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LIMITE

UK

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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Commission non-papers on the implementation of the Protocol on Ireland and Northern Ireland

Please find attached four Commission non-papers on the implementation of the Protocol on Ireland and Northern Ireland:

- Sanitary and phytosanitary (SPS) issues
- Customs
- Medicines
- Engagement with Northern Ireland Stakeholders and Authorities

The non-papers will be presented to the Working Party on the UK on 15 October.

The non-papers should be treated with care until they have been made public by the Commission.

The secretariat will send you a message when the Commission non-papers are made public.

Please note that this document bears the marking "LIMITE" and as such is covered by the obligation of professional secrecy in accordance with Article 339 of the Treaty on the Functioning of the European Union (TFEU) and Article 6(1) of the Council's rules of procedure. Moreover, it must be handled in compliance with the relevant EU legislation.

PROTOCOL ON IRELAND AND NORTHERN IRELAND

NON-PAPER

SANITARY AND PHYTOSANITARY (SPS) ISSUES

1) Issue

1. The implementation of the Protocol on Ireland / Northern Ireland ("the Protocol") in the area of SPS (feed, food, plants, animals) is unsatisfactory. European Union (EU)'s SPS law is not correctly applied or not applied at all as regards goods moving from Great Britain to Northern Ireland as a result of the United Kingdom (UK)'s unilateral decisions (grace periods) and the lack of proper infrastructure and staff to perform border controls in Northern Ireland.

2. The UK Government and stakeholders point to the Protocol imposing disproportionately high administrative burdens on Great Britain-Northern Ireland movements of SPS goods, allegedly leading in particular to delays in and shortages of certain food supplies in supermarkets and Northern Ireland consumers being deprived of access to "national identity goods" from Great Britain.

3. This non-paper provides elements for a durable solution to the implementation of the Protocol in the SPS area, in the form of a genuine simplification of processes and procedures for a significant range of goods destined solely for sale to end consumers in retail shops in Northern Ireland ("retail goods"), within the existing framework and in the interest of all communities in Northern Ireland. This would be the basis for further discussions with the UK.

2) Framework

4. The Treaty on the Functioning of the European Union (TFEU) requires the control of external borders to protect the internal market in agricultural products as well as the health of citizens, animals and plants and provides that a high level of protection in human health, animal health and plant heath must be ensured in the definition and implementation of all Union policies and activities (Articles 26(2), 28(1), 39(1), 114(3), 168 and 207 TFEU).

5. Pursuant to Article 5(4) of the Protocol, the provisions of Union law listed in Annex 2 to the Protocol apply to and in the UK in respect of Northern Ireland from 1 January 2021 (i.e. as from the end of the transition period, cf. Article 185 of the Withdrawal Agreement). Accordingly, SPS goods placed on the Northern Ireland market have to comply with the relevant EU SPS requirements.

6. Northern Ireland is part of the EU's SPS area and treated as if the UK were a Member State as regards the territory of Northern Ireland. Northern Ireland and Ireland are treated as a single SPS region for the purposes of managing the consequences of any health outbreaks, including on a global level. Conversely, as from the end of the transition period, Great Britain is no longer part of the EU's SPS area. This means that SPS goods shipped from Great Britain to Northern Ireland are subject to the regime (health conditions/requirements, certification and controls) applicable to imports from any third country, including any mandatory checks, and must fully comply with the relevant EU SPS requirements.

7. The rules and procedures laid down in the Protocol are necessary to protect the Single Market in agricultural products as well as the health of consumers, animals and plants, in line with the TFEU.

3) Possible solution

Durable solution for Great Britain - Northern Ireland movements of SPS retail goods

8. This would be a bespoke solution for Great Britain – Northern Ireland movements of SPS goods to deliver simplified access (simplified certification + reduction of physical checks) in respect of Great Britain – Northern Ireland movements of a significant range of retail goods, which is the current main concern of the UK Government and stakeholders. This should focus on addressing identified real supply problems for retail goods within scope due to the implementation of the Protocol but would neither abolish certification nor all SPS checks.

9. The proposed solution would deliver significant trade facilitations, while ensuring that animals, plants or products circulating in the EU SPS area would not create risks for public, animal or plant health and safeguarding the integrity of the SPS status of the island of Ireland.

10. Any EU's move towards a bespoke solution is subject to a number of pre-conditions, such as the UK delivering on access to IT systems in the customs area and completion of the construction and staffing of permanent Border Control Posts, in accordance with the findings and recommendations of the Commission's recent audit report on the functioning of Border Control Posts in Northern Ireland.

11. Addressing these issues of principle and, importantly, also the scope of any bespoke solution must be based on a thorough risk assessment and an analysis of changes that have already happened or are being implemented in supply chains (based on evidence from the UK and stakeholders and EU's own statistical data - for instance, there is clear evidence that supermarkets have already managed to restructure their supply chain to an extent), and any evidence of or possibilities for further supply chains adaptation.

Criteria for the proposed solution for Great Britain – Northern Ireland movements of SPS retail goods

12. The following criteria would inform this approach:

1/ Simplified certification and reduced checks, with conditions. No full abolition of certification or checks.

