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Documents considered by the Committee on 24 March 2021

Report, together with formal minutes

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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) and letters issued by the Ministers can be downloaded from the Cabinet Office website: http://europeanmemoranda.cabinetoffice.gov.uk/.

Staff

The current staff of the Committee are Ravi Abhayaratne (Committee Operations Assistant), Joanne Dee (Deputy Counsel for European and International Law), Alistair Dillon and Leigh Gibson (Senior Committee Specialists), Nat Ireton and Apostolos Kostoulas (Committee Operations Officers), Luanne Middleton (Second Clerk), Daniel Moeller (Committee Operations Manager), Jessica Mulley (Clerk), Foeke Noppert (Senior Committee Specialist), Indira Rao (Counsel for European and International Law), Paula Saunderson (Committee Operations Assistant), Emily Unwin (Deputy Counsel for European and International Law), Dr George Wilson (Second Clerk), Beatrice Woods (Committee Operations Officer).

Contacts

All correspondence should be addressed to the Clerk of the European Scrutiny Committee, House of Commons, London SW1A 0AA. The telephone number for general enquiries is (020) 7219 3292/5467. The Committee's email address is escom@parliament.uk.

Contents

1 UK-Euratom Nuclear Cooperation Agreement[1]

This EU document is politically important because:

- it sets the framework for future cooperation between the EU and UK on nuclear matters, supporting nuclear safety, research and the safe transfer of nuclear material.

Action

- Report to the House.
- Draw to the attention of the Business, Energy and Industrial Strategy Committee.

Overview

1.1 Nuclear Cooperation Agreements (NCAs) give legal underpinning to civil nuclear cooperation and provide key non-proliferation assurances, including in respect of nuclear safeguards, and a framework for nuclear trade. The UK and the European Atomic Energy Community (Euratom)—legally separate from the EU but comprising all of the EU Member States and no other countries—have agreed a NCA, which is separate from the wider UK-EU Trade and Cooperation Agreement (TCA).[2] There is, however, a link between the two Agreements as the TCA governs UK participation in specific nuclear research programmes (i.e. the Euratom Research and Training Programme and "Fusion for Energy"—the European Joint Undertaking for the ITER fusion project).[3]

1.2 The UK-Euratom NCA covers the following:

- safeguards—mutual assurances that traded nuclear material will remain subject to safeguards, verifying compliance with international obligations not to use nuclear materials for nuclear explosives;
- nuclear transfers—the NCA facilitates civil nuclear trade by providing a framework and assurances for transfers of nuclear materials and related items, including procedures for retransfers to third countries;

1 Recommendation for a COUNCIL DECISION approving the conclusion, by the European Commission, of the Agreement between the Government of the United Kingdom of Great Britain and Northern Ireland and the European Atomic Energy Community for Cooperation on the Safe and Peaceful Uses of Nuclear Energy and the conclusion, by the European Commission, on behalf of the European Atomic Energy Community, of the Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part; Council and COM number 14337/20, COM(20) 857; Legal base: Article 101, Euratom; Department: Business, Energy and Industrial Strategy; Devolved Administrations: Not consulted; ESC number: 41766.

2 Article 18 of the NCA confirms that it is not a "supplementing agreement" to the TCA.

3 Launched in 2005 and now involving seven global partners (Euratom, US, Russia, Japan, China, South Korea and India), ITER (International Thermonuclear Experimental Reactor) is a project to build and operate an experimental facility to demonstrate the scientific viability of fusion as a future sustainable energy source.

- medical radioisotopes—cooperation on issues such as security of supply or the development of novel technologies and treatments;
- nuclear safety—commitments from both sides to improving global standards, and maintaining their existing safety standards;
- sharing of information and technical expertise, including the option for the UK's participation, as a third country, in systems such as the European Community Urgent Radiological Information Exchange (ECURIE) and the European Radiological Data Exchange Platform (EURDEP) as well as various other expert advisory groups; and
- nuclear research cooperation.

1.3 A Joint Committee will be established to oversee the implementation of the Agreement.

1.4 On research cooperation, the NCA notes that such cooperation may include UK participation in Euratom's research and training programmes (Euratom R&T), and membership of Fusion for Energy (F4E) which is the Euratom body responsible for delivering Euratom's contribution to the international ITER fusion project. Detailed arrangements were outlined in the separate TCA.

1.5 The TCA sets out the terms for the UK's participation in various Union programmes and activities, including those relating to cooperation on nuclear research and development. These terms provide for the UK to make a fair and appropriate financial contribution towards the relevant programmes and activities, fair treatment of UK participants, balanced provisions to ensure the sound financial management of funds, and appropriate governance arrangements. The TCA's Protocol on UK participation in Union programmes and activities (once adopted by a Specialised Committee under the TCA) will mean that the UK shall participate as an associated country in all parts of the Euratom R&T programme and as a member of F4E for the next multiannual financial framework 2021–2027.

1.6 In her Explanatory Memorandum, the Minister of State for Business, Energy and Clean Growth (Rt Hon. Anne-Marie Trevelyan MP) says that the UK-Euratom NCA sends a clear message to the wider international community, the nuclear sector, and the public that both parties are fully committed to cooperation on civil nuclear, including safeguards, safety, and security. It provides a framework for trade in nuclear materials and technology and, while trade would have been possible without the NCA, the Minister says that it would have been more-time consuming and complex.

1.7 The Minister goes on to note that the TCA's provisions on nuclear research ensure that UK researchers and UK companies will continue to have full access to funding and commercial opportunities under Euratom R&T and F4E. This includes the ability for the UK to attend and participate in governance boards and influence decision-making in the UK interest. This agreement also secures full access to ITER, which the Minister describes as "one of the largest international science collaborations in the world". Remaining part of ITER through F4E, she says, means the UK can access scientific outputs crucial for supporting the development of fusion energy, as well as substantial commercial opportunities.

Action

1.8 We welcome the NCA between Euratom and the UK, which not only places cooperation on a secure footing but also ensures continued UK involvement in ITER, which we were aware was an important objective for the Government.

1.9 We are separately scrutinising the broader Trade and Cooperation Agreement, including the provisions on UK participation in EU programmes and will monitor the financial and governance aspects of that participation closely.

1.10 We report the document to the House and draw it to the attention of the Business, Energy and Industrial Strategy Committee, which may wish to pursue the detail of the Agreement, including scrutiny of the Joint Committee.

2 EU-UK Relations: Equivalence of various seeds and plants[4]

These EU documents are politically important because:

- the EU remains reluctant to grant equivalence to a number of plant products produced in the UK, including seed potatoes and vegetable seed, with a consequent impact on the export of those products from Great Britain to the EU and Northern Ireland.

Action

Write to the Minister.

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

Overview

2.1 In advance of the UK's withdrawal from the European Union on 31 January 2020 the UK submitted a request to the Commission for seed, plants and plant propagating material, including Forest Reproductive Material ("FRM"),[5] to be recognised as equivalent to such material produced in the EU in order to allow material produced in Great Britain to continue to be exported to the EU and Northern Ireland.

