ireland created serious risks to medicines supply., notably by requiring many medicines to have separate licences for Northern Ireland and Great Britain, often making supply to Northern Ireland unviable for manufacturers. Changes to EU legislation in April 2022 addressed some of these issues in the short term, and the arrangements under the Windsor Framework (agreed in April 2023) are a long term solution. The Statutory Instrument (SI) implements the Framework in domestic law; without it, there would be a risk of shortages in medicines in Northern Ireland, and inequitable access, or access under different conditions, to certain medicines between Great Britain and Northern Ireland.

What are the policy objectives of the action or intervention and the intended effects?

The legislation enacts several policy changes for medicines for human use in the UK as set out in the Windsor Framework, including the legislation passed by EU as part of the agreement, and accompanying domestic changes to make the negotiated position work as effectively as possible. This is to ensure that patients in Northern Ireland have the access to the same medicines at the same time and under the same conditions as those in the rest of the United Kingdom.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

1. **Baseline for comparison: not bringing the Windsor Framework into effect, thereby continuing with the arrangements under the old Northern Ireland Protocol with agreed derogations –** Innovative medicines would continue to be licensed by the EU for Northern Ireland and prescription medicines supplied to NI would continue to be required to follow EU Falsified Medicines Directive rules (with an existing partial derogation (exemption) agreed in April 2022 due to expire on 1 Jan 2025).
2. **Option 1 - Implementation of Windsor Framework on 1st January 2025** – The agreement with the EU is implemented, meaning the UK regulator, the MHRA, will be able to license medicines for the whole UK. Falsified Medicines Directive barcoding and scanning requirements will be disapplied in Northern Ireland. This option brings the Windsor Framework changes for human medicines into effect through legislation, and mitigates the risks under the baseline, of shortages and inequitable access to medicines across the UK. The Framework has been welcomed by the pharmaceutical industry and healthcare professionals

The Windsor Framework has already been adopted by the EU and UK Government. Alternative options have not been considered, as they would be subject to agreement with the EU and therefore outside of our control. No further negotiation is planned. Implementing the benefits of the Windsor Framework, but not the agreed protections for the EU's Single Market would not be negotiable and is not considered.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date: n/a**				
Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** n/a	**Non-traded:** n/a	

Signed by the responsible Minister: Andrew Gwynne Date: 29/7/2024

Summary: Analysis & Evidence

Policy Option 1

Description: Implementation of Windsor Framework, 1st January 2025.

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	PV Base Year 2024	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: -34.4	High: 66.7	Best Estimate: 13.0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	62.9		0	**62.8**
High	83.8		0	**83.6**
Best Estimate	73.3		0	**73.2**

Description and scale of key monetised costs by 'main affected groups'

The most significant costs, an estimated £50 – 71m, are one-off expected to be incurred by Market Authorisation (MA) holders to apply a `UK only' mark onto all medicine packs for use in the UK. Other costs to MA holders include application fees for notifying MHRA of licence and packaging changes, familiarisation costs, and in some cases the cost of temporarily adding `UK only` stickers to medicines packs where permitted. MHRA has simplified the notification process to the maximum extent possible within the regulations.

Other key non-monetised costs by 'main affected groups'

Opportunity costs for MHRA to process bespoke applications for product packaging changes, increased reporting costs for licence holders of certain products (less than 3% of all licences); increased operational costs in processing any product recalls and identifying falsified medicines.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			5.9	**49.2**
High			15.6	**129.5**
Best Estimate	0		10.4	**86.2**

Description and scale of key monetised benefits by 'main affected groups'

The primary quantified benefits are time avoided from the application of Falsified Medicines Directive (FMD) rules for products exported from the EU, estimated between £2.2m and £7.9m annually and time saved by pharmacists sourcing medicines, estimated to result in a benefit of between £1.9m and £5.8m annually. Wholesalers and healthcare institutions in NI benefit from the disapplication of FMD rules, avoiding all barcoding, scanning and 'decommissioning' requirements. Time will also be saved by staff not needing to follow up in cases where scans are not successful in correctly identifying the product's information.

Other key non-monetised benefits by 'main affected groups'

The most significant benefit of the Windsor Framework is in addressing the risk of severe shortages of medicines in NI, which would create serious disruption for patients in accessing treatment and with consequences for public health. This long-term solution also means UK patients will be treated by the same medicines on the same terms. It removes the need and workforce requirement for temporary solutions to enable products to be supplied to NI. There may also be savings for manufacturers from not having to produce two different medicine packs for the UK.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5

Costs are assessed over a 10-year time span, but costs are only expected to be incurred in years 0 and 1 as transitional costs. Once all firms have implemented the required changes to operate under the agreed terms of the Windsor Framework there are not expected to be ongoing costs. Formal consultation of industry has not been undertaken so assessment is based on the best available data and evidence, including information provided by trade associations.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:

Costs: 8.5	**Benefits:** 6.3	**Net:** 2.2	13.8

Evidence Base

Problem under consideration and rationale for intervention

1. Northern Ireland is integrated into UK-wide medicines supply chains, with the vast majority of medicines supplied from Great Britain (estimated at up to 98%[1]). Prior to the introduction of the Northern Ireland Protocol in 2021, the UK formed a single regulatory unit, with medicines licensed under whole UK licences by the MHRA, or under EU licences for novel medicines, which covered the whole of the UK. Regulatory requirements for the movement and supply of medicines between Great Britain and Northern Ireland were no different to any movement or supply within the UK. The EU's Falsified Medicines Directive (FMD) applied across the UK.
2. Following the UK's exit from the European Union, under the terms of the Northern Ireland Protocol (NIP), EU law for medicines continued to apply in Northern Ireland. This made Great Britain a third country for the purposes of supply to Northern Ireland, imposing significant barriers to the supply of medicines from Great Britain to Northern Ireland – for instance in requiring batches of medicines to be tested in the EU or Northern Ireland even if the process had already been carried out in Great Britain. This risked the supply of medicines to Northern Ireland, as complying with the requirements for many medicines was not viable.
3. During a temporary grace period for compliance, in April 2022 the EU introduced new legislation enabling a range of regulatory functions to take place in Great Britain on a permanent basis, for medicines supplied to Northern Ireland. The legislation enabled the MHRA to authorise all medicines in Northern Ireland except novel medicines that the EU regulates through its Centralised Procedure (CP). This supports the continuation of whole UK medicines licences. Finally, the legislation provided for a derogation until 31 December 2024 from the usual requirement for medicines supplied from the EU to Northern Ireland via Great Britain to be 'decommissioned'[2] when moving from the EU to Great Britain, and then have the FMD unique identifier 're-affixed' when moving from Great Britain to Northern Ireland – which industry has indicated is not viable.
4. Following this EU legislation, two significant problems that had the potential to impact medicines supply to Northern Ireland and equitable access between Great Britain and Northern Ireland remained. These risks were raised by the pharmaceutical industry and healthcare professionals at the time as matters in urgent need of resolution. For medicines within the scope of the EU's Centralised Procedure, EU medicines licences continued to apply in Northern Ireland. This meant a separate medicines pack was needed to supply the same medicine to Great Britain and Northern Ireland, which created challenges to supply and meant that the licence indications (i.e. the clinical situations in which the product should be used) between Great Britain and Northern Ireland may be divergent. In addition, the ongoing application of the EU's FMD in Northern Ireland imposed a significant resource burden and provided an incentive for suppliers to limit supply to only Great Britain. Furthermore, the end of the derogation on 31 December 2024 would have been likely to cause significant new issues for medicines supply given Great Britain-based wholesalers do not have the systems in place to de-commission/upload barcodes as would be required.
5. In May 2023, the National Pharmacy Association (NI) cited evidence that "74% of [community] pharmacists were spending between 1-3 hours per day sourcing medicines,

[1] Concerns about the supply of pharmaceuticals to Northern Ireland - Committees - UK Parliament

[2] Decommissioning involves reading (scanning) a unique 2D bar code printed on every manufactured medicinal product pack; it indicates that the pack has been supplied, so any other pack bearing the same unique identifier cannot be verified or decommissioned.

with shortages on approximately 1000 medicine packs per pharmacy per month"[3]. Whilst not all the challenges in medicines supply can be attributed to the Northern Ireland Protocol, the National Pharmacy Association suggested that the Windsor Framework appears to address the challenges associated with shortages.

6. These problems could only be solved through government intervention, given the necessity of ample and fair medicines supply. The small scale of the Northern Ireland market and high barriers to entry, due to costs of compliance with EU rules means that without intervention, the rational response of firms would be to reduce supply. The relatively small size of the Northern Ireland market (given a population of 1.91m, 2.9% of Great Britain[4]) and the high cost of expanding or continuing supply to Northern Ireland is a deterrent to profit-driven firms. Medicines licensed for the Republic of Ireland are not normally valid for the Northern Ireland market and so could not be substituted.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

7. This Impact Assessment considers the costs and benefits of the policy changes set out in the Windsor Framework for medicines for human use in the UK. Implementation of these changes is already in progress but is not yet underpinned by legislation. No formal IA was conducted prior to the Framework being agreed given the confidential nature and urgency of the negotiations[5] and so rather than comparing a baseline of 'implementation of the Windsor Framework without enacting legislation', the analysis compares a baseline of 'no Windsor Framework' to an option of implementing the agreement.

8. This Impact Assessment uses the best available data and evidence currently available to assess the options under consideration. It has not been possible to gather detailed new evidence for this review given implementation of the new arrangements has been in progress since mid-2023. High level engagement with several industry trade associations has been undertaken using a short questionnaire and/or targeted queries to understand likely impacts and sense check key assumptions used. The evidence in the public domain from governments, regulators, think tanks and industry has informed this assessment. Existing evidence held by DHSC and MHRA from previous industry engagement exercises designed to inform other decisions about medicines supply to Northern Ireland has also been adapted for use here.

9. The proposal under consideration is for the implementation of a package of measures within the Windsor Framework. The Framework has already been adopted by both the EU and the UK – subject to the UK Government providing written guarantees of compliance to the EU that the measures agreed on 'UK only' labelling and UK enforcement of the measures have been given effect. The changes for medicines supply address many of the issues raised by industry and as reported by the House of Lords Protocol on Ireland/Northern Ireland Committee, the pharmaceutical industry has "strongly welcomed the provisions on human medicines"[6].

