House of Commons

European Scrutiny Committee

Sixth Report of Session 2022–23

Documents considered by the Committee on 18 July 2022

Report, together with formal minutes

Ordered by The House of Commons
to be printed 18 July 2022

HC 119-v
Published on 25 July 2022
by authority of the House of Commons

Notes

Numbering of documents

Three separate numbering systems are used in this Report for European Union documents:

Numbers in brackets are the Committee's own reference numbers.

Numbers in the form "5467/05" are Council of Ministers reference numbers. This system is also used by UK Government Departments, by the House of Commons Vote Office and for proceedings in the House.

Numbers preceded by the letters COM or SEC or JOIN are Commission reference numbers.

Where only a Committee number is given, this usually indicates that no official text is available and the Government has submitted an "unnumbered Explanatory Memorandum" discussing what is likely to be included in the document or covering an unofficial text.

Abbreviations used in the headnotes and footnotes

AFSJ	Area of Freedom Security and Justice
CFSP	Common Foreign and Security Policy
CSDP	Common Security and Defence Policy
ECA	European Court of Auditors
ECB	European Central Bank
EEAS	European External Action Service
EM	Explanatory Memorandum (submitted by the Government to the Committee)*
EP	European Parliament
EU	European Union
JHA	Justice and Home Affairs
OJ	Official Journal of the European Communities
QMV	Qualified majority voting
SEM	Supplementary Explanatory Memorandum
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

Euros

Where figures in euros have been converted to pounds sterling, this is normally at the market rate for the last working day of the previous month.

Further information

Documents recommended by the Committee for debate, together with the times of forthcoming debates (where known), are listed in the European Union Documents list, which is published in the House of Commons Vote Bundle each Monday and is also available on the parliamentary website. Documents awaiting consideration by the Committee are listed in "Remaining Business": www.parliament.uk/escom. The website also contains the Committee's Reports.

*Explanatory Memoranda (EMs) can be downloaded from GOV.UK: https://www.gov.uk/government/collections/explanatory-memoranda-on-eu-documents. EMs can be searched by Council or Commission reference number. Letters from the Committee and those issued by Ministers can be found in the correspondence section of the Committee's website: https://committees.parliament.uk/committee/69/european-scrutiny-committee/publications/3/correspondence/.

Explanatory Memoranda and letters published before 31 March 2022 can be found on the National Archives website—https://webarchive.nationalarchives.gov.uk/search/—by restricting searches to https://europeanmemoranda.cabinetoffice.gov.uk/

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Contents

1 Northern Ireland Protocol: Veterinary Medicines[1]

This EU document is politically important because:

- it relates to the implementation of the new EU veterinary medicines framework in Northern Ireland which could halve the amount of veterinary medicines placed on the Northern Ireland market; and
- while negotiations between the EU and UK on the implementation of the Northern Ireland Protocol continue, the UK has said that it will not implement the new EU rules.

Action

- Write to the Minister.
- Draw to the attention of the Northern Ireland Affairs Committee.

Overview

1.1 A new EU Regulation on veterinary medicines (Regulation (EU) 2019/6) applied from 28 January 2022.[2] Under the terms of the Northern Ireland Protocol, the Regulation applies in Northern Ireland (NI), including restrictions on the import into the EU and NI of veterinary medicines from Great Britain. While grace periods are currently in place,[3] the full application of the new rules to NI would leave potentially half of all veterinary medicines for a variety of animals and livestock facing discontinuation in NI.[4] The UK Government has consequently said that,[5] while negotiations on the implementation of the NI Protocol continue, it does not intend to apply Regulation (EU) 2019/6, including new transitional arrangements for labelling and packaging proposed by the Commission. The Government has been seeking to alter the operation of the Protocol to reduce the direct application of EU law in NI,[6] having in June 2022 published a Bill to amend the operation of the Protocol in UK domestic law, but the outcome of that process is not clear at this stage.

1 Proposal for a Regulation laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004; 6864/22, COM (22) 76; Legal base: Articles 114 and 168(4) (b) TFEU, QMV, Ordinary legislative procedure ; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC number: 42041.