2.2 The Commission has already granted the UK equivalence for fruit and vegetable plants and plant propagating material.[6] Equivalence for Forest Reproductive Material and for seed of the main agricultural species was proposed at the end of December (documents (a) and (b)). The UK's initial application for equivalence for seed potatoes, however, has not been accepted. EU plant health restrictions[7] currently prevent seed potatoes being imported into the EU (and Northern Ireland) from non-EU countries, with the exception of Switzerland, unless "special requirements, or equivalent requirements"[8] are fulfilled. There is also an outstanding query regarding the equivalence of vegetable seed produced in the UK.

4 (a) Proposal for a Decision amending Council Decision 2008/971/EC as regards the equivalence of forest reproductive material produced in the United Kingdom to such material produced in the Union (b) Proposal for a Decision amending Council Decisions 2003/17/EC and 2005/834/EC as regards the equivalence of field inspections and the equivalence of checks on practices for the maintenance of varieties of agricultural plant species carried out in the United Kingdom; Council and/or COM number: (a) COM(20) 852 (b) 5004/21; Legal base: Article 43(2) TFEU; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC number: (a) 41765 (b) 41769.

5 Seed units, parts of plants (such as cuttings), and planting stock.

6 Commission Implementing Decision (EU) 2020/2219.

7 Annex VI of Commission Implementing Regulation (EU) 2019/2072 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031, as regards protective measures against pests of plants.

8 Article 41 of Regulation (EU) 2016/2031, as regards protective measures against pests of plants.

The Government's position

2.3 In the Explanatory Memoranda[9] on the two documents, the Government observes that the Northern Ireland Protocol requires that EU plant health legislation will continue to apply in Northern Ireland under the terms of the Protocol on Ireland/Northern Ireland annexed to the Withdrawal Agreement. As a consequence of this, equivalence decisions—or a lack of them—between the UK and EU apply only to GB. In the case of seed potatoes, for example, Northern Ireland remains able to export to the EU despite the prohibition on exports from the rest of the UK. Equally, however, GB is unable to export seed potatoes to Northern Ireland.

2.4 The Government adds that, for technical reasons, the "tested"[10] category of FRM was excluded from the equivalence Decision, but the Government is exploring whether this category can be included in the future as it will otherwise impact on British nurseries exporting to the EU and Northern Ireland.

2.5 The Government explains that the UK has, in parallel, taken steps to recognise EU processes and controls for seed, FRM and fruit and vegetable plants and plant propagating material as equivalent to GB processes for a period of two years. This is except for seed potatoes for which England and Wales are granting the EU equivalence for a six-month period. Although the UK is broadly self-sufficient in the total quantity of seed potato production, it does not currently produce the range of varieties required by the UK market. Permitting the import of seed potatoes into England and Wales for six months allows for planting in spring 2021 and affords businesses a further period of adaptation. The Government is continuing to work for a reciprocal agreement with the EU in time for the 2022 growing season, allowing longstanding trading patterns to resume.

2.6 On the lack of any decision to grant equivalence for the vegetable seed produced in the UK, the Government will be exploring this with the Commission.

Our assessment

2.7 A number of issues remain outstanding based on the Explanatory Memoranda submitted by the Government. These are:

- extension of FRM equivalence to include the "tested" category;
- equivalence of seed potatoes produced in the UK; and
- equivalence of vegetable seed produced in the UK.

2.8 We note that the UK's plant health regulations remain largely aligned with those of the European Union and we will therefore seek clarification as to the concerns expressed by the Commission to explain the reluctance in granting equivalence in the above circumstances. We will ask the Government to set out the obstacles encountered and the latest state of play in resolving them.

9 Explanatory Memorandum on document (a); Explanatory Memorandum on document (b).
10 Tested material from tested seed orchards or stands which can produce seed of improved quality.

Action

2.9 We have written to the Government as set out below raising queries regarding the outstanding equivalence decisions.

2.10 We are reporting the documents to the House as politically important and we draw them to the attention of the Environment, Food and Rural Affairs Committee and the Northern Ireland Affairs Committee.

Letter from the Chair to the Minister for Rural Affairs and Biosecurity (Lord Gardiner of Kimble)

We considered the Explanatory Memoranda on the above documents at our meeting of 24 March 2021.

We note that, despite Great Britain's plant health regulations remaining largely aligned with those of the European Union and Northern Ireland, the Government has encountered problems in securing equivalence for the following plant products:

- "Tested" Forest Reproductive Material.
- Seed potatoes.
- Vegetable seed.

It would be helpful if you could set out the obstacles encountered, the reasons for them and the latest state of play in resolving them.

We would welcome a response within ten working days.

3 EU-UK Health Security Cooperation[11]

These EU documents are politically important because:

- they are relevant to EU-UK cooperation on serious cross-border health threats, linking to the health security provisions in the EU-UK Trade and Cooperation Agreement; and
- they provide for the potential acceleration of the placing of medicinal products and medical devices on the Northern Irish market.

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 Recognising that the Covid-19 pandemic has demonstrated the need for stronger EU-level provisions to tackle serious cross-border health threats, the European Commission tabled three draft Regulations as well as an over-arching Communication on a "European Health Union". Once adopted, the legislation will not apply to the United Kingdom, but elements of it relating to the placing on the market of medicinal products and medical devices have implications for Northern Ireland due to the terms of the Ireland/Northern Ireland Protocol to the UK/EU Withdrawal Agreement. Furthermore, the Commission's proposed approach to tackling serious cross-border threats to health—including those between the EU and third countries—dovetails with the health security provisions in the EU-UK Trade and Cooperation Agreement.

3.2 The current EU health security arrangements provide a limited legal framework[12] for EU level coordination, based on the Early Warning and Response System (EWRS) and the exchange of information and cooperation within the EU's Health Security Committee (HSC). The proposed new health security legal framework would allow the EU to react more rapidly and comprehensively. Based on lessons learnt from combatting the Covid-19 pandemic, the new framework will extend the role of EU agencies in the coordination of preparedness and response measures.

11 (a) Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control (b) Proposal for a Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU (c) Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (d) Commission Communication—Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats; COM number: (a) COM(2020) 726 (b) COM(2020) 727 (c) COM(2020) 725 (d) COM(2020) 724; Legal base: (a) Article 168(5) TFEU, QMV, Ordinary legislative procedure (b) Article 168(5) TFEU, QMV, Ordinary legislative procedure (c) Articles 114 and 168(4)(c) TFEU, QMV, Ordinary legislative procedure (d)—; Department: Health and Social Care; Devolved Administrations: Consulted; ESC numbers: (a) 41652 (b) 41653 (c) 41654 (d) 41655.

