

# HOUSE OF LORDS

## Secondary Legislation Scrutiny Committee

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### 34th Report of Session 2022–23

**Drawn to the special attention of the house:**

**Draft Windsor Framework (Democratic Scrutiny)  
Regulations 2023**

**Branded Health Service Medicines (Costs)  
(Amendment) Regulations 2023**

**Includes information paragraphs on:**

Draft Flags (Northern Ireland) (Amendment) Regulations 2023      Gas Safety (Management) (Amendment) (No.2) Regulations 2023

Gas Safety (Management) (Amendment) Regulations 2023

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## *Secondary Legislation Scrutiny Committee*

The Committee's terms of reference, as agreed on 12 May 2022, are set out on the website but are, in summary:

To report on draft instruments published under paragraph 14 of Schedule 8 to the European Union (Withdrawal) Act 2018; to report on draft instruments and memoranda laid before Parliament under sections 8 and 23(1) of the European Union (Withdrawal) Act 2018 and section 31 of the European Union (Future Relationship) Act 2020.

And, to scrutinise –

- (a) every instrument (whether or not a statutory instrument), or draft of an instrument, which is laid before each House of Parliament and upon which proceedings may be, or might have been, taken in either House of Parliament under an Act of Parliament;
- (b) every proposal which is in the form of a draft of such an instrument and is laid before each House of Parliament under an Act of Parliament,

with a view to determining whether or not the special attention of the House should be drawn to it on any of the grounds specified in the terms of reference.

The Committee may also consider such other general matters relating to the effective scrutiny of secondary legislation as the Committee considers appropriate, except matters within the orders of reference of the Joint Committee on Statutory Instruments.

## *Members*

[Lord De Mauley](#)

[Baroness Harris of Richmond](#)

[Lord Hunt of Wirral](#) (Chair)

[Lord Hutton of Furness](#)

[Baroness Lea of Lymm](#)

[Lord Powell of Bayswater](#)

[Baroness Randerson](#)

[Baroness Ritchie of Downpatrick](#)

[Lord Rowlands](#)

[Lord Russell of Liverpool](#)

[Lord Thomas of Cwmgedd](#)

## *Registered interests*

Information about interests of Committee Members can be found in the last Appendix to this report.

## *Publications*

The Committee's Reports are published on the internet at <https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/publications/>

## *Committee Staff*

The staff of the Committee are Christine Salmon Percival (Clerk), Philipp Mende (Adviser), Chris Smith (Adviser), Jane White (Adviser) and Glenn Chapman (Committee Operations Officer).

## *Further Information*

Further information about the Committee is available at <https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/>

The progress of statutory instruments can be followed at <https://statutoryinstruments.parliament.uk/>

The National Archives publish statutory instruments with a plain English explanatory memorandum on the internet at <http://www.legislation.gov.uk/uksi>

## *Contacts*

Any query about the Committee or its work, or opinions on any new item of secondary legislation, should be directed to the Clerk to the Secondary Legislation Scrutiny Committee, Legislation Office, House of Lords, London SW1A 0PW. The telephone number is 020 7219 8821 and the email address is [hlseclegscrutiny@parliament.uk](mailto:hlseclegscrutiny@parliament.uk).

# Thirty Fourth Report

## DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

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### Draft Windsor Framework (Democratic Scrutiny) Regulations 2023

*Date laid: 20 March 2023*

*Parliamentary procedure: affirmative*

*These draft Regulations propose to implement in domestic law the so-called Stormont Brake, a key part of the Windsor Framework which was agreed by the Government and the EU in February to address “political, economic and societal difficulties” caused by the operation of the Northern Ireland (NI) Protocol. Specifically, the draft Regulations seek to deal with the “democratic deficit” around the application of EU law in NI by introducing a mechanism for the NI Assembly to trigger a veto by the Government in the application of certain new or amended EU laws in NI which would otherwise have a “significant impact” on NI businesses or citizens. The draft Regulations were laid before Parliament under the affirmative procedure on 20 March and have been scheduled for debate in the House on 29 March. We regret that this has reduced the time available to the House to scrutinise the instrument, compared to the time that is usually available. In this report we note political concerns about the proposals but do not offer any comment on these concerns, and that further legislation will be needed to implement other aspects of the Windsor Framework.*

**The draft Regulations are drawn to the special attention of the House on the ground that they are politically or legally important and give rise to issues of public policy likely to be of interest to the House.**

1. These draft Regulations have been laid before Parliament by the Northern Ireland Office (NIO) to implement in domestic law the so-called Stormont Brake (“the Brake”), a key part of the Windsor Framework (“the Framework”) which was agreed by the Government and the EU on 27 February 2023.