2 Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC

3 Commission Notice—Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland (2021/C 524/02)

4 Foreign, Commonwealth and Development Office, 'Northern Ireland Protocol: the UK's solution', Policy Paper, 13 June 2022.

5 Veterinary Medicines Directorate, 'VMD Information Hub, Northern Ireland Update' [Accessed 11 July 2022]

6 HM Government, 'Northern Ireland Protocol: the way forward' (CP 502, July 2021).

1.2 The new transitional rules (which were formally adopted on 30 May 2022)[7] will enable veterinary medicines that comply with the packaging and labelling rules under the previous veterinary medicines legislation to remain on the market until 29 January 2027, even if they are not in compliance with the new EU Regulation. The application of the Regulation is back-dated to 28 January 2022. If that change was not made, a significant number of existing medicines would not be available as new batches of products could not be released onto the market until those changes had been made, with consequent animal health and welfare implications. Despite the Government's concerns around the implementation of the EU Regulation in Northern Ireland, the Government confirms in its Explanatory Memorandum (EM) that it has no concerns about the new transitional arrangements.

1.3 We have written to the Government expressing our profound concerns about the impact of the Northern Ireland Protocol on the availability of veterinary medicines in Northern Ireland and asking the Minister to keep us updated with relevant developments as far as possible.

UK Government approach to the regulation of veterinary medicines under the Northern Ireland Protocol

1.4 Under the terms of the Northern Ireland Protocol, most of the rules of the EU's internal market for goods apply to Northern Ireland to avoid the need for physical customs and regulatory checks or controls at the border between Northern Ireland and the Republic of Ireland. The list of laws that Northern Ireland is obliged to apply is set out in the Protocol's Annex 2. Where the laws listed in Annex 2 are amended or replaced, Northern Ireland should apply the revised rules. The list of laws includes legislation covering both human medicines and veterinary medicines.

1.5 A strict application of the Protocol to both human medicines and veterinary medicines would be challenging given the reliance of supply chains on imports from, or through, Great Britain. As a consequence, grace periods were applied to both sets of medicines. While a longer-term solution has been agreed for human medicines, and already adopted into EU law,[8] the solution did not extend to veterinary medicines. The grace period for veterinary medicines applies until 31 December 2022.

1.6 In the long term, though, the challenges remain serious. If the EU rules were to be applied in full to NI, a large number of medicines flowing to NI either could not use their established supply chains, or the changes required would affect the commercial viability of those products for the NI market. Given the small size of the veterinary medicines sector and the number of species, the returns on investment are relatively low in comparison to human medicines, meaning that the economic impacts of complying with the EU legislation may be disproportionately high. Industry would be likely to withdraw products from the NI market rather than make the changes. Furthermore, veterinary medicines could not in any case be sourced directly from GB as medicines placed on the NI market would need to have been separately batch-tested and authorised in the EU or NI.

7 REGULATION (EU) 2022/839 of 30 May 2022 laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004

8 European Commission, 'EU-UK relations: European Union ensures continued supply of medicines to Northern Ireland, as well as Cyprus, Ireland and Malta', 12 April 2022. [Accessed 1 June 2022]

1.7 The Minister for Rural Affairs and Biosecurity (Lord Benyon) said in his Explanatory Memorandum—published before the Northern Ireland Protocol Bill was introduced—that the Government is continuing to press the Commission on veterinary medicines issues and is urgently seeking a long-term solution that safeguards the availability of veterinary medicines in Northern Ireland. In the meantime, the UK is not implementing[9] either Regulation (EU) 2019/6 or Regulation (EU) 2019/4,[10] except for operational aspects concerning applications for new marketing authorisations and associated life-cycle management. This will enable pharmaceutical companies placing veterinary medicines on the EU market to apply and receive marketing authorisations for use in Northern Ireland.

1.8 Regulation (EU) 2019/6 was agreed while the UK was still an EU Member State. It aims to simplify the regulatory environment, stimulate the development of new veterinary medicines and strengthen EU action to fight antimicrobial resistance. The Minister notes that the UK Government was significantly involved in the negotiations on the Regulation and many of the changes are desirable from a UK policy perspective. The Veterinary Medicines Directorate is currently in the process of reviewing and updating the Veterinary Medicines Regulations 2013 (VMR) as they have effect in GB. Any proposed changes to the VMR will be subject to public consultation.