12 Decision No 1082/2013/EU on serious cross-border threats to health and repealing Decision No 2119/98/EC.

3.3 Particular features of the proposed framework include:

- a Regulation on serious cross-border threats to health—replacing the current framework—to strengthen preparedness, reinforce surveillance and improve data reporting;
- continuation of the EWRS, but with an expanded provision for it to be used to notify an urgent need or shortage of medical supplies to counter a threat ("medical countermeasures") and to make requests and offers for cross-border emergency assistance;
- the declaration of an EU emergency situation under the terms of the new Regulation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis-relevant medical products;
- an enhanced mandate to the European Centre for Disease Prevention and Control (ECDC) covering areas such as real-time epidemiological surveillance, preparedness and response planning, risk management options and coordination across Member States; and
- a reinforced mandate for the European Medicines Agency (EMA) to enhance its role in crisis preparedness and management for medicinal products and medical devices in response to public health emergencies such as Covid-19.

The Government's view

3.4 The Secretary of State for Health and Social Care (Rt Hon. Matt Hancock MP) submitted his Explanatory Memorandum (EM) shortly before the UK-EU Trade and Cooperation Agreement was agreed. He noted that the pandemic had underlined the importance of international cooperation on health security. The UK was working closely with international partners, including the EU, to support international efforts to combat the virus and provide global leadership. He indicated that this cooperation with the EU would continue.

3.5 In addition, the UK would ensure the highest standards of health protection were upheld, in line with its obligations under the International Health Regulations. The UK would continue to receive critical information on public health risks and incidents through its existing access to international surveillance systems, such as the Event Information System (EIS) operated by the WHO. The Minister added that, in England, a new National Institute for Health Protection would ensure the best capability to control infectious disease and deal with pandemics or health protection crises.

3.6 The Minister offered substantial comment on the proposed Regulation reinforcing the role of the European Medicines Agency as it links to the Ireland/Northern Ireland Protocol annexed to the Withdrawal Agreement. While the EMA should be in a stronger position to identify, and advise on, crisis-relevant medicinal products and medical devices in a timely manner, such products and devices would still be subject to robust assessment procedures. The Minister noted that the Regulation would enable certain products to be brought to market quicker and those products would automatically be licenced in

Northern Ireland under the terms of the Protocol. In the event of any risk to patient safety from any of these products, however, the Minister stated that the UK's regulator (MHRA) would still have the power to withdraw these products from the Northern Ireland market.

3.7 The Minister did not expect that the EU was likely to propose that the new Regulation be added to the list of EU legislation which must be applied in Northern Ireland as the current EU legislation in the fields of medicinal products and medical devices—with which Northern Ireland must comply—would not be affected by the new Regulation.

3.8 It is anticipated, he added, that the package would contribute indirectly to international cooperation priorities by supporting the development of, and access to, potential treatments and vaccines during public health crises.

3.9 This legislation could enable EU Member States and drug manufacturers to benefit from the scientific advice given on clinical trial protocols and their recommendations on the use of such medicines in national indications, also known as 'off-label use', as a result of this legislation. The UK would only benefit from this, noted the Minister, if the UK were to have a binding bilateral or multilateral confidentiality agreement with the European Commission, EMA and EU Member States.

Trade and Cooperation Agreement

3.10 The EU-UK Trade and Cooperation Agreement includes a section on health security, providing mostly for cooperation on serious cross-border threats to health affecting the UK and at least one EU Member State. In particular, it gives the UK access to the EU's Early Warning and Response System (EWRS) in respect of a specific serious cross-border threat to health to enable the EU and UK to exchange relevant information, to assess public health risks, and to coordinate the measures that could be required to protect public health. The EU may also invite the UK to participate in a EU-level committee composed of Member State representatives for the purposes of supporting the exchange of information and of coordination in relation to the serious cross-border threat to health.

3.11 The EU and UK should respectively designate a "focal point" with a view to exchanging information in the event of a serious cross-border threat to health and to facilitating understanding as to whether or not a threat is a serious cross-border threat to health.

3.12 Finally, the TCA provides for EU-UK cooperation in international forums on health security and for a memorandum of understanding between the European Centre for Disease Prevention and Control and the relevant body in the United Kingdom responsible for surveillance, epidemic intelligence and scientific advice on infectious diseases.

Analysis

3.13 For the most part, this package of legislation is of indirect interest only to the UK. The EU recognises that it needs to be nimbler in responding to serious cross-border threats to health than has been the case with the Covid-19 pandemic. Clearly, a more effective EU response to a serious cross-border threat to health that also affects the UK is positive for the UK and may also contribute helpfully to the UK's own response to any such crisis. For that reason alone, this package of legislation is to be welcomed.

3.14 We note that Northern Ireland is potentially affected if speedier EU procedures lead to the placing on the Northern Ireland market of medicinal products or medical devices that have not also been authorised in Great Britain. While the MHRA may be able to suspend the use of medicinal products and medical devices in Northern Ireland, we note that these arrangements are caveated by EU law. Where a medicinal product has been centrally-authorised (by the EMA), EU law gives Member States—including the UK in respect of Northern Ireland for the purposes of laws applicable under the Northern Ireland Protocol—the right to suspend the use of that product to protect human health or the environment, pending the outcome of a review by the EMA and the Commission.[13] The final decision concerning the availability of the product would, ultimately, be a matter for the EU itself. For those products authorised under the decentralised procedure (by one Member State acting as a reference for other Member States), the MHRA would only be able to suspend the use of a product if one of the 27 Member States had triggered a review of the product.[14] The MHRA would be obliged to withdraw a product found to be harmful or ineffective.[15] For medical devices, the MHRA could withdraw a medical device from the market if it was considered to represent an unacceptable risk to health and safety, although that assessment would be subject to challenge by EU Member States and the Commission and could be overturned by the Commission.[16]

3.15 Furthermore, we also observe that—since the Minister submitted his EM—the EU and UK have agreed arrangements for future cooperation on health security, including ad hoc UK access to the EWRS to deal with specific serious cross-border threats to health. In that context, it is relevant that the Commission has proposed not only the continuation of the EWRS but with an extended capability for it to be used to notify an urgent need or shortage of medical countermeasures and to make requests and offers for cross-border emergency assistance.

3.16 Also of relevance to the provisions in the TCA is the proposed extension of the remit of the European Centre for Disease Prevention and Control (ECDC), given that the TCA provides for a Memorandum of Understanding between the ECDC and the relevant UK body. Logically, a wider ECDC remit should add greater value to that avenue of EU-UK cooperation, particularly as regards surveillance. We note too that provision is made in the legislation for third country access to the ECDC's surveillance monitoring digital platform

Action

3.17 We have no further queries but we highlight:

- the salience of this package of legislation to EU-UK cooperation on serious cross-border health threats, linking to relevant provisions in the EU-UK Trade and Cooperation Agreement; and
- the potential acceleration of the placing of medicinal products and medical devices on the Northern Irish market.

13 Article 20 (4), Regulation 726/2004
14 Article 31(3) of Directive 2001/83/EC
15 Article 117 of Directive 2001/83/EC as implemented by Regulations 68 and 69 of the Human Medicines Regulations 2012
16 Articles 95 and 96 of Regulation (EU) 2017/745 on medical devices (applicable from 26 Mary 2021).