#### *Purpose of the Stormont Brake*

2. According to the Government’s Command Paper, the Framework seeks to address “acute political, economic and societal difficulties” caused by the operation of the Northern Ireland (NI) Protocol over the last two years.<sup>1</sup> The Government say that the Brake is to apply to new or amended EU rules which would otherwise be applied automatically in NI and which would have a “significant impact on the day-to-day lives of businesses and citizens” in NI. Once activated, the Brake would give the Government power to veto new or amended EU rules from applying in NI. The Government emphasise that the Brake would operate “in line with the normal operation of cross-community safeguards in Northern Ireland, fully in line with the spirit and practice of the Belfast (Good Friday) Agreement”.
3. The Brake cannot become available until the NI Executive is restored and is operational, including with a First Minister and deputy First Minister

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<sup>1</sup> HM Government, *The Windsor Framework: A new way forward*, CP 806 (27 February 2023): [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1138989/The\\_Windsor\\_Framework\\_a\\_new\\_way\\_forward.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1138989/The_Windsor_Framework_a_new_way_forward.pdf) [accessed 23 March 2023].

in post, and the NI Assembly is sitting regularly. The NIO states in the Explanatory Memorandum (EM) that Members of the Legislative Assembly (MLAs) “wishing to operate the Brake must be individually and collectively seeking in good faith to fully operate the institutions, including through the nomination of Ministers and support for the normal operation of the Assembly”.

*How the Stormont Brake would operate*

4. The draft Regulations propose the framework, processes and timescales for operating the Brake. Under this new mechanism, 30 MLAs from at least two different parties (which could be of the same community designation) may notify the Government that the Brake has been initiated in cases where a “significant amended or replaced EU goods rule, or part of a rule, would have a significant impact specific to the everyday lives of communities that would be liable to persist”.
5. According to a House of Commons Library Research Briefing, the Brake “will only apply to changes to EU goods, agriculture and some customs laws (also known as rules or acts) within the scope of the original Protocol”, While there is no process for the Assembly or the Government to object to the amendment or replacement of EU laws outside the scope of the Brake, that is those which relate to State aid, the Single Electricity Market or most of the EU’s customs code<sup>2</sup>. The notification that the Brake has been initiated by MLAs would go directly to the Government without any form of vote or approval in the Assembly.
6. Once the Brake has been initiated by the Assembly, the draft Regulations propose a binding statutory obligation on the Government to trigger the Brake with the EU. The Government would do so by notifying the EU in writing via the Joint Committee, which was established under the Withdrawal Agreement, that the Brake has been applied. Once the Brake has been triggered in this way, the new or amended EU goods rule are suspended automatically from applying in NI. They can subsequently be applied only if the Government and the EU both agree to this in the Joint Committee, but the draft Regulations further propose that the Government must not agree to apply any new or amended EU law that has been subject to the Brake in NI through the Joint Committee unless there has been cross-community agreement to this in the Assembly. In any cases where the Government do not accept a notification by MLAs that the Brake has been initiated, the Secretary of State has to set out the reasons in writing to the Assembly.
7. The draft Regulations provide for a new “Windsor Framework Democratic Scrutiny Committee” (“the Committee”) in the Assembly to support MLAs in considering whether the new power should be used, including through inquiries and reports. To support this scrutiny function, the Government will notify the Committee of any new legislative proposals or acts published by the EU.
8. According to the NIO, it is not intended that the Brake will be available for “ordinary political or policy preferences”. The Government state that the Brake “will not be available for trivial reasons: there must be something ‘significantly’ different about a new rule, whether in its content or scope, and

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2 House of Commons Library, Northern Ireland Protocol: The Windsor Framework, Research Briefing, [CBP 9736](#), 21 March 2023 [accessed 21 March 2023].

MLAs will need to show that the rule has a ‘significant impact specific to everyday life’ that is liable to persist”.<sup>3</sup> The Regulations further propose that the Brake must not be initiated where there is cross-community support for a new or amended EU rule, where the rule would not create a new regulatory border between Great Britain and NI, or in other exceptional circumstances. If a new rule is proposed to be added to the Framework in either of those scenarios, a Minister must make a statement to Parliament before doing so, setting out why these circumstances have been met.