Our assessment

1.9 The EU's readiness to amend its rules on human medicines to take into account supply chains between GB and Northern Ireland—as well as Cyprus, Ireland and Malta—but not to amend its rules on veterinary medicines is frustrating. This is particularly so given the relatively small and fragmented nature of the veterinary medicines market, leaving Northern Ireland highly vulnerable to a significant reduction in the availability of veterinary medicines, with consequent implications for animal health and welfare.

1.10 We recognise that, to a degree, the situation is mitigated by the continuation of the grace period but it is clearly necessary to arrive at a more sustainable solution that provides the necessary clarity.

1.11 How the Government's Northern Ireland Protocol Bill, which was published in June 2022, would affect the application of EU veterinary medicines rules in Northern Ireland remains unclear but those rules are within scope of the Bill.

1.12 We are writing to the Minister to offer our support to the Government's position and to request an update in the autumn.

Action

1.13 We have written to the Minister as set out below.

1.14 We are drawing this document and our letter to the attention of the Northern Ireland Affairs Committee.

9 Veterinary Medicines Directorate, 'VMD Information Hub, Northern Ireland Update' [Accessed 1 June 2022]

10 Regulation (EU) 2019/4 of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC

Letter from the Chair to the Minister for Rural Affairs and Biosecurity (Lord Benyon)

We considered your Explanatory Memorandum on the above document at our meeting of 14 July 2022. We note that, in the meantime, the Government has introduced a Bill seeking to alter how the Protocol operates, although the outcome of that legislative process and any subsequent action is unclear.

We believe that the EU's readiness to amend its rules on human medicines to take into account supply chains between GB and Northern Ireland, as well as Cyprus, Ireland and Malta, but not to amend its rules on veterinary medicines is frustrating. This is particularly so given the relatively small and fragmented nature of the veterinary medicines market, leaving Northern Ireland highly vulnerable to a significant reduction in the availability of veterinary medicines, with consequent implications for animal health and welfare.

While the situation is, to a degree, mitigated by the grace period in place until 31 December 2022, we support the position that you are taking and would welcome an update on the progress of discussions with the EU by early October.

2 Northern Ireland Protocol: Fertilising products[11]

These EU documents are politically important because:

- they will apply in Northern Ireland and form part of a larger set of new fertiliser rules applicable in Northern Ireland, but not Great Britain, from 16 July 2022; and
- the policy area is subject to review in Great Britain, with responsibility devolved to the UK's constituent nations, and so there is uncertainty around the emerging level of divergence across the UK.

Action

- Write to the Government.
- Draw to the attention of the Environment, Food and Rural Affairs Committee, the Northern Ireland Affairs Committee, the Scottish Affairs Committee and the Welsh Affairs Committee.

Overview

2.1 Fertilisers are everyday products used in agriculture and horticulture to improve plant growth and yields. They can be either inorganic (man-made) or organic (derived from plant or animal). Given the increasing number of organic fertilisers on the market, the EU has updated its rules on fertilisers to ensure that they cover both inorganic and organic fertilisers. These new rules, set out in Regulation (EU) 2019/1009 ('the new Regulation') came into effect in the EU on 16 July 2022 and apply also in Northern Ireland under the terms of the Northern Ireland Protocol. The previous rules (Regulation (EC) 2003/2003) remain in place in Great Britain as EU retained law, thus leading to divergence between GB and NI.