10. The main costs of the proposals are monetised and arise during transition; the requirement for all medicines on the UK market to be labelled as "UK only" is relatively low per product but high value when scaled up across almost 20,000 products. The main and most important benefit of the Windsor Framework is removing the risk of large numbers of

[3] committees.parliament.uk/writtenevidence/120896/html/

[4] Population estimates - Office for National Statistics (ons.gov.uk)

[5] Informal testing of outcomes with industry was undertaken at the time.

[6] The Windsor Framework (parliament.uk) (page 41,paragraph 116)

medicines being withdrawn from the Northern Ireland market and this benefit cannot be quantified. The *monetised* benefits of the provisions are lower value marginal cost reductions and efficiency savings for medicines manufacturers, wholesalers and dispensers from the removal of trade frictions. The benefits will be realised recurrently over the long-term (due to the permanent nature of the changes), benefitting patients and the healthcare sector across the UK from the alignment of access to medicines across Great Britain and Northern Ireland. While it has not been possible to quantify all savings to compare against the main cost impact of the Framework, the positive response of clinicians and other healthcare professionals in Northern Ireland, as well as the industry to the proposals is an indication that the benefits, which are long term, justify the costs, which are transitional.

11. Due to the global nature of the pharmaceutical industry it has not been possible to isolate the impacts of the changes on firms in the UK. Organisations impacted are those in the production and supply chain of medicines that are authorised for distribution in the UK and this will include products with touchpoints overseas. Notwithstanding, the costs and benefits presented in this assessment reflect those to UK society since impacts will be felt by patients, the public and the health sector in the UK.

Description of options considered

Continuation of the provisions in the old Northern Ireland Protocol with agreed derogations

12. The old Northern Ireland Protocol (NIP) set out the relationship between the UK and EU in respect of arrangements applying in Northern Ireland, which was in effect from 1 January 2021. It has now been replaced by the Windsor Framework, from March 2023, though the legislation to bring the medicines aspects of the Framework into effect has not yet been laid and so the changes outlined in the Windsor Framework do not feature in this baseline.

13. In 2022, the EU took unilateral action to address some challenges with medicines supply to Northern Ireland, however it did not address the following aspects of NIP, which the Windsor Framework subsequently addresses and are relevant to this impact assessment:

    a. *Licensing arrangements* - EU Centralised Procedure would continue to be used for authorisation of novel medicines in Northern Ireland, with MHRA licensing novel medicines only for Great Britain. A new 'bridging mechanism' has been in force from June 2023 enabling UK-wide licensing of products in scope of the EU's Centralised Procedure for a time-limited period.

    b. Falsified Medicines Directive – Northern Ireland would follow the EU's FMD, which is not aligned to requirements in Great Britain. Under the existing derogation, medicines can only move through Great Britain without decommissioning until the end of 2024, after which the EU FMD rules would apply in full, with medicines moving to Northern Ireland needing to be 'decommissioned' to move to Great Britain, and the FMD unique identifier 're-affixed' to move on to Northern Ireland. The FMD has been described as the "single biggest factor" creating prescription medicine supply issues to Northern Ireland and could create a situation that would be "untenable"[7] for prescription products.

    c. *Packaging requirements* – There would be no labelling requirement, but novel products licensed by the EU would continue to need to be supplied to Northern

[7] Letter to the Rt Hon James Cleverly MP, Secretary of State for Foreign, Commonwealth and Development Affairs, FCDO on follow-up scrutiny of medicine supple to Northern Ireland, 24 February 2023 13.10.21 Introductory inquiry Government response (parliament.uk)

Ireland. This could have led to split licensing and over time, divergence in product availability between Northern Ireland and Great Britain which would have had negative effects on UK-wide supply.

d. *Intellectual property* – data and marketing exclusivity periods in Northern Ireland continue in line with those attaching to the EU authorisation (given novel medicines are regulated via the Centralised Procedure). This would be problematic for UK-wide supply, given the exclusivity periods could gradually diverge between Great Britain and Northern Ireland, risking discontinuation of supply to the relatively small Northern Ireland market.

14. Continuation of the status quo is presented in this impact assessment as the counterfactual for comparison. The scenario is presented as having zero costs or benefits (because it forms the baseline) and the impact of option 1 is assessed as marginal changes against this baseline. Preservation of the status quo represents a failure to bring the Windsor Framework into effect through legislation and this would be in breach of the political agreement between the UK and EU.

Option 1: Implementation of Windsor Framework, 1st January 2025.

15. Implementation of the Windsor Framework regulatory changes for medicines, Option 1, is to introduce a statutory instrument enforcing the agreed terms of the framework. This means that novel medicines will become part of the UK regulatory regime with all types of medicines, in the same packs, with the same labels available across the whole of the UK. These elements were agreed as part of a negotiation with the EU Commission, and the packaging requirements represent a protection for the EU Single Market which enables the other changes to be brought into effect. It would not be possible to implement some of the changes but not others.

    a. *Licensing arrangements* - MHRA will authorise all UK medicines that previously fell to the EU's Centralised Procedure. This prevents the significant risks to supply inherent in the status quo position from the use of separate licences as well as divergence in terms of the medicines that are available in GB compared to NI (e.g. novel cancer treatments).

    b. *Falsified Medicines Directive* - EU law on Falsified Medicines Directive (FMD) to be disapplied and the existing derogation will no longer be relevant, preventing product discontinuations that industry suggested would otherwise have occurred. Companies are no longer permitted to include compliant features on medicines packs, and all associated activity (e.g. scanning and decommissioning) is discontinued. This removes the risk of product discontinuations that suppliers have warned of.

    c. *Packaging requirements* - "UK only" label needs to be featured on all medicine boxes in the UK.

    d. *Intellectual property* – Given innovative medicines will be licensed across the UK, they will become valid pan-UK reference products. The legislation provides that a UK reference product must be used for UK-wide generic medicine applications. There are therefore changes in that the only data and marketing exclusivity periods (DME) for UK licensed medicines will be those of the UK medicine which is the Reference Medicinal Product (RMP). This prevents supply risks from the

potential for different exclusivity periods between Great Britain and Northern Ireland.

16. Other options have not been considered. The Windsor Framework has already been adopted by the EU and UK Government. There are therefore no other possible options to be considered. Any alternative options would require agreement with the EU and be subject to its legislation, and so outside of our control. The UK Government would have the option to not bring the changes into effect through legislation and thereby remaining with the status quo, but failure to implement the Windsor Framework would be in breach of the political agreement.

Policy objective

17. The policy objective is to establish a long-term solution for the supply of medicines into Northern Ireland. The aim is to ensure that patients in Northern Ireland have the same access, at the same time, to medicines as the rest of the United Kingdom. Further, it is to ensure that access to medicines in Great Britain and Northern Ireland is on the same terms and under the same licences, to ensure equitable access to medicines for patients. Healthcare in Northern Ireland is highly aligned with healthcare in the rest of the UK, for example with Northern Ireland relying on NICE assessments in determining whether a medicine is cost-effective, so it is important that patients with the same indications in Great Britain and Northern Ireland are treated the same way with the same medicines.
18. Present arrangements have supported the continued supply of medicines to Northern Ireland, but represent a temporary solution, with risks to supply and equitable access remaining. The most present risk is the end of the FMD derogation in 2024. Longer term, the need to supply novel medicines to Northern Ireland in separate packs from Great Britain represents a risk to supply under the status quo, and there are increasing risks to equitable access with more new medicines having divergent licences.
19. This Statutory Instrument (SI) implementing the Windsor Framework and making accompanying domestic changes is intended to resolve medicines supply challenges and risks for Northern Ireland for the long term, and ensure that medicines in the whole of the UK are used by patients under the same conditions with the same licence indications.

Summary and preferred option with description of implementation plan

20. The Windsor Framework, agreed in March 2023, replaces the old Northern Ireland Protocol, establishing a new framework to address the range of issues that the original Protocol caused. The changes have been implemented through changes to the text of the Protocol itself, alongside substantial revisions to EU law. The Windsor Framework is being implemented in stages.
21. The regulatory changes agreed for medicines form a key part of the Windsor Framework. The EU has passed legislation (Regulation 2023/1182[8]) necessary to bring it into effect in the form of amendments to Directive 2001/83/EC, which governs the licensing of medicines in the EU.
22. The Windsor Framework also includes substantial changes to customs arrangements for moving products from Great Britain to Northern Ireland which are of benefit to medicines suppliers. These changes apply to all types of goods, and are not being considered as part of this Impact Assessment.

[8] Regulation - 2023/1182 - EN - EUR-Lex (europa.eu)

23. The changes in the SI are to the UK Human Medicines Regulations. They include changes that are necessary to ensure UK domestic law is in compliance with the Windsor Framework, alongside other changes where the UK has latitude in how the changes are implemented or is making accompanying changes to ensure the Windsor Framework works effectively and achieves its objectives. For instance, to ensure an equitable supply of medicines across the UK and to ensure that medicines with a UK licence are consistently in compliant packs, the SI applies 'UK only' labelling requirements to UK licensed medicines supplied to all parts of the UK.

24. The changes introduced following the Windsor Framework can be summarised in four categories:

    a. changes to the licensing of innovative medicines, so the MHRA can authorise all medicines falling into the mandatory or optional scope of the EU's Centralised Procedure under UK law.

    b. The disapplication of Falsified Medicines Directive requirements to include unique identifiers on medicines in Northern Ireland, with all associated scanning and decommissioning requirements disapplied.

    c. A new requirement for all UK-licensed medicines to include a label stating 'UK only'.

    d. A corollary of the changes to the licensing of innovative medicines is that UK-licensed innovative medicines will become valid Reference Medicinal Products (RMPs) for applications for UK-wide generics licences, with UK Data Marketing Exclusivity (DME) periods applying in these cases. This SI provides that for UK-wide generics, a UK RMP must be used.

25. Taken together, these changes enable all types of medicines to be licensed UK-wide by MHRA, and removes the primary barriers to the supply of medicines to Northern Ireland, and equitable access between Great Britain and Northern Ireland. Implementation of the changes has been in progress since the Windsor Framework agreement was reached in March 2023. MHRA has published several pieces of guidance, including on labelling[9] and licensing[10]. These set out the actions necessary from Marketing Authorisation (MA) Holders, including how they can notify MHRA of labelling and packaging changes, and what medicines with what labelling can be released to the market at different times.

26. Medicines supplied under parallel import licences will also have their licences converted automatically such that they can be supplied UK wide.