3.18 On that basis, we report the documents to the House as politically important and draw them to the particular attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

4 EU Pharmaceutical Strategy[17]

This EU document is politically important because:

- it suggests changes to EU pharmaceutical legislation with which Northern Ireland must remain aligned;
- this is an area of regulation where the EU and UK agreed to cooperate under the terms of the EU-UK Trade and Cooperation Agreement;
- any EU changes to incentives for the production of medicines could have implications for the competitiveness of the UK pharmaceutical industry if the UK did not adopt a similar approach; and
- research is an important element of the Strategy and is an area where the UK has negotiated continuing participation in an EU programme.

Action

- Write to the Minister.
- Draw to the attention of the Business, Energy and Industrial Strategy Committee, the Health Committee, the Northern Ireland Affairs Committee and the Science and Technology Committee.

Overview

4.1 The objective of the Commission's Strategy is to ensure patients have access to innovative and affordable medicines and to support the competitiveness, innovative capacity and sustainability of the EU's pharmaceutical industry. It is founded on the hypothesis that incentives for pharmaceutical companies to innovate are not aligned with the interests of patients and thus need to be reviewed.

4.2 The Strategy is directly relevant to the UK as it suggests changes to the "pharmaceutical legislation"[18] and other pieces of legislation such as Regulations on paediatric[19] and orphan[20] medicines, all of which Northern Ireland must remain aligned under the terms of the Northern Ireland Protocol annexed to the Withdrawal Agreement. There may also be wider UK relevance in terms of: competitiveness if the EU and UK pursue different approaches to incentives; research endeavours given that the UK has secured participation in the EU's research framework for 2021–27; and international collaboration, particularly as that type of regulatory cooperation on medicines is foreseen in the EU-UK Trade and Cooperation Agreement.

17 Commission Communication—Pharmaceutical Strategy for Europe; COM number: COM(20) 761; Legal base:—; Department: Health and Social Care; Devolved Administrations: Consulted; ESC number: 41687.

18 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

19 Regulation (EC) No 1901/2006 on medicinal products for paediatric use.

20 Regulation (EC) No 141/2000 on orphan medicinal products.

The Commission's Strategy

4.3 The Commission notes that while strong progress has been made in developing innovative medicines to tackle some of the leading causes of disease and life-threatening illnesses, many patients do not benefit from that innovation, because medicines are either unaffordable or unavailable. There is also greater awareness of the need to ensure that use of pharmaceuticals is sustainable.

4.4 There are four work strands identified in the Strategy. The first concerns unmet medical needs and ensuring accessibility and affordability of medicines:

- noting that the development of novel antimicrobials or alternatives is a prime example of unmet need, the Commission suggests further research and legislative measures to restrict and optimise the use of antimicrobials;
- revise paediatric and rare diseases legislation to address unmet needs (such as treatments for paediatric cancer) through more tailored incentives;
- integrate the European Medicine Agency's (EMA) priority medicines scheme (PRIME)—a voluntary scheme to enhance support for the development of medicines that target an unmet medical need—into the regulatory framework; and
- review the system of incentives and obligations, taking into account the relationship with intellectual property rights, and to address market competition considerations, improving access to generic medicines and improving affordability.

4.5 The EU's current system of pharmaceutical incentives, including market exclusivity and extended patent protections, was summarised and reviewed in 2018 and will form the basis of the Commission's further work in this area.[21]

4.6 Second, the Commission aims to support a competitive and innovative European pharmaceutical industry through a number of initiatives, including:

- introduce a new "European Health Data Space", enabling better healthcare, health research, innovation and evidence-based decisions;
- revise the pharmaceutical legislation to adapt to innovative developments;
- implement fully the clinical trials regulatory framework, which supports innovative trial designs and a more patient-oriented medicine development; and
- simplify the pharmaceutical legislation.

21 Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report, 2018.

4.7 The third strand of the Communication focuses on "resilience", including supply and sustainability. Suggestions include:

- revise the pharmaceuticals legislation to introduce stronger obligations for supply and transparency, earlier notification of shortages and withdrawals, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages;
- strengthen the environmental sustainability requirements in the pharmaceutical legislation; and
- propose an EU Health Emergency Response Authority to strengthen the coordination of operations across the whole value chain and develop strategic investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures.

4.8 The fourth strand concerns the EU's international work in this area, with suggestions actions including:

- work at global level, with the EMA and the network of national regulators, in international fora and through bilateral cooperation to promote regulatory convergence to ensure access to safe, effective high-quality and affordable medicinal products globally; and
- advance international harmonisation by proactively proposing topics in line with the latest scientific developments; promoting the uptake and implementation of international standards, and ensuring a level playing field for operators on the international market by enhancing the EU's bilateral and multilateral relations.

The Government's position

4.9 In his Explanatory Memorandum (submitted prior to the conclusion of negotiations on the EU-UK Trade and Cooperation Agreement), the Minister of State for Health (Edward Argar MP) noted that any changes to legislation on medicinal products would "likely be subject" to the Northern Ireland Protocol (NIP), and products that would automatically be authorised in Northern Ireland would need to comply with the regulatory requirements of the EU legislation for the duration that the Protocol will be in force.

4.10 The Minister adds that, while it is anticipated that the Strategy will support international collaboration between the EU and other countries, as well as advance international harmonisations standards for medicine regulation, it is unclear how this would be of benefit to the UK's relationship with the EU. The aim of the strategy, noted the Minister, is to promote EU interests in both multilateral and bilateral relations with other countries especially in enhancing regulatory convergence of medicines globally where possible. Such an objective, said the Minister, was contrary to the Government's position that any agreement on the future EU-UK relationship must respect the autonomy of both parties and it could not therefore include any regulatory alignment.

The EU-UK Trade and Cooperation Agreement

4.11 The EU and UK have provisionally applied a Trade and Cooperation Agreement, which includes an Annex on Medicinal Products. This aims to facilitate the availability of medicines in each Party's territory and to promote public health by safeguarding patient safety and animal health and welfare, as well as to protect high levels of consumer and environmental protection, where relevant, by promoting regulatory approaches in line with the relevant international standards.

4.12 Standards for medicinal products should be in line with standards, practices and guidelines developed by the World Health Organization (WHO), the Organization for Economic Cooperation and Development (OECD), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

4.13 The parties agreed to regulatory cooperation with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines including, where feasible, through the presentation of joint initiatives, proposals and approaches in the international organisations and bodies highlighted in the preceding paragraph.

4.14 Finally, the TCA established a Working Group on Medicinal Products to support the implementation of the Annex on Medicinal Products.

Our assessment

4.15 The Strategy is relatively high-level, but it nevertheless signals a clear intention to change the system of incentives in place, including intellectual property protection, to encourage innovation. This could represent a substantial shift for the pharmaceutical sector and, similarly, would lead to a divergent approach between the UK and the EU to the development of innovative, affordable and accessible medicines. For that reason, we ask the Minister in his response to set out the Government's response to the Commission's fundamental hypothesis that incentives for pharmaceutical companies to innovate are not aligned with the interests of patients and thus need to be reviewed.