2.2 Previously, virtually all product types carrying the 'EC fertiliser' designation were conventional inorganic fertilisers, whilst those produced from organic materials or recycled bio-waste were excluded. The new Regulation establishes conditions with which all 'CE' marked fertiliser products—including those made from recycled or organic materials—must comply in order to move freely on the internal market. These include limits on the presence of heavy metals, such as Cadmium, and contaminants in fertilising products. Organic fertilisers have historically been regulated at national level, making it

11 (a) COMMISSION DELEGATED REGULATION (EU) …/... of 14.3.2022 supplementing Regulation (EU) 2019/1009 of the European Parliament and of the Council by laying down criteria on agronomic efficiency and safety for the use of byproducts in EU fertilising products (b) COMMISSION DELEGATED REGULATION (EU) …/... of 22.3.2022 amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding recovered high purity materials as a component material category in EU fertilising products; (c) COMMISSION DELEGATED REGULATION (EU) …/... of 5.5.2022 amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the requirements applicable to EU fertilising products containing inhibiting compounds and the post processing of digestate; Reference numbers: (a) C(2022) 1437 (b) C(2022) 1422 (c) C(2022) 2882; Legal base: (a), (b), (c) Regulation (EU) 2019/1009; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC numbers: (a) 42063 (b) 42065 (c) 42066.

difficult to operate an effective internal market for such goods. The new Regulation also introduces a new system of conformity assessment for manufacturers to demonstrate that their products meet the conditions before they are placed on the market.

2.3 The European Commission prepared three separate Delegated Regulations setting out additional details concerning the products covered by the new Regulation.

2.4 In her Explanatory Memorandum, the then Parliamentary Under-Secretary of State (Jo Churchill MP) described the UK's domestic regulatory regime for fertilisers as "outdated and in need of modernisation". She said that the UK's withdrawal from the EU and the EU's own overhaul of its legislation "provides the opportunity to carry out a full review of the domestic regulations and develop a new framework based on UK requirements." That review would take into account the standards set out in these Delegated Regulations and in the rest of Regulation (EU) 2019/1009.

2.5 The Minister considered that the suggested EU regulatory amendments would not cause any difficulties in moving goods between GB and NI, or vice versa. It was not clear whether she was referring only to the details proposed in the Delegated Regulations or to the wider changes reflected in the new Regulation.

2.6 The Minister noted that fertiliser regulation is a devolved policy area that is subject to a common framework.[12] As such, Scotland and Wales can in principle take their own decisions on future policy, cooperating with the UK Government and Northern Ireland Executive within the common framework with the objective of developing a common approach to regulating fertilisers that may be produced and sold in the UK.

Our assessment

2.7 We scrutinised the new EU Regulation when it was first proposed by the Commission in 2016, following the negotiation through to its conclusion over two years late.[13] The Government said at the time that it supported the proposal with some concerns about limits on the level of Cadmium in fertilisers The Government was successful in negotiating with other Member States to amend the text satisfactorily. In her recent Explanatory Memorandum, the then Minister confirmed that the UK was involved in the earlier development of the Regulation (EU) 2019/1009 and was broadly supportive of the introduction of a conformity assessment regime for fertilisers.

2.8 The original proposal was published before the UK took the decision to withdraw from the EU. While most of the negotiations took place after the referendum, there was doubt as to the nature of the future relationship between the UK and the EU and therefore how relevant rules such as this would be to the UK in the future. The ultimate outcome of the Brexit negotiations was that these rules would be directly applicable in Northern Ireland, potentially affecting the rest of the UK as a consequence of domestic policy choices linked to the UK internal market.

2.9 The then Minister failed to recognise the complexity of the interaction between the new rules, the Protocol and the UK internal market. She concluded that the amendments

12 HM Government, 'Fertilisers Common Framework: Provisional framework outline agreement and concordat' (February 2022).

13 European scrutiny Committee, Thirty-second Report HC 342–xxxi (2015–16), chapter 4 (4 May 2016) and European Scrutiny Committee, Fifty-seventh Report HC 301–lvi (2017–19), chapter 11 (6 March 2019).

would not cause any difficulties in moving goods between GB and NI or vice versa. While we understand how that may be the case for goods being moved from NI to GB, we note that goods being moved in the other direction from 16 July 2022 must comply with the new EU Regulation. We struggle to understand how that situation cannot cause any difficulties for the movement of goods from GB to NI unless GB aligns with the EU rules with immediate effect or unless producers simply follow the EU rules in any event. We will therefore ask the Government to explain the then Minister's comment in more detail with reference not only to the specific Delegated Regulations under scrutiny but to the whole of the new Regulation.