27. MHRA has engaged regularly with trade associations and industry representatives and continues to do so. This engagement is on its guidance, alongside readiness and preparations to operationalise the changes. DHSC has run two public webinars on the changes and actions required from industry. DHSC and MHRA will continue to engage to run webinars.

28. In 2024, the UK Government will provide Written Guarantees of its compliance with the terms of the EU regulation, in order for the EU to publish a notice in its official journal bringing the WF changes into effect on 1 January 2025.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

[9] Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK (www.gov.uk)

[10] UK-wide licensing for human medicines - GOV.UK (www.gov.uk)

MHRA will authorise all UK medicines that previously fell to the EU's Centrally Authorised Product (CAP) process.

Baseline/Do nothing/counterfactual scenario:

29. The changes to licensing arrangements affect medicines that are within the scope of the EU's Centralised Procedure, these are largely innovative medicines. Under current arrangements, there are three different ways that such products are made available to patients in Northern Ireland, as follows.

European Commission licensed products

30. Under the terms of the old NIP, medicines within the scope of the CP that have a marketing authorisation from the European Commission can be marketed in Northern Ireland, and the MHRA cannot licence medicines in these categories for Northern Ireland (products marketed in Great Britain must be authorised by the MHRA).

31. While the European Commission issues licences for novel medicines that cover Northern Ireland, in practice there are no innovative medicinal products marketable in Northern Ireland that are not available in Great Britain. This is due to post-licensing processes to make medicines available to patients and means that any product with an EMA licence but no MHRA licence, is not currently available in Northern Ireland:

    Once products have been licensed, to get on to the market a subsequent assessment is made to decide if they should be made available as part of free healthcare. In Northern Ireland, the Department of Health, Social Services and Public Safety (DHSSPS) decides if products should be available, on the basis of guidance by expert institutions such as the National Institute for Health and Care Excellence (NICE). DHSSPS usually approves most NICE guidance and does not assess products that have not been by NICE. NICE assesses products that have been licensed by the MHRA for use in Great Britain, not any for which there is only a licence in Northern Ireland[11]. This means that where products are licensed by the European Commission for use in Northern Ireland but are not licensed by the MHRA, DHSSPS does not have access to evidence necessary to decide whether the product should be made available as part of free healthcare, and under which conditions (such as only for certain people with a condition).

32. As of March 2024, 87% (1,193[12]) of all human medicinal products that had an active marketing authorisation through the EU Centralised Procedure (1,375) also had an MHRA authorisation, meaning that as well as being licensed, they had been assessed by NICE and so had a determination as to whether they should be supplied to patients.

NIMAR listed products (Unlicensed)

33. There are a range of products that are supplied to Northern Ireland on an unlicensed basis, many now covered by the Northern Ireland MHRA Authorised Route (NIMAR) list. NIMAR became effective from 1 January 2022 and provides a route to supply prescription only medicines in Northern Ireland where there is a risk of unmet clinical need and no licensed alternative is available.

[11] How medicines become available on the NHS and HSC | Cancer Research UK

[12] These values refer to individual brands of medicine, for example "Abilify" is a branded medicine with authorisations by the MHRA for eight variations (five different strengths and some available in multiple formulations), this is counted as one medicine in these figures.

34. Products on the NIMAR list are unlicensed in Northern Ireland but approved for use in Great Britain, or licensed across the UK but not compliant with FMD requirements in Northern Ireland. There are 67 branded medicines currently listed on NIMAR (across 112 individual products). While NIMAR enables the use of medicines in Northern Ireland, it creates costs and risks, including:
    - Short delays (from as little as 48 hours to a few weeks) between identifying clinical need and the product being listed for use;
    - Products on the list cannot be promoted to healthcare professionals (though this does not preclude legitimate interactions and communications necessary to maintain medicines supply).
    - Confusion for wholesalers, who can see a product is authorised for Great Britain only from the licence number and then need to check the online NIMAR list to see if it can be supplied to Northern Ireland. This can lead to delays and increased costs.

35. While these products are unlicensed in Northern Ireland, there is low risk for the clinicians prescribing them because the medicine is licensed in Great Britain and so will have met the MHRA's requirements for safety, quality and efficacy.

36. Use of the NIMAR route is lawful but was not a negotiated solution with the EU in the same way as the CAP bridging mechanism is, as outlined below. This means that although NIMAR does prevent patients in Northern Ireland going without medicines that they need, it is not designed for large scale or long-term supply. There are currently 67 branded products on the list.

37. In the absence of the Windsor Framework, it is uncertain whether NIMAR remains a sustainable basis for the supply of medicines in the long term. Over time, it would be expected that the number of medicines on the NIMAR list would increase, exacerbating the limitations, delays and resource costs associated with supplying medicines in this way, as identified above. NIMAR represents a method to supply medicines outside of the terms of their licence, which is not an appropriate method to secure a large proportion of the medicines supply to Northern Ireland. However, given the patient safety risks if any future supply of medicines to Northern Ireland were limited or put at risk, we expect NIMAR or an equivalent process would remain available for Northern Ireland patients to access medicines where there is a clinical need. As such, for the purposes of comparison, we assume the continuation of NIMAR in the absence of any agreed negotiated solution.

CAPs bridging mechanism products:

38. Since June 2023, a 'bridging solution' has been in place, allowing any new novel medicine authorised in Great Britain to be temporarily supplied to Northern Ireland. This Centrally Authorised Products (CAPs) Bridging Mechanism applies until the Windsor Framework takes effect and allows for products receiving a new Great Britain licence from the MHRA to be supplied to Northern Ireland for a period of six months, or until the EC authorises the product or refuses the application, whichever is sooner.

39. Where a new innovative medicinal product is likely to be approved by the MHRA before the same product is authorised for use in the EU, the MHRA will place the product on the CAP bridging list at the time of Great Britain authorisation and issue a licence that is also valid in Northern Ireland [2]. This means that there is no delay between a new product's availability in Northern Ireland compared to Great Britain. There are currently two products on the CAP bridging list and no expired products[13].

[13] As at 16th February 2024: Active CAP Bridging List - GOV.UK (www.gov.uk)

40. If the EC approves the product within the six-month timeframe, it can be supplied in Northern Ireland under the marketing authorisation of the CAPs product's route. The MHRA authorisation will continue to apply for Great Britain. If the EC refuses the application, the product can no longer be supplied to Northern Ireland under the licence issued by the MHRA and "an alternative mechanism such as the Northern Ireland MHRA Authorised Route (NIMAR) will be considered […] if required, ensuring the clinical needs of patients are met. This will be determined on a case-by-case basis."[14]

41. As with NIMAR, the CAPs bridging mechanism is not intended as a long-term solution for supplying licensed novel medicines in Northern Ireland, but a short-term measure with considerable uncertainty given the product approval could have been removed within a six-month timeframe. Since the arrangement is in place "until such time as the Windsor Framework takes effect", we assume that the mechanism remains as the baseline scenario for comparison in this analysis.

Comparison of medicines availability in Northern Ireland and Great Britain

42. The current arrangements as described above mean that patients in Great Britain and Northern Ireland largely have access to the same innovative medicines as a result of a combination of the following routes:

- Innovative medicines licensed by the EMA prior to 1st January 2021 – unless MA holders opted out, these licences were automatically converted to Great Britain licensed products on that date and Northern Ireland retained access via the EMA licence. The MHRA converted ("grandfathered") EU MA licences for 1,014 products in January 2021, 257 products authorised via the CAPs process were opted-out of being converted to Great Britain licences by the MA holders;
- Products listed on NIMAR – the number of branded products on the NIMAR list has increased since its introduction to 67 products across over 100 variants (i.e. varieties of product strengths and pack sizes) currently;
- Products on the CAPs bridging list – all innovative medicines approved by MHRA since June 2023 and where the EMA has not already made a licensing decision (2 currently);
- Products separately approved by both the MHRA and the EMA and designated as available as part of free healthcare in England and Northern Ireland – there are currently 229 products on the Union Register that have been authorised by the European Commission since January 2021, of those 195 also have a marketing authorisation for Great Britain.

43. While the supply of innovative products in Great Britain and Northern Ireland is largely the same, this is due to the mitigations in place. While together these provide a safety net and prevent divergence in supply, it is not a long-term stable situation for UK medicines supply.

Windsor Framework scenario:

44. From 1st January 2025, the UK regulator, the MHRA, will be able to authorise all products falling under the scope of the Centralised Procedure (CP) in Northern Ireland. These products will only be able to be sold in the UK and will not be available on the market in Ireland, or elsewhere in the EU.

45. New applications for products that currently fall under the mandatory or optional scope of the EU centralised procedure will be licensed under UK law and on a UK-wide basis. All

[14] Centrally Authorised Products (CAPs) Bridging Mechanism - GOV.UK (www.gov.uk)

new and innovative medicines, orphan medicinal products, Advanced Therapy Medicinal Products (ATMP) and paediatric medicines authorised will be granted UK-wide product licences by the MHRA[15].

46. The changes for medicines within the scope of the CP mean that UK-licensed innovative medicines will be valid reference medicinal products for applications for UK-wide generics (as opposed to needing both a CAP for Northern Ireland, and a UK-licensed medicine for Great Britain for products within the scope of the CP). In addition, the SI enables the MHRA to update guidance on comparator products in bioequivalence/therapeutic equivalence studies to adopt the present approach used for Great Britain medicines on a UK-wide basis. These changes will enable a UK-wide approach to be taken for generic medicines outside the CP.

47. The actions that are required from MA holders depend on the existing licences of their products:
    - For products that have an existing Great Britain licence, MHRA will automatically convert these products to have UK-wide licences from 1st January 2025. No action is necessary by the MA holders of these products. However, where required, updated packaging and labelling information will need to be submitted to the MHRA (see labelling section below). Around 2,900[16] medicines currently licensed for Great Britain are expected to be converted to UK-wide licences from 1 January 2025.

    - For products that have licences for both Great Britain and Northern Ireland, action is required by MA holders who want their product to remain available in Great Britain. They will need to cancel the Northern Ireland licence for the Great Britain element to automatically be converted to a UK-wide licence.

    - Products licensed only for Northern Ireland and not Great Britain can retain such licences after 1st January 2025, including by remaining as a concerned member state (CMS) in the EU procedure. New licence applications will be required to make these products available UK-wide.

Costs:

Transition costs

48. All products already on the market on 1 January 2025 will be able to remain on the market until their date of expiry[17] meaning that there is no product wastage or associated costs.