9. Asked for further detail about the exceptional circumstances under which the Brake may not apply, the NIO explained that:

“Exceptional circumstances is intended to take its usual meaning. Given the broad range of potential rules to which a decision may apply, and the circumstances in which a decision could be made, it would not be a matter for an exhaustive technical definition. We have, however, explicitly clarified that it includes circumstances in which the Assembly and Executive are not functioning (in paragraph 18(5) [of the draft Regulations]), given that there is no means for an applicability resolution to be passed in those circumstances”

10. The NIO states in the EM that the operation of the Brake process is “solely an internal one” for the UK, with “no role” for the EU, and that the only step the EU can take during the process is “to request further information on the basis on which the Brake has been triggered [ ... ] limited to a single request within a fortnight of the notification being provided, to which the UK responds within a fortnight, avoiding any delay in the process overall”. According to the NIO, the EU “is only able to challenge the use of the Brake after a decision has been made and the rule has been suspended, and may do so only through the normal international arbitration route” and not through the Court of Justice of the EU “which has no role”. The NIO adds that the exercise of the UK’s veto in the Joint Committee “is also solely a matter for the UK”.

### *Consultation*

11. The EM states briefly that the Government “considered and reflected engagement and consultation with interested stakeholders, including the Northern Ireland parties, in drafting these Regulations”. Asked for further information on this consultation and engagement, the NIO told us that:

“Ministers and officials briefed representatives from the five largest NI parties on a number of occasions over the past few weeks. This was followed up with engagement with businesses and community representatives this week.”

### *Concerns*

12. While we understand that there will be concerns and questions about the proposed Brake and about potential political and constitutional implications of the new mechanism for NI and the rest of the UK, we do not consider it appropriate to comment on these issues in this report.

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3 HM Government, *The Windsor Framework: A new way forward*, CP 806 (27 February 2023): [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1138989/The\\_Windsor\\_Framework\\_a\\_new\\_way\\_forward.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1138989/The_Windsor_Framework_a_new_way_forward.pdf) [accessed 23 March 2023].

*Other aspects of the Windsor Framework*

13. The EM does not state whether further secondary legislation will be needed to implement other aspects of the Framework. The NIO told us that:

“As the Government’s Command Paper sets out, both the UK and EU will need to take forward further legislative measures to translate the solutions of the Windsor Framework into law in respective legal orders.

This will include, for example, those measures necessary to give effect to the zero rate on the installation of energy-saving materials, or to remove any requirement to apply the ecommerce One Stop Shop requirements for internal UK movements; to underpin the operation of the new green lane; to further enshrine unfettered access for Northern Ireland goods to the whole UK market; and to apply the new UK-wide medicines licensing framework. The full range of measures required is the subject of ongoing consideration, but we would expect to put many of these arrangements into force using statutory instruments under existing powers.”

*Urgency*

14. The draft Regulations were laid before Parliament under the affirmative procedure on 20 March, were debated and voted on in the House of Commons on 22 March and have been scheduled for debate in the House of Lords on 29 March. The Government state that “[i]mplementing the Framework expeditiously is essential to providing assurance and certainty as to what the Framework will mean in practice”. **We regret that this urgency has reduced the time available to the House to scrutinise the instrument, compared to the time that is usually available. We hope that further legislation laid to implement other aspects of the Windsor Framework will adhere to the usual timescales and scrutiny arrangements.**

**Branded Health Service Medicines (Costs) (Amendment) Regulations 2023 (SI 2023/239)**

*Date laid: 20 March 2023*

*Parliamentary procedure: negative*

*The Government run two parallel schemes for controlling the cost of branded medicines to the NHS: a voluntary scheme to which more than 90% of pharmaceutical companies belong and a default statutory scheme for the rest. These Regulations amend the clawback rate in the default scheme to 27.5% for the rest of the calendar year.*

*The Association of the British Pharmaceutical Industry has written to us with a number of objections, in particular focusing on its view that the increased payment to the NHS will damage the development and launch of new medicines and lead to disinvestment in the UK. The Department of Health and Social Care has provided a robust response, setting out a well-evidenced but different point of view. Both are published in full on our website. The House will wish to note that the current voluntary scheme is due to run out at the end of this year and that negotiations for another five years are about to start.*

**These Regulations are drawn to the special attention of the House on the grounds that they are politically or legally important or give rise to issues of public policy likely to be of interest to the House.**