2.10 The then Minister was critical of the current laws in place in GB and noted that the EU's overhaul of its own legislation is one factor behind the need to modernise the legislation in place in the UK. She acknowledged that the review would consider the revised EU legislation. This implies that the UK may well choose to amend its rules in a similar policy direction to that of the new EU rules. Such an approach would be understandable given that the UK was closely involved in the negotiation of the EU rules, based presumably on some form of assessment as to the impact on the UK. Given that such work was done in the past, we will clarify with the Government whether previous analysis is being used in the assessment on future policy direction, accepting of course that the policy choices open to the UK are distinct now that it is outside the EU and now that GB at least is outside the internal market for goods. Again, noting the existing analytical work in the area, we will clarify the likely timing of developing a new UK policy approach.

2.11 Finally, we note that this area falls within devolved competence. What approach the Welsh and Scottish administrations decide to take is therefore very important to the future evolution of the internal market in these products. We will clarify with the Government what discussions have already taken place with the other administrations towards developing a common approach to regulating fertilisers.

2.12 While the Government has been seeking to alter the operation of the Protocol to reduce the direct application of EU law in Northern Ireland,[14] having in June 2022 published a Bill to amend the operation of the Protocol in UK domestic law, the outcome of that process is not clear at this stage.

Action

2.13 We have written to the Minister as set out below.

2.14 We are drawing these documents and our letter to the attention of the following Committees for policy reasons and because of the issues relating to devolution: the Environment, Food and Rural Affairs Committee; the Northern Ireland Affairs Committee; the Scottish Affairs Committee; and the Welsh Affairs Committee.

Letter from the Chair to the Parliamentary Under-Secretary of State (Steve Double MP)

We considered your predecessor's Explanatory Memoranda on the above documents at our meeting of 18 July 2022.

14 HM Government, 'Northern Ireland Protocol: the way forward' (CP 502, July 2021).

As you will be aware, we scrutinised Regulation (EU) 2019/1009 and we do recall that the Government was largely content, while negotiating some changes such as Cadmium limits. Of course, that negotiation largely took place after the EU referendum but before the negotiations had concluded with the EU on the UK's withdrawal.

The ultimate outcome of the Brexit negotiations was that rules such as Regulation (EU) 2019/1009 would be directly applicable in Northern Ireland, potentially affecting the rest of the UK because of the UK internal market. We appreciate that the Government is actively seeking to alter how the Protocol operates, having published a Bill to that effect in June 2022. The outcome of that process is, however, unclear and we are keen to understand the implications of the new EU Fertilisers Regulation and the related Delegated Regulations under the terms of the Protocol as it currently exists.

The Explanatory Memorandum failed to recognise the complexity of the interaction between the new rules, the Protocol and the UK internal market. It concluded that the amendments would not cause any difficulties in moving goods between GB and NI or vice versa. While we understand how that may be the case for goods being moved from NI to GB, we note that goods being moved in the other direction from 16 July 2022 must comply with the new EU Regulation and therefore we struggle to understand how no difficulties arise. We ask that you explain the conclusion in more detail with reference not only to the specific Delegated Regulations under scrutiny but to the whole of the new Regulation.

The Explanatory Memorandum noted that the current laws in place in GB are being reviewed and that the review would take into account the revised EU legislation. We assume that some form of assessment about the impact on the UK of the new EU Regulation was undertaken when the Regulation was first being negotiated. Is previously analysis being used in the assessment on future policy direction, accepting of course that the policy choices open to the UK are distinct now that it is outside the EU and now that GB at least is outside the internal market for goods? Given that such analytical work has already been done, what is the timing for the review and the development of a revised policy?

Finally, we note that this area falls within devolved competence. What discussions have already taken place with the other administrations towards developing a common approach to regulating fertilisers?

We would welcome a response to this letter by the end of September.

3 Supply of medicines from Great Britain to Northern Ireland

These EU documents are politically important because:

- they aim to ensure the continued long-term supply of medicines from Great Britain to Northern Ireland following difficulties encountered as a result of obligations set out in the Ireland/Northern Ireland Protocol; and
- they contain provisions which could lead to future divergence between medicines available in Great Britain and Northern Ireland and provisions which may constrain some of Great Britain's regulatory autonomy over rules governing medicines.