49. There will be familiarisation costs for each Marketing Authorisation (MA) holder to understand the implications of the Windsor Framework. We assume that the time taken for familiarisation per firm is 3 – 5 days at a staff cost of £29.11 per hour[18]. There are 1,036[19] firms with medicines on the market in Great Britain and Northern Ireland and so this equates to a cost of £630k to £1m. The time estimate is modest, reflecting the long lead-in time for this change and the high level of stakeholder engagement and communications that MHRA has already undertaken with the pharmaceutical sector as explained in the

[15] UK-wide licensing for human medicines - GOV.UK (www.gov.uk)

[16] An additional 6,500 parallel import licences are also expected to be converted to UK-wide licences.

[17] Windsor Framework medicines announcement - GOV.UK (www.gov.uk)

[18] Annual Survey of Hours and Earnings (ASHE) 2023, median hourly wage for production managers and directors, functional managers and directors, production and process engineers (table 14.5a)

[19] Estimate provided by MHRA to DHSC, March 2024: Internal analysis of licensing information

implementation plan above. The change is also a simplification of the system compared to the bridging mechanism.

50. Firms needing to change the licences for their products will incur administrative costs associated with notifying the relevant regulators about the changes required. Associated administration costs incurred by MHRA are within scope of this IA but costs to EU Reference Member States are out of scope. Further information about licence change costs is included in the labelling section of this document.

51. We assume that where a product is already on the market in Great Britain, those licences will become UK-wide, including for the 27 products where there is both a licence for GB (referred to as "PLGB") and Northern Ireland ("PLNI"). PLNI licences will need to be cancelled and while there is no MHRA fee to cancel a licence, there will be administrative costs for MA holders to notify MHRA and for MHRA to process the request. Due to the small number of dual licensed products, this activity is expected to be absorbed in the business-as-usual activities of MA holders. In addition to processing these 27 licence changes, MHRA will need to convert 2,931 PLGB licences to UK-wide licences, "PLs". This is also expected to be low cost as licence numbers will not change (one of several measures taken to minimise impacts on businesses of bringing the Windsor Framework changes into effect). Following the change, MA holders will need to ensure that products comply with relevant labelling and packaging requirements. The associated costs are covered in the labelling section of this impact assessment (below).

52. Products currently authorised for Northern Ireland but not Great Britain are not expected to become UK-wide. We assume that products would already have been authorised for Great Britain if there was demand due to the larger and greater profitability of that market under current arrangements. No licence change process is required for these products.

Ongoing costs

53. For the vast majority of medicines, there are no ongoing costs for changing the licensing authority for innovative medicines in Northern Ireland. There is no expectation that licence applications to MHRA will increase under the proposal, rather just that the MHRA will authorise products for the whole of the UK rather than Great Britain alone.

54. For a small subset of licences, currently estimated to be approximately 500 out of almost 20,000, the removal of the option for GB-only licences will create ongoing costs due to additional reporting requirements, with certain additional safety data needing to be submitted to the EU to facilitate the conversion of the GB-only licence to cover Northern Ireland. Further guidance will be published by the MHRA.

55. No significant costs associated with increases in the volumes of medicines traded is anticipated since most products for which there is demand in Northern Ireland are available under current arrangements. For products currently only available via the NIMAR list, once the new measures commence these products can be promoted to healthcare professionals and others who prescribe or supply the product in Northern Ireland. While these licence holders may increase expenditure on such activities, they are only expected to do this if it does not adversely impact profit margins meaning any additional spending is not a cost of the policy.

Benefits:

56. As of 1st January 2025, all products with a PLGB licence (around 2,900) will be valid in Northern Ireland. This will increase the number of licensed products available in Northern

Ireland and is expected to benefit patients and clinicians by easing access and increasing choice for drugs to prescribe in Northern Ireland. Most products for which there is demand in Northern Ireland are available under current arrangements, but removing the need for the NIMAR and CAP bridging list will bring more consistency and certainty to the availability of these products especially over the longer term. There are currently 69 brands of product available through these routes and once the Windsor Framework measures are in effect, they will be licensed for use in Northern Ireland under the same conditions as they are in Great Britain. Access under NIMAR and the CAPs bridging mechanism do not carry the certainty of the supply of licensed medicines and the extent to which these would continue to be viable mechanisms in the long term is uncertain.

57. Removing the requirement for products to have separate licences in Great Britain and Northern Ireland is expected to reduce supply issues in Northern Ireland. The National Pharmacy Association (NI) has reported that "74% of [community] pharmacists have spent between 1-3 hours per day sourcing medicines"[20]. A conservative assumption based on an internal assessment, is that the arrangements for medicines under the Windsor Framework will reduce the scale of this work by half. There are c.900 full-time equivalent community pharmacists employed in Northern Ireland[21], with a median hourly wage of £24.87[22], these total search costs are equivalent to between £16k and £50k per day. Scaled up for working days in the year, and assuming these costs halve after implementation, the value of time saved is between £1.9m and £5.8m annually, equivalent to £32m over 10 years (range £16.0m - £47.9m, all values discounted).

58. The use of NIMAR creates costs to wholesalers in Great Britain due to the need to check the list to identify whether stocks of PLBG licensed products can be supplied to Northern Ireland or need to be stored and distributed separately. Industry evidence provided by one trade association[23] suggests that these checks require an estimated 0.5 of full-time equivalent (FTE) staff time per wholesaler. Avoiding these costs will generate a total industry benefit of around £140,000 per year and £1.12m over 10 years.

59. For the 67 products on the NIMAR list, the use of UK-wide licences will increase the population within scope of a licence by almost 2 million. All products authorised by the MHRA in future will also have access to this broader population.

60. Implementation of the Windsor Framework will remove the need to operate the CAPs bridging mechanism. For MHRA, the costs of running the bridging list are low since products are automatically added to the list when a new licence is authorised if it is not already approved via CAPs. The cost of the list to MA holders is staff time to notify MHRA of progress with CAPs applications and manage product codes with manufacturers and wholesalers if/when products obtain CAPs authorisation. These costs will be avoided once the mechanism ends, due to the small numbers of products utilising this route, the savings are expected to be low and have not been quantified. Based on an average of six innovative medicines authorised via CAPs per month (229 products added to the Union Register over 38 months – from Jan 2021 to Mar 2024) and 85% similarly being approved by the MHRA, only one or two products are expected to be added to the bridging list per month. Since June 2023, only two products have been added to the list.

61. The six-month limit for products to be on the CAPs bridging list creates uncertainty for medicines supply as Great Britain authorised products are not licensed for use in Northern Ireland after this period. If the EU licences the product, the version supplied to Northern

[20] committees.parliament.uk/writtenevidence/120896/html/

[21] Community Pharmacy Workforce Survey report (communitypharmacyni.co.uk) (page 15)

[22] Annual Survey of Hours and Earnings: median wage for "pharmacists" (SOC 2251) – Table 14.5a, hourly pay (gross)

[23] Information provided in correspondence with DHSC

Ireland must switch to the CAPs approved pack. If the product does not receive EU approval and there is demand in Northern Ireland, another route to supply the Great Britain pack, such as NIMAR, will be required. This means that manufacturers need to plan production processes in line with these timescales, factoring in that demand for a new drug across a small population may be uncertain. Removing this time constraint will enable longer-term planning of production processes and with lower risk of incurring costs associated with under/over production as a product in a single pack can be supplied to a market of Northern Ireland and Great Britain, for the lasting shelf-life of the medicine (which typically exceeds six months).

62. Removing the six-month time limit on the availability of Great Britain-licensed products in Northern Ireland also generates benefits for patients and clinicians by removing uncertainty about ongoing supply. This removes the risk of any delay in access to future supply that could occur if the bridging period ends and a new route, such as NIMAR needs to be secured to enable ongoing supply and treatment. We do not have data to quantify the likelihood of products falling into this category.

63. The current requirement for different licences for medicines supplied to Great Britain and Northern Ireland means that some manufacturers supplying both territories produce Northern Ireland-only packs. Due to the integration of supply chains, typically running from Great Britain to Northern Ireland, manufacturers produce two packs for the UK (one for Great Britain and one for Northern Ireland) rather than for example, Northern Ireland accessing packs destined for Ireland and the rest of the EU. The Windsor Framework eliminates this requirement by ensuring all types of medicines will be supplied in single UK-wide packs, generating savings in terms of avoided costs of designing and producing a duplicate package for Northern Ireland; down-time to switch production runs to fill the separate packs and the logistics and handling costs of maintaining separation between the packs destined for different markets. It is uncertain how many products this applies to and so it has not been possible to quantify the scale of this impact.

Risks:

64. In July 2023, the House of Lords Protocol on Ireland/Northern Ireland Committee (now the House of Lords Windsor Framework Sub-Committee) reported concerns that Northern Ireland may get slower access to cutting-edge products than Ireland after the implementation of the Windsor Framework[24]. The opposite situation could also arise, but these scenarios are not a direct result of the new measures. As described above, the availability of medicines requires both a licensing authorisation and a subsequent post-licensing assessment. So, one regulator licensing a product sooner than another is not a guarantee of faster availability to patients and it is a false comparison to draw parallels with approvals in Ireland under the EMA process.

65. During 2021, UK authorisation dates for new medicines were on average 27.5 days behind corresponding EU authorisation dates (346 and 320.5 days behind FDA authorisation dates, respectively)[25]. The new International Recognition Procedure (IRP) introduced by the MHRA from 1 January 2024 is expected to bring approval times up to, or better than the EU, certainly by 2025. The IRP is a licensing route for products that have already received an authorisation from another regulator recognised by the MHRA, such as the United States Food and Drug Administration (FDA) and Health Canada. The MHRA will conduct a targeted assessment of IRP applications with a timetable for recognition of products within either 60 or 110 calendar days.

[24] https://www.parliament.uk/business/lords/media-centre/house-of-lords-media-notices/2023/july-2023/windsor-framework-an-improvement-on-the-protocol-but-problems-remain-lords-committee-finds/

[25] https://www.frontiersin.org/articles/10.3389/fmed.2022.1011082/full

66. Once authorised, products are not available in Northern Ireland until NICE has completed its product appraisal to inform a decision by DHSSPS to make the product available. This means that the novel medicines that are or have been available in Northern Ireland are only those that have also been licensed for use in Great Britain (medicines that currently only have an EU licence in Northern Ireland are not available in practise). This process makes it unlikely that Northern Ireland patients currently have and will lose access to any medicines that are not yet available in Great Britain. Further, a study for the period 2016-2019, when licences for innovative products in the UK were under the CAPs regime (and so authorised at the same time as for Ireland (and the rest of the EU)) showed that the average time to availability of medicines in England was shorter than in Ireland: 335 days compared to 477[26].