- **Simplified certification for retail goods**: e.g. simplified official certificate globally stating that all goods of different type, class or description transported by the same lorry meet the requirements of EU legislation, with detailed documentation for each product available electronically for inspection.
    - However, when the consignment includes products which are subject to prohibitions/restrictions for import into the EU (to be specifically defined in a list by the EU), such as certain meat and meat products or certain plants or plant products, those products should be accompanied by an individual official certificate, for which a specific model would be provided.
- **Reduced checks**: while documentary checks should remain compulsory and can be performed remotely through electronic means, the frequency of identity and physical checks to be performed at the points of entry in Border Control Posts in Northern Ireland, as provided for in EU legislation, could be reduced. The level of checks would not be managed at the level of individual traders / consignments / products but as part of an overall system defining the risk management principles and related decisions, as provided for in EU SPS legislation.

2/ The following conditions would apply:

- If, despite the further adjustment of supply chains, the bespoke solution would also include some meat and meat products subject to prohibitions and restrictions, **basic production requirements** in Great Britain would need to remain aligned with those in the EU. Given the risk that diseases spread, the need for alignment with those production requirements might need to be considered for other areas as well.
- **Products packed for end consumers and labelled as such:** labelling requirements at the level of the individual end-consumer packaging, with a mention such as "*products for sale only in the United Kingdom*", should effectively prevent any further movement of the goods concerned into the EU Internal Market.
- **Goods not for further circulation into the EU Internal Market:** the above facilitations would only be available in respect of products destined solely for sale to end consumers in retail shops located in Northern Ireland (i.e. movements of SPS goods to other operators of the food chain such as farmers or other food processors in Northern Ireland would be excluded).
- **Origin of the primary products:** the above facilitations should only be applicable to end products produced from primary products originating in UK in accordance with the EU-UK Trade and Cooperation Agreement or coming from the EU. As the UK is no longer aligned on EU import conditions, products introduced from third countries must not end up in the EU's SPS area.
- **Reinforced monitoring of supply chains**:
  - Facilitations available to authorised traders / establishments only; channelling procedure (with special monitoring from the point of entry to the point of destination);
  - Double listing of those establishments in Great Britain (points of departure) and in Northern Ireland (points of destination) which would be authorised to participate in the scheme, with operational means of verification (access to IT databases from Northern Ireland) and a withdrawal procedure in case of non-compliance.

3/ Structural safeguards to ensure that the above-mentioned conditions are respected in practice:

- **Solution** subject to a **review clause**.
- **Rapid reaction mechanism** to any identified problems in relation to individual products or traders.
- **Unilateral measures by the EU** in case of failure by UK competent authorities or the trader concerned to react to or remedy an identified problem: e.g. suspension or revocation of the facilitation for the products / traders concerned.
- Union representatives in Northern Ireland and relevant **market surveillance** authorities would have to play an active monitoring role.
- **Compliance verification mechanism** by the Commission, e.g. through audits, on-site inspections of traders and establishments, etc., relying as much as possible on the existing presence of Union representatives in Northern Ireland.

Other flexibilities / solutions already identified by the EU in an effort to facilitate the full implementation of the Protocol

13. These flexibilities / solutions concern in particular Great Britain – Northern Ireland movements of live animals, assistance dogs, high-risk plants, animals returning to Northern Ireland after participating to trade and exhibition fairs in Great Britain, control of scrapie conditions for sheep and goats moving from Great Britain to Northern Ireland and developing an interface between the EU and UK's respective SPS databases. Please see the annex for the details.

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ANNEX

Flexibilities / solutions identified by the EU in an effort to facilitate the full implementation of the Protocol on Ireland / Northern Ireland

Solutions already found to facilitate Great Britain – Northern Ireland movements of live animals requiring EU action

The Commission has identified a number flexibilities, which address the specific issues raised in this area by the UK in previous technical discussions and various non-papers. These flexibilities can be implemented within existing EU law to facilitate the movement of live animals from Great Britain to Northern Ireland, as follows:

- **Tagging of live animals moving from Great Britain to Northern Ireland**: Commission Implementing Regulation (EU) 2021/1064 of 28 June 2021 enables Northern Ireland animals to be identified in accordance with EU rules and therefore removes the need for re-tagging when animals move multiple times between Great Britain and Northern Ireland during their life.
- New legal framework to allow re-exports to the EU and Northern Ireland of **EU-origin animal products** that are **moved to Great Britain for storage:** Commission Implementing Regulation (EU) 2021/1469 of 10 September 2021.
- **Facilitating the return to Northern Ireland of livestock from trade / exhibition fairs in Great Britain**, so that the animals concerned will not have to wait for a minimum residency period in Great Britain (Commission delegated and implementing acts are under preparation).
- Work is also ongoing on a solution regarding the **risk control of scrapie**, to facilitate the **movement of sheep and goats** between Great Britain and Northern Ireland (Commission Regulation under preparation).
- Amendment of EU import requirements on **animal by-products obtained from animals slaughtered in Great Britain**: this simplifies certification requirements and reduces the residency period for animals brought into Great Britain from Northern Ireland, the EU or any other third country before they can be slaughtered: the amendment of Regulation (EU) No 142/2011 is expected be adopted in October 2021. Meanwhile, it was agreed with the UK and Member States that they can start implementing the new measure through bilateral arrangements.
- Amendment of EU import requirements on **animal by-products** to authorise Ireland and Northern Ireland to **export category 1 meat-and-bone meal to Great Britain for combustion**: Commission Delegated Regulation (EU) 2021/899 of 3 June 2021 amending Regulation (EU) No 142/2011.
- Amendment of EU import requirements on **racing pigeons** to avoid a 30-day quarantine for pigeons brought into the EU or Northern Ireland from Great Britain: the amendment of Commission Delegated Regulation (EU) 2020/692 will be adopted in October 2021. Meanwhile, it was agreed with the Member States that they can use the transition period offered through the new Animal Health Law to continue accepting entries without quarantine.

No further action appear necessary on the EU side. To be noted that the approach for movements of live animals set out in UK Command Paper of 21 July 2021 foresees systematic checks also on Great Britain – Northern Ireland movements, albeit based on UK law rather than EU law. The principle that live animals should be systematically checked, also in the context of Great Britain – Northern Ireland movements, is therefore uncontroversial.

Other solutions already found, not requiring any particular further step on the EU side

Other solutions have already been found, which do not require any specific measure at EU level for their implementation, as follows:

- Developing an interface between the EU and UK's respective SPS databases: the interface on the EU side is ready, the UK is now in the process of developing its own interface. There are regular contacts between the respective IT teams to ensure that the interface will be ready as soon as possible. This will enable e-certification and a swift handling of entry/exit data for SPS goods that will speed up documentary checks, especially on goods moving from Great Britain to Northern Ireland and help identify discrepancies on entry/exit data.

- Assistance dogs: the issue can be solved through the application of a derogation clause built into Regulation No. 576/2013 on the non-commercial movement of pet animals (Article 32). That provision provides the necessary flexibilities as regards the temporary introduction of assistance dogs coming into Northern Ireland from Great Britain. On that basis, Northern Ireland SPS authorities can therefore develop the operational details. Further discussions can take place at expert level on practical implementation aspects as necessary.

- High-risk plants: the EU side has facilitated contacts between the UK and European Food Safety Agency (EFSA) to assist in the preparation by the UK of complete dossiers concerning high-risk plants intended for export from the UK (Great Britain) to the EU. The completeness of the file is the main relevant factor affecting the timing of EFSA's risk assessment. All requested explanations/clarifications were provided to the UK representatives. Following EFSA's positive assessment, the exports of the plants concerned from the UK (Great Britain) to the EU will be authorised. The first dossier from the UK was submitted to EFSA in September 2021.

PROTOCOL ON IRELAND / NORTHERN IRELAND

NON-PAPER – CUSTOMS

1) Issue

1. One of the key concerns raised by the Government of the United Kingdom (UK) and by many stakeholders in Northern Ireland, in particular business, is the new obstacles since the end of the transition period to the flow of goods from Great Britain to Northern Ireland i.e. East/West trade. They have pointed, in particular, to the customs procedures and requirements, such as the supplementary declarations[1], which apply now to such movements that create administrative burden and compliance costs.

2. The UK's withdrawal from the European Union (EU) had indeed as a consequence that customs formalities and compliance requirements apply to movements of goods between the Union and the UK, which did not exist when the UK was part of the Union's Single Market and Customs Union. The firm commitment of the Union and the UK to no customs and regulatory checks or controls and related infrastructure at the border between Ireland and Northern Ireland has led the Union and the UK to agree to a common balanced solution for customs in the Protocol on Ireland/Northern Ireland (the 'Protocol'). As a result, the external border of the Union's Single Market for goods and Customs Union has been established between Northern Ireland and Great Britain respective territories. This external border of the Union is managed and controlled by the UK authorities.

3. The UK Government refers now to obstacles resulting from the Protocol in the area of customs that have a negative impact on Northern Ireland business as regards East-West trade and the place of Northern Ireland in the UK internal market[2]. It has however not provided any concrete economic evidence nor substantiated the precise difficulties faced resulting from the implementation of the agreed solution which would outweigh the benefits and opportunities that Northern Ireland business has by remaining de facto part of the Union's Single Market for goods and are confirmed by a majority of Northern Ireland businesses[3].

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[1] A supplementary declaration, in the form of a full customs declaration, must be submitted to the customs authorities by the holder of an authorisation to submit simplified declarations. Such authorisations allow for some particulars of the declaration to be omitted at the lime of lodging of the customs declaration. Some of the data requirements are postponed to the supplementary declaration, in general 10 days after the release of the goods.