Action

- Report to the House.
- Draw to the attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

Overview

3.1 The Protocol on Ireland/Northern Ireland ('the Protocol') of the Withdrawal Agreement requires that Northern Ireland (NI) remain aligned with EU medicines rules but NI's historical reliance on medicinal products from, or through, Great Britain (GB) has made that requirement difficult to comply with in practice. On 17 December 2021, the European Commission put forward proposals[15] to ensure the continued long-term supply of medicines from GB to NI. This means that the same medicines will continue to be available in NI at the same time as in the rest of the UK, while specific conditions ensure that UK-authorised medicines do not enter the Single Market. The legislation was adopted in April 2022 and applied retroactively from January 2022.[16]

3.2 A six-month bridging mechanism will allow any novel medicine authorised in the UK (but not in the EU) to be supplied to NI for a period of up to six months, until the relevant authorisation is also given in the EU. This 'bridging solution' is in addition to the existing compassionate and emergency use mechanisms under EU law.

15 (a) Proposal for a Directive amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta (b) Proposal for a Regulation amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta (c) Commission Communication: Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland (d) Commission Delegated Regulation (EU) …/… of 17.12.2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom; COM numbers: (a) COM(21) 997, (b) COM(21) 998, (c) C(2021) 9668 (d) C(2021) 9700; Legal base: (a) Article 114 TFEU (b) Articles 114, 168(4)(c) TFEU (c) Not applicable (d) Directive 2001/83/EC; Department: Health and Social Care; Devolved Administrations: NI consulted; ESC numbers: (a(41987, (b) 41988, (c) 42010, (s) 42011.

16 Directive (EU) 2022/642 and Regulation (EU) 2022/641.

3.3 The proposals also require the UK to respect certain conditions: packaging requirements to ensure that UK-authorised medicines do not enter the EU Single Market; and the UK's laws on the production, distribution and use of medicines should guarantee a level of public health protection that remains "essentially equivalent" to that provided by EU law. If the Commission considers that the UK's laws no longer provide an equivalent level of protection, or if the Commission has insufficient information to make that assessment, it reserves the right to suspend some or all the provisions following a process of engagement.

3.4 Finally, the EU has granted a further extension[17] to the full implementation of the Falsified Medicines Directive,[18] so that, until 31 December 2024, EU medicine unique identifiers won't have to be removed from products transiting from the EU through GB to NI and then reaffixed when entering NI.

3.5 We outlined the proposals in our Report of 9 March 2022.[19] Since then, the Government has concluded its analysis of the legislation. The Government does not consider the package to be comprehensive, identifying two areas where continued vigilance will be required. The first is a concern that novel medicines will still, ultimately, require an EU authorisation and an EU pack, potentially meaning that some novel medicines may be discontinued in NI or not launched there at all. This is in contrast to the changes for generic medicines (such as paracetamol), which can be authorised and packed under UK procedures. The second concern is around the continued application of the Falsified Medicines Directive in Northern Ireland, despite the derogation until 31 December 2024.

UK Government position

3.6 The Minister of State for Health (Edward Argar MP) says in his letter of 30 June 2022 that close engagement has taken place with stakeholders to assess the impact of the legislation. While industry has been broadly positive, the package is not considered to be comprehensive. Two supply risks have been identified, which the Government will keep under close review.

3.7 First, notes the Minister, EU-authorised packs of novel medicines are still required for NI. As part of a temporary UK easement for industry until January 2024, suppliers can use EU packs for existing products in GB. Without a UK-wide route for these products, companies would need to supply NI and GB with two separate packs. The Minister says that UK officials have warned the EU that this need for separate GB and NI licenses may lead to some companies discontinuing novel medicines in NI or not launching them at all. The Government will monitor how suppliers can adapt to supplying separate packs to GB and NI over time.