Falsified Medicines Directive – safety features:

Baseline/Do nothing/counterfactual scenario:

67. The European Union passed the Falsified Medicines Directive (FMD) in 2011 with the aim of increasing the safety and control measures of medicines. The final part of the Directive, regarding safety features, came into effect in February 2019, requiring that packs of prescription medicines bear certain safety features, with an end-to-end verification system for identification and authentication. The system is detailed in the published Delegated Regulation (EU 2016/161). The UK agreed to implement the FMD in 2019 but it ceased to have effect in Great Britain from 31 December 2020, when the UK left the EU[27]. The FMD continues to apply in Northern Ireland.

68. The verification system requires manufacturers to include a unique identifier for each pack encoded within a 2D data matrix code. Manufacturers upload the data embedded in the 2D barcode into a repository prior to placing the product on the market and this enables products to be verified across Europe. The code is scanned at various points of the supply chain to confirm that the medicine is 'authentic'. Upon reaching patients, the unique identifier must be 'decommissioned' from the repository. Decommissioning indicates that the pack has been supplied, so any other pack bearing the same unique identifier cannot be verified or decommissioned.

69. The Regulation requires that packs exported outside of the EEA are decommissioned upon export. For products entering Northern Ireland via Great Britain, this would mean that products are decommissioned when entering Great Britain then re-uploaded to the repository prior to export from Great Britain to Northern Ireland and decommissioned again at the point of reaching the patient in Northern Ireland. A derogation from the FMD regulations is currently in effect to avoid these steps: products exported to the UK and destined for Northern Ireland do not need to have their unique identifier decommissioned when exported to the UK but these packs are still required to be decommissioned in Northern Ireland [28]. This arrangement expires on 31st December 2024 after which full FMD requirements would be expected to be re-instated. Unlike other changes made to medicines supply chains in April 2022 that were established as permanent, the derogation for decommissioning of products passing through Great Britain and destined for Northern Ireland is time limited.

[26] Microsoft Word - Root Cause Unavailability Delays CRA Report May 2021 Final.docx (efpia.eu)

[27] https://www.bma.org.uk/advice-and-support/gp-practices/prescribing/the-falsified-medicines-directive

[28] Application of the Falsified Medicines Directive: Safety Features in Northern Ireland - GOV.UK (www.gov.uk)

70. FMD requirements currently apply to most prescription medicines with a UK-wide marketing authorisation and all products with a PLNI[29], affecting almost 15,000[30] product lines on the market. In addition to this figure, FMD also applies to parallel import licences valid in Northern Ireland. Anecdotal evidence provided to the Government by trade associations has suggested that in this scenario, Northern Ireland could lose access to up to one-third of the medicines currently available. The Government was also warned of a significant increase in costs to supply the remaining medicines, to come into compliance with the requirement to decommission medicines from the EU on export to Great Britain, and then reaffix the FMD unique identifier when travelling from Great Britain to Northern Ireland. Risks to supply and product costs would also have been expected given the impact of the requirements on medicine suppliers, but evidence has not been identified to support the reported scale of disruption.

Windsor Framework scenario:

71. The Framework removes any EU FMD packaging, labelling and barcode requirements for medicines in Northern Ireland from 1st January 2025; features included for the purposes of compliance with EU FMD requirements may be removed or covered. All existing safety requirements under UK law remain unchanged and MA holders are encouraged to continue using anti-tamper packaging.

72. The disapplication of FMD is intended to prevent supply disruptions in Northern Ireland which would adversely impact patients and the healthcare sector. The current derogation from the Regulation was agreed due to a lack of any infrastructure or viability for supply chain actors in Northern Ireland moving product from Great Britain to re-commission medicines packs that had previously been decommissioned upon export from the EU to Great Britain. This would result in companies needing to set up separate stock keeping units for Great Britain and Northern Ireland.

73. Transition arrangements mean that any stock in existing packaging already placed on the market in Northern Ireland and Great Britain can continue to be supplied to patients in the relevant territory until the date of their expiry.

Costs

74. The disapplication of FMD labelling requirements could create costs for manufacturers to remove the relevant features. In practice, we expect firms to continue using anti-tamper devices and so the only change is to remove FMD compliant barcodes. We expect this to happen at the same time as MA holders update their packaging to reflect the new UK only labelling requirement; these costs of packaging changes are covered under “labelling” below.

75. Falsified medicines can pose a risk to health if they are not properly checked for quality, safety and efficacy. Falsified medicines may amongst other things, contain ingredients of bad or toxic quality, or have been poorly manufactured. The disapplication of FMD in Northern Ireland is not expected to be associated with increased risk as no such change has been observed in Great Britain since the disapplication of FMD requirements. The MHRA will continue to monitor and inspect the supply chain across the UK, to identify risks to patient safety and prevent falsified medicines from circulating within the legitimate supply chain.

[29] Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK (www.gov.uk)

[30] Value provided to DHSC by MHRA, total number of licensed prescription only medicines with a UK-wide or Northern Ireland only licence. The value reflects all combinations of pack sizes and product strengths that are licensed. This figure is not directly comparable with others in the document that count all variations of size and strength as a single product.

76. The Medicines & Medical Devices Act 2021 included provisions that enable the introduction and use of a falsified medicines system in the United Kingdom. The Government is considering the right approach for the future, and regulations would be needed to set out the detail of any scheme, which would require consultation.

77. Previous analysis of the verification system and use of unique identifiers has suggested that there will be benefits through reduced resource requirements to process product recalls. No data has been found to quantify this impact, but the higher costs of recalls without FMD in place is a cost of implementing the Windsor Framework.

Benefits

78. Once the current derogation from the FMD Regulation ends in December 2024, there would be significant cost implications for prescription medicines destined for the UK that will be avoided by bringing the Windsor Framework into effect through legislation:
    a. Packs exported outside of the EEA need to be decommissioned, meaning that all prescription medicines with UK-wide or Northern Ireland licences imported to Great Britain from the EU would need to be decommissioned upon export;
    b. Products moving through Great Britain into Northern Ireland would need to be re-uploaded to the verification system as they enter Northern Ireland; and,
    c. End users in Northern Ireland will need to continue to verify and decommission all packs with the FMD safety features.

79. This would impact exporters of prescription medicines to the UK from the EU, and wholesalers and other supply chain actors moving medicines from Great Britain to Northern Ireland.

80. These are tangible costs of moving products into the UK and so could be expected to be passed on to actors in the UK market. However, medicines licence holders have indicated that these costs are prohibitively high and are unlikely to be affordable to UK consumers. As such, the expected outcome is for medicines that become unprofitable to be withdrawn from the market. The Government has heard anecdotal evidence from the pharmaceutical sector that a significant proportion of products (as much as one-third) risk stopping being supplied to Northern Ireland in the event that FMD regulations are applied in full, with many remaining supply chains eventually re-routed away from Great Britain. Over several years, the House of Lords European Affairs sub-committees have repeatedly heard examples from industry of the anticipated challenges of the permanent application of FMD in Northern Ireland[31]. It has not been possible to assess the health impacts of medicines being withdrawn from the market as any impact is highly sensitive to the availability of alternative products and the level of health gain the product is expected to deliver. No information is available about the products at highest risk of discontinued supply to assess any potential health loss.

81. For those products that would continue being supplied, the avoided costs associated with FMD requirements are a benefit of the Windsor Framework. The extent to which these costs would be absorbed by medicines licence holders or passed on through prices is unknown and so no attempt is made to assess what the second order impacts would have been on consumers. Based on anecdotal evidence, it is assumed that two-thirds of products would continue being supplied. No further information is available to put a range around this value. Any change to this proportion will impact the relative scale of the benefits

[31] 13.10.21 Introductory inquiry Government response (parliament.uk)

arising from cost savings versus health benefits from products not being stopped, but does not change the overall benefit of the policy. The following assessment estimates the costs of adhering to FMD requirements for products that would continue to pass through Great Britain to Northern Ireland. In the absence of available evidence, no assessment has been made of the cost impact of re-routing supply chains to avoid Great Britain.

82. Based on separate evidence provided to the inquiries into the impact of Brexit, the number of medicine packs imported into the UK from the EU is estimated at 500 million[32] to 729 million[33] per year. If one-third of these stop being supplied, the number of packs within scope is 248 to 361million. Assuming that pack numbers are in proportion to the number of licences by product type, 74%[34] of all packs entering the UK from the EU would be for prescription medicines within the scope of FMD. This assumption is uncertain as there is wide variation in the number of medicine packs across licences and is likely to be an underestimate because more products in scope are likely to be higher volume generic medicines. Previous analysis by MHRA estimated that decommissioning and checking anti-tampering devices will take 2 to 5 seconds per pack. Based on these ranges, the central estimate of the total time to decommission products from the EU is 305,000 hours per year, equivalent to 141 FTE (range 65 to 239 FTE). At a labour cost of £13.20[35], the central estimate of annual costs is £3.9m, equivalent to £32.4m over 10 years (range £15m - £55m, discounted values). Additional scanning equipment may be required but the scale is unknown and so these costs have not been quantified. For context, MHRA has previously estimated that the cost per scanner is between £200 and £750[36].

83. For those products from the EU that pass through Great Britan to Northern Ireland, wholesalers in Northern Ireland will avoid the costs of re-affixing the FMD unique identifier and re-uploading the information from those packs to the repository. An industry trade association has provided an estimate that this would take around 80,000 hours per year, equivalent to 38FTE at a cost of £1.2m, , equivalent to £9.9m for ongoing costs over 10 years (discounted). This process would have also required additional hardware and floor space, at additional cost that it has not been possible to quantify.

84. Further, the disapplication of existing FMD requirements in Northern Ireland will generate savings for wholesalers in-country as the current requirement to decommission products as they reach patients in Northern Ireland will end. An industry trade association[37] has estimated that FMD costs for wholesalers in Northern Ireland are around 15 FTE at an annual cost of around £500k, £4.1m over 10 years, and will not be incurred after implementation of the Windsor Framework.