4.16 In the event that the EU and UK approaches to pharmaceutical innovation diverge, there may be implications for decisions made by pharmaceutical companies as to where they develop, and seek to market, new medicines. We will invite the Minister to identify any risks or opportunities that arise for the UK.

4.17 In terms of opportunities for the UK arising from other elements of the Strategy, we note that the Commission's Strategy contains initiatives relating to research in this area. Given that the UK and EU agreed in the Trade and Cooperation Agreement that the UK could associate to the EU's research programme (Horizon Europe), we will ask the Minister what opportunities the Government sees for EU-UK research cooperation in the development of pharmaceutical products.

4.18 At a regulatory level, it is of fundamental significance that the Commission intends to present amendments to the pharmaceutical legislation and legislation on orphan and paediatric medicines. This is all legislation with which Northern Ireland must remain

aligned. The pharmaceutical legislation governs the placing of medicines on the EU and Northern Ireland markets and it follows that any changes could affect the nature of medicines placed on the Northern Irish market and speed of doing so. In the event of substantial regulatory divergence between Great Britain and Northern Ireland, it is at least possible that a medicine authorised for use in GB is not authorised for use in Northern Ireland and vice versa. While the UK Government could temporarily suspend the use of a medicine on the Northern Irish market, it could not do so indefinitely as the EU would ultimately decide.[22] Only under emergency circumstances could the UK Government currently place on the NI market a medicinal product that was not already authorised for use in the EU.[23]

4.19 In reality, therefore, the Commission's suggestions are possible changes with which the Government must engage as it will need to be mindful not only of the direct implications for Northern Ireland, but also of the impact of regulatory divergence between Great Britain and Northern Ireland concerning medicinal products. We will require from the Minister an outline of the Government's intentions in this regard in terms of both analysis of the regulatory options and implications and intended engagement with the European Commission. If the Government has no such plans, it is imperative that the Minister explains why that might be the case.

4.20 The Minister's EM was notably defensive in tone, which was arguably understandable at the time it was signed as the UK and EU were in the last fortnight of negotiations on the Trade and Cooperation Agreement. As it transpired, the EU-UK TCA respected the autonomy of both parties and did not include any regulatory alignment. It did, however, provide for regulatory cooperation between the parties, including within international fora, and it links medicinal product standards to those developed globally.

4.21 In his original position—submitted prior to the TCA's political agreement—the Minister was lukewarm on the EU's proposals concerning regulatory cooperation, suggesting that the EU's agenda was to promote its own interests and ensure regulatory convergence. As the UK then went on to agree to regulatory cooperation with the EU on medicinal products, including within international fora, we will ask the Minister to update his position and seek clarity on the UK's own objectives for its international engagement, both with the EU and others. It would be helpful to understand if the UK sees any benefits for the UK of third countries being encouraged, whether only by the EU or by the EU in partnership with the UK, to strengthen their regulatory and intellectual property standards.

4.22 Concerning international engagement in this area, the UK is—alongside the EU—a member of the International Coalition of Medicines Regulatory Authorities. Unlike the EU, it is not listed as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) nor of the International Pharmaceutical Regulators Programme (IPRP). Membership of the IPRP and ICH includes the EU but extends to many others including the US, Canada, New Zealand and Australia. We note that the TCA provides that the ICH standards are part of the baseline for the respective EU and UK approaches to pharmaceuticals regulation. We will invite the Minister to explain why the UK is not a member and also to set out the range of international partnerships in which the UK is engaged in this area.

22 Article 20(4), Regulation 726/2004.

23 Article 5(2), Directive 2001/83/EC.

4.23 Finally, we will request information on the Government's own ideas to resolve the challenges identified in the document, such as: addressing unmet medical needs and ensuring accessibility and affordability of medicines; and promoting innovative, sustainable and patient-oriented pharmaceutical development.

Action

4.24 For the reasons identified in our assessment above, we are reporting this document to the House as politically important.

4.25 We are drawing it to the attention of the Business, Energy and Industrial Strategy Committee, the Health Committee, the Northern Ireland Affairs Committee and the Science and Technology Committee.

Letter from the Chair to the Minister for Health (Edward Argar MP)

We considered your Explanatory Memorandum (EM) on the above document at our meeting of 24 March 2021.

While the Strategy is high-level, it nevertheless signals a clear intention to change the system of incentives in place, including intellectual property protection, to encourage innovation. This could represent a substantial shift for the pharmaceutical sector and, similarly, would lead to a divergent approach between the UK and the EU to the development of innovative, affordable and accessible medicines. What is your response to the Commission's fundamental hypothesis that incentives for pharmaceutical companies to innovate are not aligned with the interests of patients and thus need to be reviewed? If the EU and UK pursue divergent approaches to pharmaceutical innovation, what risks and opportunities might arise for the UK? We would welcome any of its own ideas that the Government may have to resolve the challenges identified in the document, such as: addressing unmet medical needs and ensuring accessibility and affordability of medicines; and promoting innovative, sustainable and patient-oriented pharmaceutical development.

In terms of opportunities for the UK, we note that the Commission's Strategy contains initiatives relating to research in this area. Given that the UK and EU agreed in the Trade and Cooperation Agreement that the UK could associate to the EU's research programme (Horizon Europe), what opportunities does the Government see for EU-UK research cooperation in the development of pharmaceutical products?

Turning to regulation, it is of fundamental significance that the Commission intends to present amendments to the pharmaceutical legislation and legislation on orphan and paediatric medicines. This is all key public health legislation with which Northern Ireland must remain aligned. In our view, the Commission's suggestions are possible changes with which the Government must engage as you need to be mindful not only of the direct implications for Northern Ireland, but also of the impact of regulatory divergence between Great Britain and Northern Ireland concerning medicinal products. We require from you an outline of your plans in this regard in terms of both analysis of the regulatory options and implications and intended engagement with the European Commission. If you have no such plans, we ask you to explain clearly why that is the case.

In your EM—submitted prior to provisional application of the Trade and Cooperation Agreement between the EU and UK—you questioned the value to the UK of the EU's proposals concerning regulatory cooperation, suggesting that the EU's agenda was to promote its own interests and ensure regulatory convergence. The UK then went on, however, to agree to regulatory cooperation with the EU on medicinal products, including within international fora. We therefore ask that you update your position, setting out clearly the UK's objectives for its international engagement in this area, both with the EU and others. Do you see any benefits for the UK of third countries being encouraged, whether only by the EU or by the EU in partnership with the UK and others, to strengthen their regulatory and intellectual property standards as far as medicinal products are concerned?

On the detail of international engagement on pharmaceutical regulation, we note that the UK is—alongside the EU—a member of the International Coalition of Medicines Regulatory Authorities. Unlike the EU, it is not listed as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) nor of the International Pharmaceutical Regulators Programme (IPRP). Membership of the IPRP and ICH includes the EU but extends to many others including the US, Canada, New Zealand and Australia. We note that the TCA provides that the ICH standards are part of the baseline for the respective EU and UK approaches to pharmaceuticals regulation. Could you please explain why the relevant UK body is not listed as a member and could you also set out the international partnerships within which the UK is engaged in this area?