3.8 Second, the Government knows that some industry stakeholders have raised concerns over the continued application of the EU Falsified Medicines Directive (FMD) in NI. The

17 Commission Delegated Regulation (EU) 2022/315 of 17 December 2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom

18 Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal product

19 European Scrutiny Committee, chapter 2, Nineteenth Report HC 121–xviii (2021–22) (9 March 2022).

Government agrees with the view that the FMD should not apply in NI. The Commission has signalled that it would be open to discussing collaboration on the FMD with the UK in the future.

3.9 To mitigate against these two risks, says the Minister, the NI MHRA Authorised Route (NIMAR) is being used to support the continuity of supply in NI. This route, says the Minister, is fully compliant with UK law, with the NI Protocol, and with EU legislation. It ensures that patients in NI can access prescription-only medicines at the same time as patients in GB. Discontinued products will now be substituted with the NIMAR alternative, which should maintain a constant supply of medicines. NIMAR can also be used for products that will be launched in GB but not in NI in the future. All medicinal products using NIMAR will have met the MHRA's stringent requirements for safety, quality, and efficacy. The Minister says that doctors, pharmacists, and patients in NI do not need to do anything different to prescribe or access medicines through this route once medicines are included on the NIMAR list.

3.10 The Minister assures us that the Government is closely monitoring supplies and gathering evidence on the risks not dealt with in the EU's proposals. The Government's priority is patient safety and ensuring that patients in NI get the medicines that they need. If a clear risk emerges which the Government cannot address, this will be raised with the Commission.

3.11 Concerning the six-month bridging mechanism, the Government is confident that mechanisms such as NIMAR can ensure that medicines authorised in GB but not the EU can continue to be supplied to NI.

3.12 Noting that the placing of UK-authorised generic medicines on the NI market is permitted as long as the level of public health protection afforded by GB laws in this area remain "essentially equivalent" to that provided by the EU's laws, we asked the Minister if the UK's regulatory autonomy was compromised at all. The Minister does not respond directly, noting that the EU's rules follow international standards and that the Government is committed to following international standards. The Government does not consider that following international standards puts constraints on the UK's regulatory autonomy.

Our assessment

3.13 We welcome the Minister's response, despite its delay due to administrative error.

3.14 Working with stakeholders, the Minister has identified two concerns, which both potentially threaten the availability of medicines on the NI market. We welcome the Minister's commitment to gather evidence on the risks not dealt with in the EU's proposals and to raise any supply problems or risks with the Commission.

3.15 We will monitor developments with interest but require no further information at this stage.

Action

3.16 Report to the House.

3.17 Draw to the attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

4 Documents not considered to be legally and/or politically important

Department for Environment, Food and Rural Affairs

(42073) 7760/22 C(2022) 1804	Commission Delegated Regulation (EU) …/... of 28.3.2022 amending Delegated Regulation (EU) 2019/625 as regards Combined Nomenclature and Harmonised System codes and import conditions of certain composite products, amending Delegated Regulation (EU) 2019/2122 as regards certain goods and pet birds exempted from official controls at border control posts and amending Delegated Regulation (EU) 2021/630 as regards requirements for composite products exempted from official controls at border control posts.
(42083) 8416/22 C(2022) 2464	Commission Delegated Regulation (EU) …/... of 25.4.2022 amending Regulation (EU) 2019/787 of the European Parliament and of the Council as regards the definition of and requirements for ethyl alcohol of agricultural origin.
(42088) — C(2022) 3040	Commission Delegated Directives (EU) .../... of 12.5.2022 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections.
(42089) — C(2022) 3041	Commission Delegated Directives (EU) .../... of 12.5.2022 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in certain magnetic resonance imaging devices.

Department for Transport

(42085) 8830/22 C(2022) 2804	Commission Delegated Regulation (EU) …/... of 5.5.2022 supplementing Regulation (EU) 2018/858 of the European Parliament and of the Council as regards the procedure for the imposition of administrative fines and the methods for their calculation and collection.