[2] 'Supply chains have been disrupted and costs increased, with staff redeployed to deal with new bureaucracy, impacting investment and growth. Consumers have seen real impacts: at least 200 companies in Great Britain have stopped servicing the Northern Ireland market; … supermarkets have reduced their product lines due to the delays and barriers in moving goods; and the costs of deliveries for those who do serve the market have continued to increase. … In turn we have seen changes to longstanding trade flows as businesses in Northern Ireland either divert their supply chains, or businesses in Great Britain decide to no longer supply into Northern Ireland. … Half of the membership of the Northern Ireland Chamber of Commerce believed Northern Ireland's trade relationship with Great Britain under the existing arrangements had been negatively impacted, and half considered this would remain the case in the future –with only 8% seeing positive benefits. Many more have noted the increased costs and the challenge that poses to their viability in the longer-term.' *Northern Ireland Protocol: the way forward*, July 2021, Command Paper 502.

[3] Northern Ireland Chamber of Commerce and Industry, *Cause for optimism as NI's economic recovery gathers pace*: (i) Business confidence improved strongly in Q2 2021, (ii) More businesses are now making plans to invest, particularly manufacturers; and (iii) 67% believe that NI's status post EU Exit presents opportunities for the region. When asked on the impact of Brexit 29% of members said that their business has adapted well to new trading arrangements, up from 15% in Q1 2021. At the same time almost a third (32%) are finding new trading arrangements difficult, however significantly less than in Q1 (41%). The Central Statistics Office of Ireland has also reported that the value of goods imported from NI to IE rose by 60% to €1bn in the first four months of 2021, compared with the same period in 2020 (€697m). Exports from IE to NI rose

2) Framework

4. As provided for in Article 6(2) of the Protocol, having regard to Northern Ireland's integral place in the UK's internal market, the Union and the UK should use their best endeavours to facilitate trade between Northern Ireland and other parts of the UK, in accordance with applicable legislation and taking into account their respective regulatory regimes as well as the implementation thereof[4].

5. As provided for in Article 5 of the Protocol goods imported into Northern Ireland from Great Britain are subject to standard customs rules, procedures and formalities according to the Union customs legislation. In particular, by default, the EU tariff applies.

6. However, imports of goods into Northern Ireland which are considered as 'not at risk of being subsequently moved into the Union' are subject to UK customs duties. As regards East/West trade, that means no customs duties are collected but, standard customs procedures apply. Indeed, there is no further customs facilitation for goods considered as 'not at risk'.

7. This concept of goods 'not at risk' has been further defined in the Joint Committee Decision No 4 of 17 December 2020[5]. The Protocol provides that goods subject to commercial processing i.e. goods which are imported for the purpose of manufacturing in Northern Ireland, are systematically considered as 'at risk' goods.

8. However, the Decision provides for some flexibilities: small businesses in Northern Ireland (on the basis of a turnover threshold) and businesses which process goods for a specific purpose such as the sale of food to end-consumers in Northern Ireland, for construction located in Northern Ireland, for health or care services, for animal feed or for not-for-profit activities, can be considered as carrying out 'non-commercial processing'.

9. As regards goods not subject to commercial processing, the Decision provides for a comparison between the UK and the Union customs duties payable. For goods brought in from Great Britain, the good is considered not at risk of being moved to the Union if the Union customs duty is equal to zero[6].

10. The Decision also provides for additional flexibilities regarding East/West trade flows. In particular, the Decision provides for a regime of authorisation for certain traders. They are considered as importing 'not at risk goods' if they can guarantee that these goods will solely be sold, via physical direct sales from physical outlets, to, or provided for final use by, end-consumers in Northern Ireland[7]. The scheme is available to business established in Northern Ireland and to business which have a fixed place of business there[8].

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by 40% to almost €977m over the same period, reflecting increased IE-NI cross-border trade since Brexit as NI remained in the EU's single market for goods.

[4] The Joint Committee should also keep the application of this paragraph under constant review and adopt appropriate recommendations with a view to avoiding controls at the ports and airports of Northern Ireland to the extent possible.

[5] Decision No 4/2020 of the Joint Committee established by the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 17 December 2020 on the determination of goods not at risk [2020/2248], OJ L 443, 30.12.2020, p. 6.

[6] For goods brought from the rest of the world, the UK tariff applies if the Union tariff is equal to or less than the UK customs tariff.

[7] These flexibilities are also applicable to goods brought from the rest of the world if the difference between the UK and the Union customs duties payable is lower than 3% of the customs value of the good.

[8] Non-established traders with an indirect customs representative in Northern Ireland and who have their customs-related operations carried out in the UK.

11. The main purpose of this scheme is to reduce the costs of moving goods from Great Britain as UK customs duties applies, which means no duties[9] for retailers established in Northern Ireland such as supermarkets and stores depending on supply chains and distribution centres established in Great Britain. In addition, such traders do not need to calculate the Union customs duties which would be payable[10]. Their compliance costs are therefore reduced.

12. The UK Trader Scheme (UKTS) implements the Joint Committee Decision in the UK. Until now more than 3.000 applications for the regime have been received by the UK authorities and close to 3.000 authorisations have been granted, which shows the great interest in this regime.