We look forward to a response by 14 April.

5 Northern Ireland Protocol: application of EU preferential rules of origin[24]

This Commission Implementing Regulation is legally and politically important because:

- it applies to Northern Ireland under the Protocol on Ireland/Northern Ireland;
- it seeks to clarify whether goods imported into Northern Ireland qualify for a preferential (lower) EU tariff under the EU's trading arrangements with third countries or the (higher) EU Most Favoured Nation (MFN) tariff;
- it must be read alongside a Decision taken by the Withdrawal Agreement Joint Committee in December 2020 setting out the criteria for determining which goods brought into Northern Ireland are to be considered "at risk" of entering the EU Single Market and subject to EU rather than UK customs duties/tariffs; and
- it highlights the complexity of the rules applicable to goods brought into Northern Ireland and the difficulties traders are likely to face in interpreting and applying them in practice.

Action

- No further action. The Minister for Trade Policy (Rt Hon. Greg Hands MP) has responded to the questions raised in our earlier Report. We draw his response and our assessment to the attention of the International Trade Committee and the Northern Ireland Affairs Committee.

Overview

5.1 This Commission Implementing Regulation ("the Regulation") seeks to clarify whether goods imported into Northern Ireland from one of the EU's trading partners qualify for a preferential EU tariff rather than the EU's standard most favoured nation (MFN) tariff. It is necessary because the Protocol on Ireland/Northern Ireland provides that EU tariffs apply to goods which are considered to be "at risk" of entering the EU Single Market based on criteria which were agreed by the EU/UK Withdrawal Agreement Joint Committee in December.[25] Different criteria apply to goods moving from Great Britain to Northern Ireland and from third (non-EU) countries to Northern Ireland. The UK's Global Tariff applies to goods which are considered "not at risk" of onward movement to the EU. The purpose of the "at risk" criteria is to prevent goods which are intended for the EU market being diverted through Northern Ireland to exploit differences in EU and

24 Commission Implementing Regulation (EU) 2020/2163 on the implementation in the United Kingdom in respect of Northern Ireland of the rules of origin laid down in Union preferential trade arrangements; Legal base: Article 66(a) of Regulation (EU) No 952/2013 laying down the Union Customs Code; Dept: International Trade: Devolved Administrations: consulted; ESC number 41759.

25 See Joint Committee Decision No 4/2020 on the determination of goods not at risk, adopted on 17 December 2020.

UK tariffs. We will shortly be publishing a Report on the Decisions agreed by the Joint Committee in December which contains further information and analysis of the "at risk" criteria.

5.2 The Regulation itself sets out the steps that need to be taken to prove and verify the origin of goods that are imported into Northern Ireland, as only "at risk" goods that comply with EU rules of origin and the procedural requirements set out in the Regulation qualify for a preferential EU tariff. Our earlier Report (agreed on 10 February) provides a more detailed overview of the interaction between the Regulation, the Northern Ireland Protocol and the Joint Committee Decision establishing the criteria for "not at risk" goods.[26]

The Government's position

5.3 The Minister for Trade Policy (Rt Hon. Greg Hands MP) confirmed in his Explanatory Memorandum of 13 January 2021 that the Commission Implementing Regulation applies in Northern Ireland (it forms part of the EU customs laws made applicable by the Protocol on Ireland/Northern Ireland) and told us that it simply "reaffirms the rules of origin required for EU trade partners to obtain EU preferential rates for their imports into Northern Ireland".

5.4 We suggested in our letter to the Minister that the brevity of the Regulation belied its complexity and that traders importing goods into Northern Ireland and seeking to determine which tariff to apply might share our concern that the Regulation, read alongside the Joint Committee Decision establishing the criteria for "not at risk" goods, is difficult to understand.[27] We asked the Minister to provide further information on:

- the European Commission's gatekeeper role in determining whether the EU's preferential tariffs are available for goods imported into Northern Ireland and when they cease to apply; and
- the practical implications of the Regulation for traders bringing goods into Northern Ireland, as well as the impact on supply chains and export patterns.

5.5 In his letter of 3 March 2020, the Minister recognises that the Commission Implementing Regulation is "intimately linked" to Joint Committee Decision No 4/2020 on the determination of goods not at risk which also established a new UK Trader Scheme for traders bringing goods into Northern Ireland from Great Britain or from a non-EU third country. The Minister notes that the Scheme "allows authorised businesses to undertake that the goods they are moving into Northern Ireland are 'not at risk', and therefore not liable to pay EU tariffs". He continues:

> As a result, it will only be goods destined for the EU, or where there is uncertainty or genuine risk of onward movement into the EU single market, where tariffs will be charged. EU preferences will only be applied to those goods. For goods remaining within the UK customs territory, or traded indirectly with Northern Ireland via Great Britain, traders using the UK Trader Scheme for movements from GB into NI would not need to

26 See our Thirty-seventh Report HC 229–xxxii (2019–21), chapter 2 (10 February 2021) and Joint Committee Decision No 4/2020.

27 Letter of 10 February 2021 from the Chair of the European Scrutiny Committee.

> complete origin certification; and if goods could not qualify for tariff-free trade under a Free Trade Agreement's Rules of Origin requirements, they could still be traded tariff-free under this deal by those businesses within the Scheme.

5.6 The Minister's response to our questions on the practical implications of the Regulation and the role of the European Commission are set out in an Annex to his letter.

The role of the European Commission

5.7 According to the Regulation, only goods from countries which the European Commission considers have taken the necessary measures to comply with EU rules and procedures on preferential origin and are listed on its website can be imported into Northern Ireland using the EU's tariff preferences. We asked the Minister whether the same listing requirement applied for goods being imported into the EU under the EU's preferential trading arrangements, how many of the EU's trading partners had been listed on the Commission's website so far, and whether some third countries might choose *not* to be listed because the requirements on proofs of origin and verification of origin were too onerous, given their volume of trade with Northern Ireland.

5.8 The Minister confirms that the rules are the same as for goods being imported into the EU. He provides a weblink to the list of third countries which have taken the necessary steps to comply with the EU's rules of origin requirements and benefit from the EU's preferential tariffs.[28] He says "there is currently no separate list for Northern Ireland"—we are unsure whether he anticipates that there might be one in the future—but considers it unlikely that third countries would choose not to be listed (as the requirements would be the same as for EU countries) and adds that the Department for International Trade "has not received any representations about these requirements".

5.9 We expressed concern in our earlier Report that the Commission would play a gatekeeper role in determining whether the EU's preferential tariffs should continue to be available for goods brought into Northern Ireland if there was evidence of non-compliance with EU rules on preferential origin. We asked whether the Minister shared our concern, given that the Protocol on Ireland/Northern Ireland makes clear that UK customs authorities are responsible for implementing and applying relevant EU customs law in Northern Ireland.