Annex

Documents drawn to the attention of select committees:

('SNC' indicates that scrutiny (of the document) is not completed'; 'SC' indicates that scrutiny of the document is completed)

Environment, Food and Rural Affairs Committee: Northern Ireland Protocol: Fertilising products [Commission Delegated Regulations][SNC]

Health and Social Care Committee: Supply of medicines from Great Britain to Northern Ireland [(a) Proposed Directive, (b) Proposed Regulation, (c) Commission Communication, (d) Commission Delegated Regulation][SC]

Northern Ireland Affairs Committee: Northern Ireland Protocol: Fertilising products [Commission Delegated Regulations][SNC]; Northern Ireland Protocol: Veterinary Medicines [Proposed Regulation][SNC]; Supply of medicines from Great Britain to Northern Ireland [(a) Proposed Directive, (b) Proposed Regulation, (c) Commission Communication, (d) Commission Delegated Regulation][SC]

Scottish Affairs Committee: Northern Ireland Protocol: Fertilising products [Commission Delegated Regulations][SC]

Welsh Affairs Committee: Northern Ireland Protocol: Fertilising products [Commission Delegated Regulations][SC]

Formal Minutes

Monday 18 July 2022

Members present:

Sir William Cash, in the Chair

Jon Cruddas

Richard Drax

Margaret Ferrier

Mr Marcus Fysh

Mr David Jones

Craig Mackinlay

Gavin Robinson

Greg Smith

Document scrutiny

Draft Report, proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1.1 to 4 agreed to.

Resolved, That the Report be the Sixth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Adjournment

Adjourned till Wednesday 7 September 2022 at 1.45 pm

Standing Order and membership

The European Scrutiny Committee is appointed under Standing Order No.143 to examine European Union documents and—

a) to report its opinion on the legal and political importance of each such document and, where it considers appropriate, to report also on the reasons for its opinion and on any matters of principle, policy or law which may be affected;

b) to make recommendations for the further consideration of any such document pursuant to Standing Order No. 119 (European Committees); and

c) to consider any issue arising upon any such document or group of documents, or related matters.

The expression "European Union document" covers—

i) any proposal under the Community Treaties for legislation by the Council or the Council acting jointly with the European Parliament;

ii) any document which is published for submission to the European Council, the Council or the European Central Bank;

iii) any proposal for a common strategy, a joint action or a common position under Title V of the Treaty on European Union which is prepared for submission to the Council or to the European Council;

iv) any proposal for a common position, framework decision, decision or a convention under Title VI of the Treaty on European Union which is prepared for submission to the Council;

v) any document (not falling within (ii), (iii) or (iv) above) which is published by one Union institution for or with a view to submission to another Union institution and which does not relate exclusively to consideration of any proposal for legislation;

vi) any other document relating to European Union matters deposited in the House by a Minister of the Crown.

The Committee's powers are set out in Standing Order No. 143.

The scrutiny reserve resolution, passed by the House, provides that Ministers should not give agreement to EU proposals which have not been cleared by the European Scrutiny Committee, or on which, when they have been recommended by the Committee for debate, the House has not yet agreed a resolution. The scrutiny reserve resolution is printed with the House's Standing Orders, which are available at www.parliament.uk.

Current membership

Sir William Cash MP (*Conservative, Stone*) (Chair)

Tahir Ali MP (*Labour, Birmingham, Hall Green*)

Jon Cruddas MP (*Labour, Dagenham and Rainham*)

Allan Dorans MP (*Scottish National Party, Ayr Carrick and Cumnock*)

Richard Drax MP (*Conservative, South Dorset*)

Margaret Ferrier MP (*Independent, Rutherglen and Hamilton West*)

Mr Marcus Fysh MP (*Conservative, Yeovil*)

Dame Margaret Hodge MP (*Labour, Barking*)

Mrs Andrea Jenkyns MP (*Conservative, Morley and Outwood*)

Mr David Jones MP (*Conservative, Clwyd West*)

Stephen Kinnock MP (*Labour, Aberavon*)

Mr David Lammy MP (*Labour, Tottenham*)

Marco Longhi MP (*Conservative, Dudley North*)

Craig Mackinley MP (*Conservative, South Thanet*)

Ann Marie Morris MP (*Independent, Newton Abbot*)

Greg Smith MP (*Conservative, Buckingham*)