3) EU Interest and Conditions

Union Interest

13. It is in the Union interest that a proper and full implementation of the agreed Protocol on Ireland/Northern Ireland takes place. However, should a precise problem in that implementation be identified, including as regards trade between Great Britain and Northern Ireland, which would affect Northern Ireland citizens and business, it would be in the Union's interest to find creative, effective and long-term solutions to such difficulties, within the framework of the Protocol.

14. In addition to the protection of the Good Friday (Belfast) Agreement, the fundamental interest of the Union is the protection of the integrity of both the Customs Union and the Single Market for goods. Considering that customs authorities play a major role in the correct application of EU market legislation on goods, and taking into account that the Union has given up its control of its external border between Ireland and Northern Ireland to the UK customs authorities, it remains of utmost importance for the EU that an effective control is in place for that purpose.

Union Conditions

15. Therefore, adjustments to the current framework, which are legally feasible under the Protocol, could be considered. However, certain conditions should be met and certain guarantees should be provided by the UK.

16. The UK should demonstrate that the existing customs simplifications and facilitations provided for in Union legislation have been fully implemented by the UK authorities and have been used by the traders and that they have not been able to address the issues which are faced with by the traders given the unique situation of Northern Ireland.

17. The solutions to be identified should not require a renegotiation of or amendments to the Protocol and should ensure stability, predictability and legal certainty in Northern Ireland for the benefit of citizens and business while fully protecting the integrity of the Union's Single Market and Customs Union and the Good Friday (Belfast) Agreement.

18. In particular, while not eliminating them completely, the solutions should reduce formalities, checks and controls at the border for East/West trade without threatening the integrity of the Union's Single Market and Customs Union.

19. The UK should have fully implemented what has been agreed under the Protocol in the area of customs. The main open issues include:

[9] Anyway, under certain conditions, as provided for in Article 5(6) of the Protocol, the UK may reimburse the customs duties levied on such imports in respect of goods that can be shown not to have entered the Union.
[10] Customs duties depend on the customs value of the goods, the customs tariff to be applied and the origin of the goods.

i. the implementation of Union's prohibitions and restrictions on export of goods from Northern Ireland to Great Britain (the prohibitions and restrictions applying at export should include dual-use items, cultural goods and waste shipment);

ii. the implementation of the customs legislation and of the UK unilateral declaration on 'unfettered access', for goods exiting Northern Ireland to Great Britain[11];

iii. the correct implementation of the customs legislation at entry into Northern Ireland of B2B[12] parcels; and

iv. full and real time access of the Union Representatives to the UK IT systems in order to carry out their monitoring duties properly as provided for in the Joint Committee Decision N° 6/2020 of 17 December 2020[13].

20. The UK should also commit to:

i. implement appropriate monitoring and enforcement measures for such adjustments in order to ensure a sufficient level of confidence that the integrity of the Union's Single Market and Customs Union is protected. Additional data collected should be shared with the Union representatives;

ii. continue the support, in particular with the Trader Support Service, which has been provided to the business in the UK when implementing the Protocol as regards East/West trade.

4) Possible Solutions

21. In order to facilitate East/West trade, the scheme applicable to 'goods not at risk of being subsequently moved into the Union' which already exists in the Protocol, and is further implemented under Joint Committee Decision No 4, could be further developed in terms of both scope - the beneficiaries and products covered - and benefits such as genuine simplifications for the business and supplies of goods eligible.

22. Criteria related to the status of the sender and recipient of the goods (e.g. business or consumer), the business activity of the parties involved (e.g. retailers, wholesalers, manufacturing industry), the nature of the goods (e.g. intermediate goods or consumers goods), the value of the goods, the nature of the consignment (e.g. parcels), the record of compliance with customs or/and taxation requirements of the business involved, could be used in the design and the scope of the scheme.

23. In terms of benefits, additional facilitation measures with regard to customs formalities and processes could be put in place for the 'goods not at risk'.

24. In any case, the eligibility criteria, the requirements to be met, the reporting obligations and enforcement tools of such a revised scheme should be robust enough to guarantee that the goods moved to Northern Ireland under the scheme would be subject to final consumption in Northern

[11] https://ec.europa.eu/info/publications/unilateral-declarations-uk-and-eu-export-procedures-goods-moving-northern-ireland-great-britain_en

[12] Business to Business.

[13] Decision No 6/2020 of the Joint Committee established by the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 17 December 2020 providing the practical arrangements relating to the exercise of the right of Union representatives referred to in Article 12(2) of the Protocol on Ireland/Northern Ireland [2020/2250], OJ L 443, 30.12.2020, p.16.

Ireland and, therefore, would not be moved subsequently to the Union. Union representatives and relevant market surveillance authorities should play an active role in monitoring the scheme.

25. The impact of the revised scheme on the implementation of indirect tax rules (Value Added Tax (VAT) and excise duties), the operation of market surveillance in respect of products made available on the Northern Ireland market and EU quotas should also be considered in this context. It should be ensured in particular that EU quotas could not be circumvented under the scheme and goods could not be consumed in Northern Ireland free of VAT and excise duties.