85. Verification of unique identifiers requires national and EU-wide repositories to upload and transmit information. The removal of FMD requirements in Northern Ireland will eliminate the need for the UK verification system, SecurMed UK. This will generate savings to MA holders with licences for Northern Ireland, who will no longer need to contract with and pay fees to SecurMed. For 2024, there was a one-off set-up fee of £1,000 for new MA holders

[32] In 2018, the House of Commons reported that 37 million packs of medicines per month leave the continent for the UK, equivalent to 440 million packs per year. The impact of Brexit on the pharmaceutical sector (parliament.uk). Value scaled up by 2% for assumed prescription medicine growth rate

[33] Brexit could hinder medicines supply to UK, MPs told - The Pharmaceutical Journal (pharmaceutical-journal.com). 90% of the UK's medicines are imported and 45% of those are from the EU. These values are applied to the estimated 1.8bn medicines dispensed in the UK annually, see para 92.

[34] Value reflects the proportion of prescription only medicines with an MHRA licence for Northern Ireland and the UK

[35] Annual Survey of Hours and Earnings 2023, an average of Process, plant and machine operatives and Elementary process plant occupations median wage

[36] Microsoft Word - FMD Safety Features - Consultation IA (publishing.service.gov.uk)

[37] Information provided in direct correspondence with DHSC.

to register but no annual operational fee[38]. In previous years, the annual fee has been £2,500 per MA holder[39]. Around 1,000 new licences may be issued in a year but it is unknown how many of those would be for products owned by new MA holders, the portfolio of a single organisation can be hundreds of products.

UK Only Labelling

Baseline/Do nothing/counterfactual scenario:

86. At present, there are no additional labelling requirements for medicines in Northern Ireland. This would continue in absence of Windsor Framework implementation, albeit the significant costs associated with split licences and labelling would apply.

Windsor Framework scenario:

87. The Windsor Framework sets out the long-term arrangements for the supply of medicines into Northern Ireland, meaning medicines can be approved and licensed on a UK-wide basis by MHRA. To preclude onward movement of these medicines into the EU, from 1 January 2025 medicines supplied to Northern Ireland must be labelled 'UK only'. To ensure medicines use the same packaging and labelling across the UK, from 1st January 2025 all medicine boxes on the whole UK market must be labelled as 'UK Only'. The 'UK Only' label must be presented anywhere on the outer packaging of the medicine.

88. The Government has taken steps to mitigate and address the costs to industry of this change to labelling. For example, MHRA has extended its deadline to allow manufacturers to supply medicines in legacy EU packaging across the UK until 31 December 2024, to support the transition to the new arrangements.

89. Any packs on the market in Northern Ireland at that time can continue to be supplied to patients until the data of the medicine expiry. This means that PLGB packs released prior to 1 January 2025, and on the NIMAR list can be supplied in their existing packaging to Great Britain and Northern Ireland, but PLGB packs released prior to 1 January 2025, but not on the NIMAR list, can continue to be supplied in their existing packaging to Great Britain only. The 'UK Only' label can also be applied to packaging and released to the Great Britain market before 1 January 2025.

90. To support transition, the 'UK Only' statement can be applied via a sticker for a limited period of six months, to 30 June 2025. After this date, 'UK Only' must be printed directly onto the packaging and stickering will not be accepted after this date.

91. From 1 January 2025, all Parallel Imports (PLPIs) will be authorised to be marketed across the UK. Any PLPIs with a current territorial limitation of 'GB' will be converted to UK-wide authorisations. PLPI licence holders should therefore not include 'GB' on the packaging materials of products entering the UK supply chain. As for other medicines, PLPIs must apply a 'UK only' label to packs, but can use stickering indefinitely. Holders of PLPIs will not ned to submit an application to MHRA to amend their packaging.

[38] MAHs - SecurMed

[39] Fee-Model-Table-2022.pdf (emvo-medicines.eu)

Costs

MHRA packaging change notification costs

92. MA holders are required to submit an application to the MHRA notifying them of packaging changes and incur the default MHRA notification charges. The associated costs vary depending on what type of notification is used by MA holders. If MA holders notify through an existing or planned application to the MHRA then there is assumed to be no additional cost to a MA holder from the addition of a 'UK only' mark. If MA holders have no planned application and are required to submit a bespoke notification notifying MHRA of the packaging change, then the usual MHRA fees apply of £570 per application[40]. MA holders can also submit a bulk application which can cover up to 25 licences in one group which incurs one full fee plus up to 24 half fees.

93. As of March 2024, 1,156 applications have been made from c. 19,500 licences. 81% of these applications have been made through the bespoke notification route. It has been assumed that the remaining applications will be made in the same proportions and that all bulk applications included the 25 licences. The total cost of MA holders to notify MHRA of packaging changes is therefore estimated at £9.6m.

Table 1 - Costs for MA holders to submit application notifying MHRA of packaging change.

Notification Route	Cost per application (£)	Estimated cost (£m)
Existing or planned application	0	0
Bespoke application	570	9
Bulk application (for 25 licences in one group)	7,410	0.6
Total		**10**

94. To submit the additional applications to the MHRA, additional staff resource is also expected to be required for both MA holders and the MHRA. Total staff resource for MA holders to implement the packaging changes are captured in the production costs section. The impact on MHRA is expected to be opportunity costs as staff re-prioritise activities to continue to process bespoke applications as they are submitted and well in advance of the implementation date. If applications are delayed and significant volumes arrive as a cluster and with limited processing time prior to implementation, surge resource may be required. MA holders are expected to submit applications in good time but if that trajectory changes there is a risk that MHRA will incur increased costs associated with employing temporary staff.

Production costs

95. To add the 'UK only' mark onto packaging, firms may be required to alter production processes and supply chains.

96. The total cost, and timings of costs, to MA holders will vary depending on the proportion of manufacturers who are adding the 'UK Only' mark to their products directly in the manufacturing process by 31 December 2024, and the proportion who will opt to utilise

[40] https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees

stickering to 30 June 2025. Based on MHRA intelligence, it is assumed that 2% of MA holders will utilise the temporary measure of applying a sticker while they adjust production processes.

97. The cost of altering production processes is likely to vary significantly by the size of MA holders and the number of products produced. Costs used are based on estimates received from two trade associations and included staff costs and packaging design costs. Cost estimates are based on the estimated cost per product and range from £2,200 to £3,500 per product. There is still expected to be a significant range due to range in number of products licensed and supplied by MA holders within each category. The estimate received has been internally validated using internal evidence.

Table 2 – Costs by firm size of MAH holders to alter production processes to apply `UK only` mark to packs.

Firm Size	Definition	Number of firms	Cost per firm (£k)	Total cost (£m)
Small firms	Under 25 licences	708	31 - 44	22 - 31
Medium firms	Between 25 and 100 licences	115	154 – 219	18 - 25
Large firms	Over 100 licences	42	247 – 350	10 - 15
Total		**865**		**50 - 71**

98. For firms which choose to utilise the temporary measure of adding a sticker, the cost is estimated to be £8.3m. This assumes that:

- An estimated 1.8bn boxes of medicines are annually supplied to the UK[41] for usage, with 18m (2%) requiring a sticker added over the first six months.
- It cost manufacturers £0.12 per label to produce[42].
- Estimated 10 seconds taken to add sticker to a box at the National Living Wage hourly wage as of April 2024[43].
- Initial sticker design costs of £1,545 per product[44]

Table 3 – Estimated costs for MA holders who opt to apply a sticker to packs

Cost	Estimated Cost (£m)
Cost of sticker design	0.6
Cost of additional resource	0.6
Cost of sticker	2.2

[41] Based on evidence provided by an industry trade association

[42] Internal analysis based on the chemical sector.

[43] National Minimum Wage and National Living Wage rates - GOV.UK (www.gov.uk)

[44] Cost of redesigning a label in the chemical sector is expected to sit between £190 – £2,900 per product. DocsRoom - European Commission (europa.eu), in 2024 prices

Total	**3.3**

99. After year 1 there are not expected to be any ongoing costs for MA holders to add the 'UK Only' mark to medicinal boxes as no further changes or notifications to MHRA will be required.

Monitoring costs

100. The information MHRA collects from packaging change applications will ensure MHRA has sufficient evidence MA holders are complying with the changes, including through collecting mock-ups of artwork on file received when MA holders notify MHRA of the packaging changes. This will form part of the written guarantees that the UK needs to provide to the EU to bring the Windsor Framework into effect by providing assurance that the measures agreed on 'UK only' labelling and UK enforcement are in place. This is not assumed to incur any additional costs to MHRA.

Total costs of packaging changes

101. The total, undiscounted cost, of updating packaging processes to include the `UK only` mark is estimated to be between £63m and £84m. The primary driver of this is the costs to alter production process to apply the mark directly onto packaging. This is expected to vary significantly by firm. Most firms are expected to alter their production processes in the build up to Windsor Framework implementation on 1st January 2025. After year 1 there are not expected to be any ongoing costs for MA holders to add the 'UK Only' mark to medicinal boxes as no further changes or notifications to MHRA will be required. These costs apply to all MA holders of UK medicines, irrespective of their country of ownership. It has not been possible to identify the extent to which UK firms are impacted.

Table 4 – Total undiscounted costs for MA holders to implement Windsor Framework change of `UK only` mark requirement.

Cost	**Cost (£m)**
MHRA Notification	10
Production	50 - 71
Labelling	3
Total	**63 - 84**

Benefits

102. Having one packet for all the UK eliminates existing commercial viability concerns of MA holders producing packs for Northern Ireland only. Over time, there would have been an increasing risk that the split licensing and split packaging arrangements under the status quo could lead to product discontinuations in Northern Ireland. One MA holder reported to the House of Lords European Affairs sub-committee that a situation requiring separate packs for Northern Ireland and Great Britain would be "untenable"[45]. This would impact the time spent by pharmacists to source medicines; time savings for community pharmacists

[45]Paragraph 46: 13.10.21 Introductory inquiry Government response (parliament.uk)

associated with the changes in the Windsor Framework are quantified in the licensing section of this document.

103. The addition of 'UK only' mark on products is also an enabling change for the other policy changes implemented as part of the Windsor Framework – it forms a protection for the EU's Single Market without which the changes to EU law agreed in the other elements of the Windsor Framework could not have been agreed. The significant benefits of these changes are in creating equitable supply of medicines across the UK.

Risks

104. The MHRA will publish guidance for manufacturers and wholesale dealers, including advice for export activity. This aims to address a potential supply risk reported by one trade association, associated with the use of 'UK only' labelling for batches of medicines intended to be split between the UK and other markets. For a limited number of medicines, where demand for a product in the UK is less than current batch sizes, the remainder of the batch is supplied to other, non-EU markets. If 'UK only' labelled packs are not accepted in these markets, it may not be viable to produce smaller batches to continue supply for the UK market.