### *Background*

15. The Government run two schemes designed to control the prices of branded medicines supplied to the NHS. Over 90% of pharmaceutical companies that sell branded medicines to the NHS belong to a voluntary scheme, those that do not default to the Statutory Scheme which these Regulations amend. (The operation of both schemes is described in more detail in the submissions mentioned below and published in full on our website.<sup>4</sup>) A significant proportion of the NHS budget in England is spent on medicines, of a total £17.8 billion spent in England in 2021–22, £13.6 billion (76%) was spent on branded medicines.
16. Both schemes were revised in 2018 when, following consultation, they changed from a price cut scheme to a rebate scheme, where, based on sales volumes, the companies have to repay a percentage of the price back to the NHS. This instrument increases that “clawback” percentage for the rest of this calendar year in the Statutory Scheme to 27.5%. This is a marked increase from 14.3% in 2022 and 10.9% in 2021 which the Department of Health and Social Care (DHSC) should justify more clearly, than is currently done in the Explanatory Memorandum (EM).
17. In the EM DHSC states that the objective is for the two schemes to work together to create an environment where medicines are supplied at an affordable price, in a way consistent with supporting both the life sciences sector and the broader economy. To this end, the Government allow annual price growth of 1.1% and aim to maintain broad commercial equivalence between the two schemes.

### *Differing views*

18. The Association of the British Pharmaceutical Industry (APBI) has sent a submission setting out its unhappiness with the increase. It also argues that this will undermine firms’ ability to conduct research into new drugs and, citing recent examples, that it will encourage pharmaceutical firms to invest in countries other than the UK. The submission states that the UK’s 27.5% clawback rate compares poorly with 12% in Germany, 7.5% in Spain and 9% in the Republic of Ireland.
19. DHSC has provided a robust response outlining where it disagrees with the APBI and why. Although its primary objective is to control expenditure on medicines (on the basis that more money spent on medicines means less money spent on operations and other types of care) the response sets out the DHSC’s view on the research landscape and lists recent successes in new medicines. It notes that in the voluntary scheme new medicines are subject to more favoured conditions with 0% clawback for the first three years. The response sets out in detail DHSC’s explanation for why the clawback rate, which was less than 10% when the schemes were set up, has escalated (in part due to a deferment from 2022).

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4 Written evidence from APBI and Department of Health on Social Care: <https://committees.parliament.uk/publications/34508/documents/189988/default/>.

*Consultation*

20. We note that all bar one of those who responded to the consultation rejected the proposal (32 of 33 respondents). We also note DHSC's defence of its short consultation period, 39 days over the Christmas period, but take the view that it was insufficient, particularly when the issue under discussion is known to be contentious.

*Conclusion*

21. Both submissions are well argued and supported by evidence but present very different viewpoints. The House will wish to note that the current voluntary scheme is due to run out at the end of this year and to be renegotiated for another five years. Should agreement not be reached, all firms will revert to the Statutory Scheme.
22. DHSC argues that the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry, negotiated and signed up to the current voluntary scheme in 2019, describing it as a "pro-innovation deal", and that the Department is simply following that agreement. We observe that the financial turbulence of the last few years and the very specific stresses put on the health sector by the pandemic, could not have been predicted when that agreement was signed.
23. We also note that DHSC says that certain factors used in setting the current clawback rate will not apply in 2024 and stresses that it is open to ideas about how the successor to the voluntary scheme should operate and looks forward to working with industry to agree a mutually beneficial successor that supports better patient outcomes, ensures the sustainability of NHS spend on branded medicines, and enables a strong UK life sciences industry. On the basis of these two submissions that may be a protracted negotiation.



## INSTRUMENTS OF INTEREST

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### Draft Flags (Northern Ireland) (Amendment) Regulations 2023

24. These draft Regulations would change the days when the Union Flag must be flown from government buildings and courthouses in Northern Ireland, to reflect the change of monarch and the new Prince of Wales. Three annually recurring dates would be removed from the list: the birthday, accession and coronation days of the late Queen Elizabeth II. Dates added would be four related to King Charles III (His wedding, birthday, coronation and accession) plus the birthday of the Queen Consort. The entry for the birthday of the Prince of Wales will also change. These alterations would align the rules in Northern Ireland with those in the rest of the UK. As required under the Flags Regulations (Northern Ireland) 2000,<sup>5</sup> the Secretary of State referred the draft Regulations to the Northern Ireland Assembly, but as the Assembly is currently suspended it has not provided any views.