26. Without amending the Protocol, such a scheme may require amendments to the Joint Committee Decisions adopted in December and/or to Union legislation made applicable to the UK in respect of Northern Ireland by the Protocol.

5) Structural safeguards

27. A review clause and a termination clause in case of non-compliance.

28. Full use of the relevant alert mechanisms to flag any identified problems in relation to individual products or traders.

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PROTOCOL ON IRELAND AND NORTHERN IRELAND

NON-PAPER

MEDICINES

1) Issue

1. Adapting supply chains to the new situation created by the United Kingdom (UK)'s withdrawal from the European Union (EU) and the application of the Protocol on Ireland / Northern Ireland ("the Protocol") remains challenging in the pharmaceutical sector, in particular for suppliers of generics and over the counter **medicines covered by national authorisations issued by the UK in respect of Northern Ireland.**

2. Specifically, it appears to be too costly for certain operators currently based in Great Britain to move regulatory compliance functions and related logistics and testing facilities (namely, the marketing authorisation holder, quality control (batch) testing, the qualified persons responsible for batch testing and release and for pharmacovigilance) to Northern Ireland or the EU, as well as to comply with the importation requirements, such as the manufacturing import authorisation, as required by the Protocol. As a result, some companies may decide no longer to supply medicines to the Northern Irish market, which might create a public health risk.

3. Stakeholders have also requested that the UK national authorisation procedures for Great Britain (governed by UK domestic law) and for Northern Ireland (governed by EU law), which are under the responsibility of the same UK regulatory authority, should be operated and coordinated in such a way as to permit the continued use of a single pack and a single leaflet for patient information for the whole UK market.

4. This non-paper sets out the EU's proposed solution to provide a long-term perspective for undisrupted **medicines supply from or through Great Britain to Northern Ireland** for the benefit of patients in Northern Ireland. It updates and replaces the non-paper published on 26 July 2021.

2) Framework

5. Pursuant to Article 5(4) of the Protocol, the provisions of Union law listed in Annex 2 to the Protocol apply to and in the UK in respect of Northern Ireland from 1 January 2021 (i.e. as from the end of the transition period, cf. Article 185 of the Withdrawal Agreement). Accordingly, medicines placed on the market in Northern Ireland must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisations) or the UK for Northern Ireland in applying the EU legislation for medicinal products listed in Section 20 of Annex 2 to the Protocol (UK national authorisations).

6. There are two possible UK national authorisation routes in accordance with the Protocol: purely UK national authorisations ("Northern Ireland-only authorisations"), which concern medicines that are made available in Northern Ireland but nowhere else in the EU, and UK national authorisations granted via the Mutual Recognition or Decentralised Procedures (MRP/DCP), which apply when a medicine is also made available in one or more Member States.[1] The

[1] Under these procedures, a Member State takes the lead in the assessment ("Reference Member State") and issues the first authorisation, on the basis of which identical national authorisations are then issued by the other "Concerned Member States". Pursuant to the Protocol, Northern Ireland participates in these two procedures but the UK cannot have the leading role.

implementation issues that have been identified in the various talks to date between the UK Government and the European Commission and with both UK and EU stakeholders solely concern **medicines covered by UK national marketing authorisations**.

7. The Commission Notice of 25 January 2021[2] provides for a grace period of one year (until end-December 2021) for maintaining batch testing and manufacturing / logistics in Great Britain (GB) to ensure undisrupted supply of medicines to Northern Ireland and those EU Member States (Cyprus, Ireland and Malta) that have been historically dependent on medicines supply from or through Great Britain.[3]

8. The grace period aimed to give all relevant stakeholders sufficient time to adapt to the UK's withdrawal and to establish new supply routes where necessary, while providing for undisrupted supply of medicines and a high level of public health protection.

3) Possible solutions

Localisation of regulatory compliance functions

9. The proposed solution would provide, as a permanent derogation from the relevant provisions of Directive 2001/83/EC (framework directive for medicinal products for human use) that regulatory compliance functions for medicines supplied to the Northern Ireland market only, pursuant to national authorisations issued by the UK in accordance with the Protocol, may be located in Great Britain. In addition, no manufacturing import authorisation would be required for bringing medicines into Northern Ireland from or through Great Britain.

10. This should greatly facilitate the operations of pharmaceutical companies in Great Britain and thus ensure medicines supply. The companies concerned would not need to relocate infrastructure (including testing facilities) or regulatory compliance functions to Northern Ireland or the EU and could therefore continue to supply the whole UK market, including Northern Ireland, from where their infrastructure and regulatory functions are currently located.