Changes in that only data market exclusivity periods (DME) for UK licensed medicines are those of the UK medicine which is the Reference Medicinal Product (RMP).

Baseline/Do nothing/counterfactual scenario:

105. Novel medicines in Northern Ireland are covered under Data Market Exclusivity (DME) as per EU authorisation where they are regulated via CAP. For a generic medicine to be authorised in Northern Ireland, an EU reference product must be used and EU DME periods, and other novel medicine protection measures, must have expired.

106. Following the UK's exit from the European Union, in Great Britain, products within the scope of the CP continue to be authorised either nationally through full applications, or via the ECDRP (EC reliance route), since 1 January 2024 superseded by the International Recognition Pathway. These innovator products are authorised presently under Great Britain -only licences. The expiration of the DME period and therefore the possibility of marketing authorisation applications for generic products is based on the Great Britain dates.

107. Where Great Britain periods expire sooner than EU periods, in some cases generics manufacturers may release a Great Britain product before the EU licence expires. Where EU periods expire sooner, in some cases generics manufacturers may release a Northern Ireland product before the EU licence expires, through an EU mutual recognition or decentralised procedure[46]. In order to release a generic valid across the UK, both the UK and the EU DME periods must have expired. This situation leads to divergence in supply of medicines and the associated costs such as inequitable access and challenges for supply chains.

[46] The mutual recognition and decentralised procedures are routes for companies to request marketing authorisations in several member states for medicines that are outside the scope of the EU centralised procedure (i.e. most generic medicines and medicines available without a prescription can be authorised through these routes).

Windsor Framework scenario:

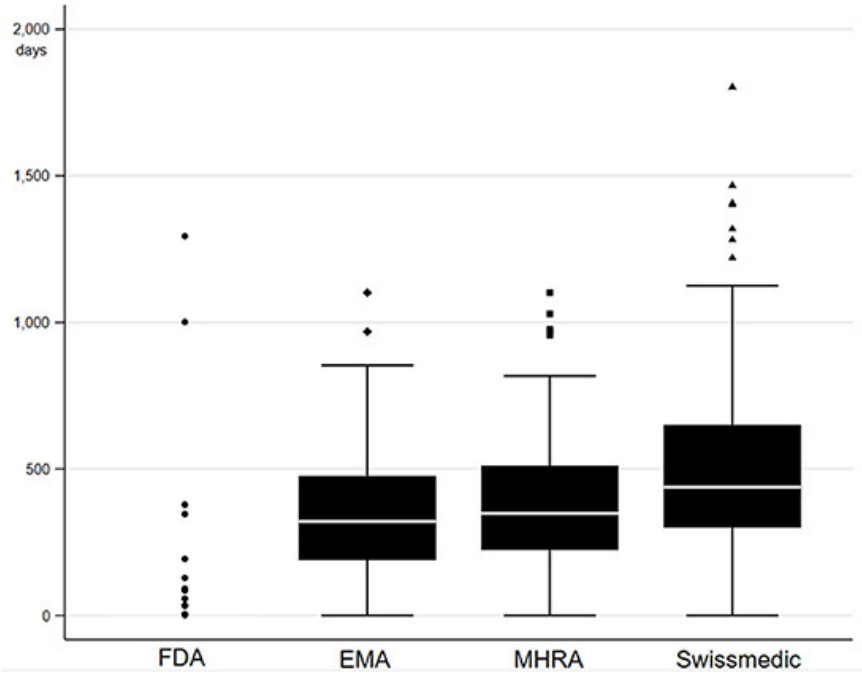
108. Under the changes introduced by the Windsor Framework, innovative medicines will have whole UK licences, and so will be valid RMPs for generic applications across the UK. The SI provides that applications for UK-wide generics must use a UK innovator as the reference product. This means that the relevant DME periods for UK generic applications using UK innovators are those of the UK medicine. The SI will provide that for an application for a UK-wide generic licence, a UK innovator product must be used. Given UK DME periods will apply to UK-wide products, Northern Ireland will get access to the same generics as Great Britain at the same time. There are currently 150 generic medicines on the NIMAR list, one reason for this is due to differences in the reference product between Great Britain and the EU. Making the UK innovator product the reference for all UK medicines will enable MHRA to switch the Great Britain licences for all generic products on the NIMAR list to be valid UK-wide. The benefits of UK-wide licensing, including to clinicians and patients in Northern Ireland are set out in paragraphs 48 to 50.

109. It will remain possible to apply for a Northern Ireland -only licence as part of the EU's MR/DC Procedure. In this case a European Reference Product (ERP) will be used, and EU DME periods will be applicable. Therefore where DME periods attaching to a UK innovator expire later than those attaching to its EU counterpart, Northern Ireland may benefit from earlier access to medicines. However, in practice, is unlikely to be attractive to many manufacturers given the size of the Northern Ireland market. Presently, Northern Ireland access to generics is usually aligned with the Great Britain and Northern Ireland benefits from supplies of generic medicines when Great Britain exclusivity periods expire, as (if the EU periods have also expired) this enables the creation of UK-wide packs. The agreed terms of the Windsor Framework result in no change to Great Britain access to medicines.

110. The scale of the costs and benefits are subject to sequencing of approvals and time taken for generics to enter market but likely to be a net benefit, given that Northern Ireland -only generics are exceedingly rare as it is rarely commercially advantageous to produce a medicines pack specifically for the Northern Ireland market, given its size. During 2021, UK authorisation dates for new medicines were on average 27.5 days behind corresponding EU authorisation dates (346 and 320.5 days behind FDA authorisation dates, respectively) as shown in Figure 1[47].

[47] Frontiers | Regulatory policy and pharmaceutical innovation in the United Kingdom after Brexit: Initial insights (frontiersin.org)

Figure 1 – Drug approval lag in days for novel medicines authorized in 2021 by regulator.



111. Where the UK approves innovative medicines before the EU, under the Windsor Framework, Northern Ireland will get access to generic versions of the medicines earlier than they would have done under present arrangements, when bound by EU DME periods. This saves costs for Northern Ireland which will avoid needing to pay higher prices for innovative products where they are exclusively on market for longer.

Direct costs and benefits to business calculations

112. Implementation of the Windsor Framework is expected to have a positive impact on business but not all benefits been able to be quantified in this assessment.

113. Total direct costs for all affected businesses are estimated to be between £68m and £88m but these are all expected to be transitional costs. For less than 3% of licences, the changes will create additional reporting requirements. The businesses holding these licences are expected to incur low value ongoing costs associated with ongoing periodic product safety reporting. No other ongoing costs have been identified post implementation of the Windsor Framework.

114. Total direct benefits to businesses arise from the permanent disapplication of FMD requirements for products in Northern Ireland. The end of the derogation from 1 January 2025 and the ongoing need for products to be decommissioned before reaching patients in Northern Ireland under the status quo imposes additional processing costs for all affected medicines and these costs are avoided as a result of bringing the Windsor Framework into effect through legislation. These benefits are annual and estimated to be between £33m and £81m over 10 years.

115. Due to the global nature of the pharmaceutical industry and insufficient data currently available to estimate production for domestic consumption compared to export, it has not been possible to isolate the costs above to those solely on businesses operating in the UK. In 2021, there were 790 businesses in the UK in the core biopharmaceuticals sector[48]. It is not known how many of these produce products licensed for and consumed in the domestic market and how many operate solely for export; the UK is broadly in balance for trade in pharmaceuticals with exports of £26.1bn and imports of £25.4bn in 2023. Separately,

[48] BaHTSS_accompanying_data_tables_2021.ods (live.com) Table 1

evidence provided to the Health and Care Select Committee in 2017 indicated that "90% of UK medicines are imported"[49], suggesting that transition costs of the policy are likely to impact firms globally.

Risks and assumptions

116. This Impact Assessment uses the best available data and evidence to assess the options under consideration but there is insufficient evidence to fully quantify all of the impacts of Windsor Framework implementation. The estimated cost to business from implementing the required packaging changes is the primary driver of costs. Assumptions used for the assessment are based on figures received by industry trade associations but are likely to vary significantly by firm. Other main assumptions used to estimate the scale of the impact related to the proportion MA holders planning on using stickers for the first six months and the amount of time currently used by organisations to source and supply medicines in Northern Ireland via the range of routes currently available.

117. One of the potential costs of implementing the Windsor Framework not captured in the quantitative assessment is the additional costs for MHRA to process the remaining licence change applications before 1 January 2025. No additional costs are required for MHRA for notifications going through existing applications as they are expected to be processed using current workforce but for bespoke notifications MHRA surge resource may be required if applications are concentrated in the latter part of 2024. It is currently unknown if additional surge resource will be required through contracting of additional staff (and beyond re-prioritising activities within MHRA to facilitate this work) and so this has not been captured in the quantitative assessment.

118. The assessment does not assume that businesses will incur any destruction costs from produced batches of medicinal not being allowed to be supplied to the market after 1st January 2025 and having to be disposed of. This is however deemed unlikely. Any product supplied to the market before the 1st of January 2025 is allowed to stay on the market until the product's expiry date. MA holders have also been given a long notice period of the changes so businesses are expected to be operationally ready by the time measures come into the force. There is a chance that excess supply will be launched to the market pre-1st January 2025 for firms to use any existing stock already produced. The extent to which this will occur is dependent on storage facility volumes.

119. Due to the global nature of the pharmaceutical industry it has not been possible to isolate the impacts of the policy on the sector in the UK. The legislation impacts all medicines authorised for distribution in the UK and the analysis presented reflects the totality of costs and benefits. The analysis may overestimate the impact on UK society if the costs that are incurred or avoided are not fully passed on to end users, including patients and the health sector in the UK.

Impact on small and micro businesses

120. Small and Micro Businesses (SMBs) are likely to be disproportionately impacted by implementation of the Windsor Framework as costs do not vary directly by firm size, but as outlined below, these are not expected to be prohibitive.

121. The costs of implementing the changes to medicines supply as set out in the Windsor Framework fall on firms in the biopharmaceuticals sector. The changes create one-off costs

[49] Brexit could hinder medicines supply to UK, MPs told - The Pharmaceutical Journal (pharmaceutical-journal.com)

for MA holders, to update product licences and to fund the changes required to the packaging of all products to be sold in the UK.