### Gas Safety (Management) (Amendment) Regulations 2023 (SI 2023/284)

### Gas Safety (Management) (Amendment) (No.2) Regulations 2023 (SI 2023/320)

25. In fulfilment of a commitment in the Energy White Paper,<sup>6</sup> **SI 2023/284** enables certain types of gas from the UK Continental Shelf to be injected into the gas network in Great Britain. These types of gas are not currently permitted unless they have been subjected to costly treatment or processing. The Regulations permit certain changes to the gas specifications, assessed as safe by the Health and Safety Executive (HSE), including the use of biomethane. HSE states that this will facilitate the increase of domestic supply and create less reliance on imported sources of gas, thus supporting energy independence.
26. The Regulations also update the definition of gas “network” to reflect modern practice and require the service for reporting gas leaks to be provided by duty holders approved by HSE. **SI 2023/320** was unfortunately necessary to correct a typographical error in the previous instrument which rendered it ineffective.

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5 Flags Regulations (Northern Ireland) 2000 ([SR 2000/347](#)).

6 Department for Business, Energy and Industrial Strategy, *Energy White Paper*, CP337 (December 2022), p 84: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/945899/201216\\_BEIS\\_EWP\\_Command\\_Paper\\_Accessible.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/945899/201216_BEIS_EWP_Command_Paper_Accessible.pdf) [accessed 21 March 2023].

## INSTRUMENTS NOT DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

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### Draft instruments subject to affirmative approval

- Draft            Flags (Northern Ireland) (Amendment) Regulations 2023
- Draft            Licensing Act 2003 (Coronation Licensing Hours) Order 2023

### Instruments subject to annulment

- SI 2023/241    Local Authorities (Capital Finance And Accounting)
- SI 2023/246    Merchant Shipping (Cargo and Passenger Ship Construction
- SI 2023/247    Health and Safety and Nuclear (Fees) (Amendment)  
Regulations 2023
- SI 2023/250    Police, Crime, Sentencing and Courts Act 2022  
(Consequential Provision) (England and Wales) Regulations  
2023
- SI 2023/265    Occupational Pension Schemes (Pension Protection Fund  
(Compensation) And Fraud Compensation Payments)  
(Amendment) Regulations 2023
- SI 2023/266    Social Security Revaluation of Earnings Factors Order 2023
- SI 2023/269    Child Trust Funds (Amendment) Regulations 2023
- SI 2023/272    Safety of Sports Grounds (Designation) (Amendment)  
(England) Order 2023
- SI 2023/273    Sea Fisheries (Amendment) Regulations 2023
- SI 2023/276    Childcare and Inspection Of Education, Children's Services  
and Skills (Fees) (Amendments) Regulations 2023
- SI 2023/277    Care and Support (Charging and Assessment of Resources)  
(Amendment) Regulations 2023
- SI 2023/279    Local Government Pension Scheme (Amendment) Regulations  
2023
- SI 2023/280    Guardian's Allowance Up-rating Regulations 2023
- SI 2023/284    Gas Safety (Management) (Amendment) Regulations 2023
- SI 2023/287    Welfare of Animals (Transport) (Miscellaneous Amendments)  
(England and Scotland) Regulations 2023
- SI 2023/288    National Health Service Commissioning Board and Clinical  
Commissioning Groups (Responsibilities and Standing Rules)  
(Amendment) Regulations 2023
- SI 2023/297    Merchant Shipping (Light Dues) (Amendment) Regulations  
2023
- SI 2023/300    National Health Service (Charges for Drugs and Appliances)  
(Amendment) Regulations 2023
- SI 2023/301    National Health Service Pension Schemes (Amendment)  
Regulations 2023

- SI 2023/302 Export Control (Military and Dual-Use Lists) (Amendment) Regulations 2023
- SI 2023/306 Health and Care Act 2022 (Consequential and Related Amendments) Regulations 2023
- SI 2023/310 Recovery of Costs (Remand to Youth Detention Accommodation) (Amendment) Regulations 2023
- SI 2023/313 Coroners and Justice Act 2009 (Alteration of Coroner Areas) Order 2023
- SI 2023/314 Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023
- SI 2023/320 Gas Safety (Management) (Amendment) (No. 2) Regulations 2023

## **APPENDIX 1: INTERESTS AND ATTENDANCE**

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Committee Members' registered interests may be examined in the online Register of Lords' Interests at <http://www.parliament.uk/mps-lords-and-offices/standards-and-interests/register-of-lords-interests>. The Register may also be inspected in the Parliamentary Archives.

For the business taken at the meeting on 21 March 2023 and included in this report, Members declared no interests.

### **Attendance:**

The meeting was attended by Lord De Mauley, Baroness Harris of Richmond, Lord Hunt of Wirral, Baroness Lea of Lymm, Lord Powell of Bayswater, Baroness Randerson, Baroness Ritchie of Downpatrick, Lord Rowlands, Lord Russell of Liverpool and Lord Thomas of Cwmgiedd.