11. The following **conditions** would apply:

    a. the UK should fully apply the relevant Union legislation on medicines - on quality, safety, efficacy, pharmacovigilance and batch testing and release - when issuing national marketing authorisations in respect of Northern Ireland;

    b. the marketing authorisation should contain a legal prohibition of sale (resale) outside its geographical scope: medicines with an authorisation for Northern Ireland cannot be legally sold anywhere else in the EU and the specific authorisation code for Northern Ireland should be stamped on each pack;

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[2] Commission Notice of 25 January 2021 on the application of the Union's pharmaceutical acquis in markets [Northern Ireland, Cyprus, Ireland, Malta, Northern Ireland] historically dependent on medicines supply from or through Great Britain after the end of the transition period, OJ C 27, 25.1.2021, p. 11. The Commission Notice implements the EU's unilateral declaration on medicinal products made in the meeting of the Joint Committee of the EU-UK Withdrawal Agreement of 17.12.2020.

[3] The current flexibilities allow: (i) wholesale distributors in Northern Ireland, Cyprus, Ireland and Malta to place medicinal products imported from Great Britain without the manufacturing authorisation required for imports from third countries; (ii) batch testing normally required to be carried out in the EU (or Northern Ireland pursuant to the Protocol) before placing medicinal products on the market to take place in Great Britain; (iii) derogations relating to the placement of the unique identifier for prescription medicines for human use.

c. the safety features for required under applicable EU law should be placed on each pack ensuring that medicines can only be sold in conformity with a valid marketing authorisation in Northern Ireland;

d. the UK should ensure and demonstrate the correct implementation/application of the Falsified Medicines Directive in respect of Northern Ireland. The EU end-to-end verification system must generate an alert if a medicine specifically authorised for Northern Ireland is scanned elsewhere in the EU Internal Market (see further under paragraphs 20 and 21 below);

e. as regards the derogation from the manufacturing import authorisation requirement, the person importing medicines into Northern Ireland should nonetheless hold a wholesale distribution authorisation issued in accordance with EU law. In addition, the relevant checks normally performed by the manufacturing authorisation holder should be performed either in the EU (as per para. 12 below) or in Great Britain applying equivalent standards to those in Union law;

f. enforcement and supervision by the UK competent authorities on economic operators and regulatory compliance activities located in Great Britain should be carried out in accordance with applicable EU law.

12. If batch testing has been carried out in the EU, it would not be necessary to repeat it for medicines which are exported to Great Britain from a Member State in view of subsequent importation into Northern Ireland. This would be on condition that the batches concerned have undergone the necessary controls in a Member State and are accompanied by the control reports signed by the qualified person meeting the legal requirements.

13. **Enhanced enforcement** by the UK competent authorities **on the Northern Ireland market** would be required **to ensure that the medicines concerned remain in Northern Ireland and are not further distributed in the EU Internal Market**, as follows:

    a. the UK should notify to the Commission the list of medicines covered by all national authorisations (Northern Ireland-only authorisations and those issued under the MRP/DCP) as well as the references of the corresponding authorisation codes that will be stamped on the medicine packs. The UK should also establish a publicly available database with this list that will be regularly updated;

    b. the UK should ensure effective supervision of wholesalers in Great Britain and Northern Ireland and pharmacists and other points of sale in Northern Ireland, the affixing of the unique identifier on the medicine packs supplied to Northern Ireland and that the verification by the person entitled to supply to the public in Northern Ireland will be carried out in compliance with the requirements of EU legislation on falsified medicines;

    c. the UK should ensure effective supervision of operators importing medicines from Great Britain into Northern Ireland by the UK competent authorities after the end of the current grace period in those cases where the marketing authorisation holder is based in Great Britain.

14. The marketing authorisation holders will always be entirely responsible for ensuring the quality, safety and efficacy of the medicinal products placed on the Northern Ireland market independently of any derogations provided.

15. The Commission, with the support of the EU Member States, will carry out inspections to verify compliance of the marketing authorisations issued by the UK in respect of Northern Ireland with relevant EU legislation and the specific conditions set out above.

Operation of the MRP/DCP in respect of Northern Ireland

16. As regards UK national authorisations issued pursuant to the **MRP/DCP**, the Commission stands ready to continue discussing with the UK and stakeholders how to ensure in practice that the UK national authorisation procedures for Great Britain (governed by UK domestic law) and for Northern Ireland (governed by EU law) are operated and coordinated in such a way as to ensure the continued use of a single medicine pack and a single leaflet for patient information for the whole UK market, in order to address the concerns raised by stakeholders in this regard.

17. After a marketing authorisation for Northern Ireland has been issued pursuant to the MRP/DCP route, any changes would continue to be processed through the EU Reference Member State. The UK should recognise those assessments and adapt its corresponding national authorisation for Northern Ireland accordingly, so as to ensure they remain fully in compliance with EU law.

18. The UK competent authorities and the EU Coordination Group for Mutual Recognition and Decentralised Procedures should work together to ensure consistency in relevant guidance issued to stakeholders.

Investigational medicinal products

19. The proposed solution would provide a derogation from the manufacturing import authorisation requirement to allow clinical trial sites or sponsors in Northern Ireland to continue to use investigational medicinal products supplied from or through Great Britain provided the conditions set out in para. 11 above are complied with.