5.10 The Minister confirms that UK customs authorities are responsible for implementation, while adding that "the EU remains responsible for the development and changes to its own tariff policy". He continues:

> Where the EU changes its tariff policy, and the legislative act is within the scope of the Protocol, the UK must be informed through the Joint Consultative Working Group, as provided in Article 15(3)(b) of the Protocol. If this is done via a new act, this needs to be agreed through the Joint Committee as set out in Article 13(4).

28 See the EU's "Arrangements" list and other information on preferential origin.

The practical implications of the Commission Implementing Regulation

5.11 The Commission Implementing Regulation provides that any Northern Ireland content (for example, materials sourced in or processing operations undertaken in Northern Ireland) which is included in goods imported into Northern Ireland from one of the EU's preferential trade partners will not count as EU content, making it less likely that these goods will satisfy the EU's rule of origin requirements and qualify for preferential tariffs. We asked what assessment the Government had made of: (i) the product categories or sectors most likely to be affected; (ii) the supply chains that might be interrupted or diverted to exclude Northern Ireland content; and (iii) the economic impact on Northern Ireland businesses and traders.

5.12 The Minister says the Government has not received representations from industry on this aspect of the Regulation. He reports that the flow of goods under the Northern Ireland Protocol is "smooth overall and there are no significant queues at NI ports", adding that the EU and UK co-chairs of the Withdrawal Agreement Joint Committee agreed to intensify the work of the Specialised Committee on the implementation of the Northern Ireland Protocol "in order to address all outstanding issues, with the shared objective to find workable solutions on the ground".[29]

5.13 In his earlier Explanatory Memorandum, the Minister told us that traders importing goods directly into Northern Ireland from the UK's continuity trade partners—that is, third countries with whom the UK has concluded trade agreements which broadly replicate those that applied when the UK was a member of the EU—would need to prove that they comply with EU *and* UK rules of origin. He also indicated that most of the goods brought into Northern Ireland from these trading partners would be considered "at risk" of entering the EU market, based on the criteria established by the Joint Committee in December, and would be subject to the EU's standard MFN tariff rather than its preferential tariff.

5.14 We asked the Minister how likely it was that traders would be willing and able to prove compliance with EU *and* UK rules of origin and what feedback the Government had received from those affected. Given that he expected most would be charged the EU's MFN tariff, we also asked why the Government had not yet established a reimbursement scheme for these goods, when it would do so and whether the scheme, once up and running, would reimburse tariffs already paid. We noted that the Minister's Explanatory Memorandum did not mention Article 2 of the Joint Committee Decision on non-commercial processing and asked him to explain how this condition would apply in establishing whether goods imported into Northern Ireland were to be considered "at risk" of entering the EU market.

5.15 The Minister says that traders importing goods from any of the UK's continuity trade partners "are for the most part" able to prove both EU and UK origin as the terms of the EU and UK agreements are "largely the same". He continues:

> At the moment, traders can use the same form as for the EU except with the wording 'the United Kingdom in respect of Northern Ireland' when claiming EU preferences. There has been some engagement in the unusual cases where a good cannot meet the EU preferences as a result of being

29 When the Minister wrote, the Chancellor of the Duchy of Lancaster (Rt Hon. Michael Gove MP) was the UK co-chair but he has since been replaced by Lord Frost.

> unable to cumulate UK content in the EU agreement, for example by the South African Customs Union. This is not an issue the other way around as the UK's continuity agreements make provision for cumulation with the EU.

5.16 The Minister reiterates the Government's commitment to establishing a reimbursement scheme for goods that attract the EU tariff, but can subsequently be shown to have remained in the UK's customs territory, adding that "further detail will be provided in due course" along with guidance on the GOV.UK website.[30] A link to that guidance (once published) will be provided in HMRC's 'not at risk' guidance. The Minister says that the current 'not at risk' guidance "sets out clearly what conditions apply for commercial processing and in what cases goods subject to processing can apply to the UK Trader Scheme".

5.17 The Minister indicated in his Explanatory Memorandum that implementation of the Regulation was unlikely to be onerous in practice as traders would already have most of the information required and that any administrative changes would be "very minor", while citing the EU-Turkey Trade Agreement as one of "a few exceptions". We requested further information on the exceptions and how they would affect traders importing goods into Northern Ireland.

5.18 In his response, the Minister says that "Turkey is currently the only exception we are aware of" but that "the number of exceptions may increase, for example if the UK and EU both sign trade agreements with a partner in the future".

5.19 We envisaged that there might be circumstances in which goods imported into Northern Ireland did not qualify for a preferential EU tariff under the Regulation or for a UK preferential tariff (because, for example, the goods failed to satisfy EU and UK rules of origin). We asked the Minister to explain how the "at risk" criteria set out in the Joint Committee Decision would apply, given our understanding that the UK's MFN tariff was generally lower than the EU's MFN tariff and that a lower UK tariff might make it more likely that the goods would be considered "at risk" and charged the EU tariff.

5.20 In his response, the Minister explains that the applicable tariff will depend, first, on whether a trader importing goods into Northern Ireland is participating in the UK Trader Scheme and, second, whether the goods in question are brought into Northern Ireland from elsewhere in the UK or from a non-EU third country. Goods brought into Northern Ireland from Great Britain by a trader authorised under the UK Trader Scheme are considered "not at risk" and do not need to meet rules of origin requirements. By contrast, goods brought into Northern Ireland from a non-EU third country are 'at risk' and the EU tariff will apply, even if the trader is authorised under the UK Trader Scheme, if the difference between the applicable EU and UK tariff is lower than three per cent of the customs value of the good. The Minister adds:

> In the case you mention, if the UK's MFN is lower than the EU's by 3% points or more then the goods would be considered 'at risk' and the EU MFN would apply. The differential is calculated on the basis of the applied

30 The Minister says that a link to the guidance on the reimbursement scheme will be provided in HMRC's 'not at-risk' guidance.

tariffs, so would include any applicable preferences to determine the rate for either the EU or UK before calculating the differential between the two rates.

5.21 Finally, we asked the Minister to point us to the relevant gov.uk guidance explaining how the Commission Implementing Regulation, read alongside the Joint Committee Decision on at risk goods, would work in practice. We also asked whether systems had been put in place to monitor the take-up of EU preferences under the Commission Implementing Regulation and its impact on businesses importing goods into Northern Ireland.

5.22 The Minister directs us to Government guidance on declaring goods brought into Northern Ireland not 'at risk' of moving to the EU and to Government guidance on rules of origin and claiming preferential tariffs.[31] He says that HMRC will continue to monitor the movement of goods into Northern Ireland.

Our assessment

5.23 Informed by the Minister's response and our own understanding of the Commission Implementing Regulation, the Northern Ireland Protocol and Joint Committee Decision 4/2020, we make the following observations.