122. Data is not available to directly measure the number of small and micro businesses that may be impacted. In terms of the UK core biopharmaceuticals sector, small and micro enterprises accounted for accounted for 57% of all sites (noting that some firms will have multiple sites) but less than 1% of total turnover generated by the sector in 2021/22[50] as shown in Table 7.

Table 5 – Number of sites and turnover in the UK associated with core biopharmaceuticals businesses by business size, 2021/22

Sector	Business size	Number of sites	Turnover (£bn)
Biopharmaceuticals – Core	Large	393	45.6
Biopharmaceuticals – Core	Medium	70	0.8
Biopharmaceuticals – Core	Small	157	0.2
Biopharmaceuticals – Core	Micro	457	0.1
Biopharmaceuticals – Core	Unclassified	7	0.0

123. Costs are dependent on the number of product licences a firm has and by definition, smaller firms are likely to have fewer licences. It is estimated that the cost per licence of implementing the Windsor Framework is less than £50,000 in one-off costs for changes to licences and packaging as shown in Table 8. In addition, any small businesses currently with PLGB licences for category 2 medicines will face additional small unmonetised reporting costs as a result of additional reporting requirements as outlined in paragraph 49. It is unknown whether any small firms will be impacted.

Table 8 – Summary of monetised costs to small businesses

Cost type	Value per firm (£)
Familiarisation costs	600 – 1,000
Licence change fees	Up to £570 per licence
Production process changes	31,000 – 44,000

124. The main benefits of the changes to MA holders are unmonetised, arising from the increased certainty for the supply of products to Northern Ireland with the implementation of permanent changes for the MHRA to be the regulator for the whole of the UK. Simplification of the licensing system, including removing the need for the NIMAR list and CAP bridging mechanism provides stability for supply and increases the population in scope of an individual licence which are expected to generate efficiencies and opportunities for licence holders.

125. In the absence of directly observable data, the assumed turnover of individual small businesses in the pharmaceutical sector is based on the small business exclusion threshold from the NHS Statutory scheme for branded medicines pricing. The scheme excludes firms with less than £5m of NHS medicine sales[51]. The assumption that small businesses in the pharmaceutical sector have turnover of £5m provides a benchmark to assess the relative scale of the costs of legislating for the changes in the Windsor Framework.

[50] Bioscience and health technology sector statistics 2021 to 2022 - GOV.UK (www.gov.uk)

[51] Proposed review of the 2023 scheme to control the cost of branded health service medicines: impact assessment (publishing.service.gov.uk)

126. Assuming that manufacturers pass the packaging change costs on to the product licence holder, for a small business with 5 licences and a turnover of £5m, this cost (£250k) represents less than 5% of turnover in one year. It has not been possible to assess the profitability of small and micro businesses within the wider pharmaceutical sector. While there is variation in the profitability of individual firms, estimates underpinning the Statutory Pricing Scheme indicated that UK shareholders in pharmaceutical companies may see an increase in profits of around £600m by 2026.

127. The main benefits of the changes to MA holders are unmonetised, arising from the increased certainty for the supply of products to Northern Ireland with the implementation of permanent changes for the MHRA to be the regulator for the whole of the UK. Simplification of the licensing system, including removing the need for the NIMAR list and CAP bridging mechanism provides stability for supply and increases the population in scope of an individual licence.

128. The other types of small businesses that will benefit from the changes are community pharmacists in Northern Ireland. The disapplication of the FMD safety regulations is expected to reduce the time currently spent sourcing medicines Evidence suggests that almost half of community pharmacies in Northern Ireland are 'independents and small chains'[52], with 265 of 532 businesses in this category. Just over one-third of the workforce (37%) are employed in this category, equivalent to an average of 1.7 pharmacists per pharmacy. Increased certainty of supply is expected to reduce time currently spent by pharmacists to source required medicines, saving an estimated £3,600 - £10,900 per community pharmacy.

129. There is no flexibility within the regulation to exempt small and micro business from the statutory instrument enforcing the agreed terms of the framework which has been negotiated with the EU. It is likely that SMBs are disproportionally affected by the implementation of the Windsor Framework arrangements on medicines, primarily due to the costs required to adjust production processes to add the 'UK only' marking to packaging. SMBs are estimated to incur 44% (£31m) of the costs to altering production processes however the costs of implementing the agreed terms of the Windsor Framework are not expected to be a prohibitive cost.

Wider impacts (consider the impacts of your proposals)

130. Implementation of the agreed terms of the Windsor Framework is likely to impact medicine licence holders, manufacturers, suppliers and distributors of medicines, MRHA, clinicians, pharmacists and patients. To assess the potential impact of the proposed policies against the Governments duties under the Equality Act 2010 a separate Equality Impact Assessment has been produced for this policy which will be published alongside this IA.

131. The terms of the Windsor Framework will not impact the competitiveness of the pharmaceutical market. While the changes may increase product choice in Northern Ireland, the medicines available will be the same as those in Great Britain. Due to the relatively small scale of the Northern Ireland market alone (by population, 2.9% of Great Britain), this small expansion of market size is not expected to strongly influence firms' decisions about whether to supply products to the UK. Implementation does not limit the number of firms which can operate in the market or discourage firms operating. Costs to individual firms may vary depending on the number of licences and the complexities of their current supply chain but are one-off costs and are not expected to be prohibitively high for

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individual firms. As an indication of the relative scale of the sector and the industry's contribution to the UK economy, in 2020, the gross value added (GVA) of pharmaceutical manufacturing in the UK was £17.1bn[53] and in 2021, the biopharmaceutical sector generated turnover of £40.8bn[54].

132. The Windsor Framework is also not expected to have significant environmental impacts with a low proportion of MA holders assumed to be utilising the temporary sticker addition to boxes. Any additional stock of medicines is also able to be put onto market pre 1st January 2025 and be used up to the point of natural expiry so there is not expected to be waste products.

A summary of the potential trade implications of measure

133. The one-off costs associated with updating licence and packaging arrangements will impact overseas businesses that have licences to supply products in the UK. These costs are small relative to the value of the UK market to these firms, worth £25.4bn in 2023 and not expected to impact trade. The benefits of bringing the Windsor Framework into effect through legislation outweigh these costs by simplifying the UK licensing regime and improving access to the population and health sector of both Great Britain and Northern Ireland simultaneously.

134. Implementation of the agreed terms of the Windsor Framework will have a positive impact on supply of medicines to Northern Ireland. Without intervention, there is a risk that in the long term there could be significant issues with the supply of medicines which could potentially have public health impacts. The Windsor Framework brings Northern Ireland into line with many arrangements already in place for Great Britain, facilitating the continuing trade in medicines between Great Britain and Northern Ireland.

Monitoring and Evaluation

135. The regulatory changes outlined in the Windsor Framework aim to give patients across the UK equitable access to medicines, facilitating more stable and consistent supply. By unifying licensing arrangements and reducing trade frictions, suppliers will be better able to plan production and manage supply chains under stable regulatory conditions, rather than current temporary and contingency provisions.

136. There are several reasons for licensed products not being available in Northern Ireland, including compliant packs not being produced for the Northern Ireland market, and the EU's FMD regulation. The NIMAR list provides a temporary solution to this and other supply issues by enabling products to be supplied on an unlicensed basis in Northern Ireland where patients would otherwise not have access to them. Both NIMAR and the CAPs bridging mechanism help to make products licensed in Great Britain available in Northern Ireland, either on an unlicensed basis (via NIMAR) or licensed for a time-limited period (via the bridging system). While these arrangements mean that most products for which there is demand in Northern Ireland are available, the administration and logistics required to supply the Northern Ireland market is a barrier to the smooth flow of supply.

137. The licensing changes introduced in the Windsor Framework remove these barriers through the disapplication of FMD in Northern Ireland and establishing MHRA as the single regulatory unit for the UK, issuing whole UK licences. This long-term solution means that one licence application and one pack design is needed to supply a product to Great Britain

[53] GVA is calculated either as the value of outputs from production minus the value of the inputs used, or revenue from pharmaceuticals minus the costs of production:

[54] Bioscience and health technology sector statistics 2021 - GOV.UK (www.gov.uk)

and Northern Ireland. This is expected to reduce medicine supply shortages in Northern Ireland by removing the duplication of licence application processes and enabling manufacturers to use single production runs for medicines that can be sold UK-wide.

138. The Department of Health and Social Care has an established process to identify threats to medicines supply and manage disruptions when it occurs and this will continue. Implementation of the Windsor Framework is expected to be associated with a reduction in reporting of supply shortages in Northern Ireland associated with packaging and licensing, and the likely elimination of the need for medicines to be supplied via NIMAR. The reasons for future reports of supply shortages will be kept under review.

139. Currently, when there are supply shortage risks in Northern Ireland due to packaging and licensing issues, the Department carries out a risk assessment on a case-by-case basis to determine whether addition to the Northern Ireland MHRA Authorised Route (NIMAR) list is required so that a GB licensed pack can be supplied, or whether another mitigation measure would be more appropriate e.g. can an alternative supplier cover. This system has been effective in preventing supply shortages as a result of packaging and licensing issues up until now. Implementation of the Windsor Framework will more closely align packaging and licensing requirements between Northern Ireland and the rest of Great Britain. The Government expects this to result in significantly less Northern Ireland-specific medicine supply issues and this will be monitored via the reporting of supply shortages.

140. The disapplication of the FMD safety regulations in Northern Ireland also permanently avoids the need for the processing of unique identifiers for products passing through Great Britain from the EU to Northern Ireland. Stakeholders had indicated that the costs associated with setting up and operating such a process created significant risks to medicines supply in Northern Ireland, with anecdotal reports of the possible removal of one-third of products from the market. The changes introduced by the Windsor Framework eliminate this supply risk.

141. The packaging requirements for all medicines on the UK market to be labelled as “UK only” represents a protection for the EU market, addressing the risk that products intended for the UK enter the EU. This measure enables the other changes to be brought into effect. Packaging design forms part of the licence conditions for a medicine and so all new designs need to be shared with the MHRA to hold on file and the updated packaging will form part of the medicine’s licence. MA holders can only use the packaging attached to a product’s licence and any breach of this condition would jeopardise a medicine’s licence and be treated accordingly as non-compliance. MA holders are already able to submit mock-ups of new packaging artwork to MHRA, progress is being tracked and as of March 2024, 1,156 applications had been made.

142. In 2024, the UK Government will provide Written Guarantees to the EU that it has put in place the measures necessary on labelling and enforcement, which will see the Windsor Framework arrangements take effect on 1 January 2025.