The role of the European Commission

5.24 We are satisfied that the EU's preferential rules of origin apply in the same way for goods brought into Northern Ireland as they do for goods imported by EU Member States. This means, however, that the European Commission is the body responsible for determining whether the EU's preferential tariffs are available for goods brought into Northern Ireland as well as for determining whether they should be suspended and when they should be restored if there is evidence of fraud or non-compliance in the countries benefiting from the preferences.

The impact on businesses in Northern Ireland

5.25 The Minister says that industry has not voiced any concerns about Article 2 of the Commission Implementing Regulation on cumulation of content. Article 2 provides that any Northern Ireland content (for example, materials sourced in or processing operations undertaken in Northern Ireland) which is included in goods imported into Northern Ireland from one of the EU's preferential trade partners does not count as EU content, thus making it less likely that these goods will qualify for the EU's preferential tariffs. He also observes that "the flow of goods under the Northern Ireland Protocol is smooth overall".

5.26 We consider that the Minister's response misses the point of our question. We would not expect the Regulation to have any significant impact on the overall flow of goods. It could, however, affect specific products or sectors of the economy or established supply chains which would not necessarily be captured in general data on trade flows. We still do not have a clear idea whether the non-cumulation of Northern Ireland content has had (or

31 Also relevant is Government guidance on claiming preferential rates of duty between the UK and EU.

may yet have) an impact in specific sectors or supply chains. We accept that the absence of representations from industry may be a positive sign. Equally, it may signify difficulties in understanding and applying a set of highly complex rules.

"At risk" goods

5.27 The Minister acknowledges that most goods entering Northern Ireland from a country with which the UK has concluded a continuity trade agreement and which comply with the UK's rule of origin requirements but not the EU's will be considered "at risk" and will be charged the EU's MFN tariff (not a preferential tariff), making it all the more important that the Government's reimbursement scheme for "at risk" goods which remain within UK customs territory is made operational as soon as possible. The Minister gives no indication of an expected date, creating further uncertainty for traders who may depend on the scheme to recover additional costs incurred under the Northern Ireland Protocol.

The UK Trader Scheme

5.28 The Minister underlines the importance of the UK Trader Scheme in enabling traders moving goods into Northern Ireland from Great Britain or from a non-EU third country to establish that their goods are "not at risk" and are not subject to EU tariffs. It is unfortunate that he does not provide data to show how many of these (potentially eligible) traders have applied for and obtained authorisation under the Scheme and how many have chosen not to do so or have had their applications rejected.

Exceptions

5.29 The Minister told us that proving compliance with EU and UK rules of origin would involve "very minor administrative change" for most traders, but cited imports under the UK-Turkey Agreement as an exception. It seems that further exceptions are possible but the Minister does not explain how these exceptions would affect the administrative burden on businesses.

Take-up of EU preferences

5.30 The Minister says that HMRC will continue to monitor the movement of goods into Northern Ireland. He does not provide the assurance we sought that the Government will also monitor the take-up of EU preferences for goods brought into Northern Ireland—while this may not directly affect the flow of goods, it may affect the costs of doing business in Northern Ireland.

Changes to EU rules of origin and preferential tariffs

5.31 While UK customs authorities are responsible for implementing EU customs laws under the Northern Ireland Protocol, the Minister confirms that the EU is responsible for developments and changes to its tariff policy. He says that the UK must be informed of these changes if they are within the scope of the Protocol. Nonetheless, as a third country

the UK will have limited means for influencing the development of the EU's tariff policy, even though changes made to it will apply in Northern Ireland. We set out (in the following bullet points) the relevant procedures under the Protocol:

- The EU must inform the UK through the Joint Consultative Working Group (established under the Northern Ireland Protocol) of "planned" EU acts which are within the scope of the Protocol. This would include new EU acts concerning preferential tariffs and rules of origin, as well as EU acts amending or replacing existing rules which already apply under the Northern Ireland Protocol.
- The UK would have no formal say over EU acts amending or replacing the EU's existing preferential rules of origin—they would apply automatically in Northern Ireland once adopted by the EU.
- The EU must inform the UK, through the EU/UK Joint Committee, of the adoption any new EU acts that are "within the scope" of the Protocol. These new acts will only apply in Northern Ireland if the UK agrees to add them to the EU laws listed in the Annexes to the Northern Ireland Protocol. If the UK does not agree and no other solution can be found within the Joint Committee, the EU may take "appropriate remedial measures".

Action

5.32 We have no further questions to raise on the Commission Implementing Regulation. We draw the latest correspondence with the Minister and our assessment to the attention of the International Trade Committee and the Northern Ireland Affairs Committee.

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

Department for Transport

(41746) 13806/20 COM(20) 818	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EEC) No 95/93 as regards temporary relief from the slot utilisation rules at Community airports due to the COVID-19 pandemic.
(41747) 14126/20 SWD(20) 341	Commission Staff Working Document Slot relief measures in light of the COVID-19 pandemic Accompanying the Proposal for a Regulation of the European Parliament and of the European Council amending Council Regulation (EEC) No 95/93 as regards temporary relief from the slot utilisation rules at Community airports due to the COVID-19 pandemic.

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)

Business, Energy and Industrial Strategy Committee: UK-Euratom Nuclear Cooperation Agreement [Recommended Council Decision (SC)]; EU Pharmaceutical Strategy [Commission Communication (SNC)]

Environment, Food and Rural Affairs Committee: EU-UK Relations: Equivalence of various seeds and plants [Proposed Decisions (SNC)]

Health and Social Care Committee: EU Pharmaceutical Strategy [Commission Communication (SNC)]; EU-UK Health Security Cooperation [(a)-(c) Proposed Regulations, (d) Commission Communication (SC)]

International Trade Committee: Northern Ireland Protocol: application of EU preferential rules of origin [Commission Implementing Regulation (SC)]

Northern Ireland Affairs Committee: Northern Ireland Protocol: application of EU preferential rules of origin [Commission Implementing Regulation (SC)]; EU Pharmaceutical Strategy [Commission Communication (SNC)]; EU-UK Health Security Cooperation [(a)-(c) Proposed Regulations, (d) Commission Communication (SC)]; EU-UK Relations: Equivalence of various seeds and plants [Proposed Decisions (SNC)]

Science and Technology Committee: EU Pharmaceutical Strategy [Commission Communication (SNC)]

Formal Minutes

Wednesday 24 March 2021

Members present:

Sir William Cash, in the Chair

Jon Cruddas	Mr David Jones
Allan Dorans	Marco Longhi
Richard Drax	Craig Mackinlay
Margaret Ferrier	Anne Marie Morris
Mrs Andrea Jenkyns	Greg Smith

Scrutiny Report

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 6 read and agreed to.

Resolved, That the Report be the Forty-second Report of the Committee to the House.

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

[Adjourned till Wednesday 14 April at 1.45 p.m.

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 (*Scottish National Party, Rutherglen and Hamilton West*)

Mr Marcus Fysh MP (*Conservative, Yeovil*)

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 (*Conservative, Newton Abbot*)

Charlotte Nichols MP (*Labour, Warrington North*)

Greg Smith MP (*Conservative, Buckingham*)