Requirements relating to the safety features for medicinal products for human use

20. In order to provide further flexibility with respect to compliance with the safety features (namely, an anti-tampering device and unique identifier) that are mandatory for prescription medicinal products for human use pursuant to applicable EU legislation, the proposed solution consists of a further three-year derogation from the obligation to decommission the unique identifier when medicines are exported from the EU to the UK in respect of both single- and multi-market packs.

21. In order to ensure that medicines made available to Northern Ireland (or Cyprus, Malta and Ireland, which may also benefit from the same flexibility[4]) are not placed on the market elsewhere in the EU, the EU repository system should be adapted so as to ensure that an alert is generated when the medicine is verified for sale outside these markets.

Veterinary medicines

22. The Commission stands ready to continue discussions with the UK and stakeholders to identify any outstanding implementation issue with a view to finding the most appropriate way forward for ensuring continuity of veterinary medicines supply to Northern Ireland.

Implementation of the proposed solutions

23. The proposed solutions set out in the above paragraphs would be implemented through:

    – a targeted legislative amendment of the relevant legal acts in the EU pharmaceutical legislation, namely Directive 2001/83/EC (framework directive for medicinal products for

[4] Pending the development of longer-term policy or legislative initiatives, a temporary time-limited derogation on sourcing medicines for Cyprus, Malta and Ireland from the UK could be considered on the basis of justified public health reasons.

human use) and Directive 2001/20/EC and Regulation (EU) No 536/2014 (good clinical practice in the conduct of clinical trials on medicinal products for human use);

- an amendment of Commission Delegated Regulation (EU) 2016/161 on safety features appearing on the packaging of medicinal products for human use.

24. The EU acts implementing the proposed solutions would be added to the list of EU legislation on medicinal products in Section 20 of Annex 2 to the Protocol and therefore apply to and in the UK in respect of Northern Ireland pursuant to Article 5(4) of the Protocol.

25. The Commission is very mindful of the need to provide business with the necessary predictability and legal certainty, pending the completion of the procedures necessary for implementing the envisaged solutions for human medicines and discussions on a way forward for veterinary medicines, in view of the fact that the grace period provided for in the Commission Notice of 25 January 2021 expires at the end of this year.

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PROTOCOL ON IRELAND AND NORTHERN IRELAND

NON-PAPER

ENGAGEMENT WITH NORTHERN IRELAND STAKEHOLDERS AND AUTHORITIES

1) Issue

1. On 21 July 2021, the UK issued a Command Paper on the way forward for the Protocol on Ireland / Northern Ireland ("**Protocol**"), requesting, *inter alia*, to "*normalise the governance basis of the Protocol*", so that the relationship between the UK and the EU is "*not ultimately policed by the EU institutions*." This implies renegotiation of several provisions of the Protocol, including parts of the Protocol that place Northern Ireland in the EU's Single Market. As part of this request, the UK is also looking for ways to ensure that Northern Ireland institutions and stakeholders are more deeply involved in shaping and bringing into force legislation applicable in Northern Ireland.

2. The EU is aware that there is a real interest in Northern Ireland for greater transparency and for Union measures to take account of implications for Northern Ireland. This was highlighted in our discussions with businesses, civic society groups and public authorities.

3. It is important to recall what already exists under the Protocol in this regard. Notably, a joint consultative working group on the implementation of the Protocol was established ("**JCWG**"), Northern Ireland authorities are actively participating in the meetings of the EU – UK Joint Committee on the Withdrawal Agreement ("**Joint Committee**") and the JCWG, the Joint Committee has a role under Article 13(4) of the Protocol regarding new Union acts that fall within the scope of the Protocol and ultimately, the Protocol provides for democratic consent in Northern Ireland to the continued application of Articles 5 – 10 of the Protocol.

4. It is worth pointing out that primarily it would be for the UK Government to engage the Northern Ireland authorities in the work of joint bodies established under the Withdrawal Agreement and the Protocol. Any solution on this point should be in line with the UK's constitutional order.

5. The purpose of this paper is to outline effective and strategic solutions to enhance engagement with Northern Ireland authorities and stakeholders, within the framework of the Protocol. These solutions are based on discussions with the Northern Ireland civic society and business.

2) Framework

6. Article 15 of the Protocol establishes the JCWG, designed as a '*forum for the exchange of information and mutual consultation'*. The JCWG is composed of representatives of the Union and the UK. It carries out its functions under the supervision of the Specialised Committee on issues related to the implementation of the Protocol on Ireland and Northern Ireland established by Article 165 of the Withdrawal Agreement ("**Specialised Committee**") to which it reports. The JCWG has no powers to take binding decisions (other than to adopt its own rules of procedure).

7. The Protocol further requires the EU to "*ensure that all views expressed by the United Kingdom in the working group and all information provided by the UK in the working […] are communicated to the relevant institutions, bodies, offices and agencies of the Union without undue delay*" (Article 15(6) of the Protocol).

3) EU interest

8. The EU will not agree to a renegotiation of the Protocol. The EU's focus remains on identifying long-term, flexible and practical solutions to address issues related to the practical implementation of the Protocol that citizens and businesses in Northern Ireland are experiencing.

4) Possible solutions

9. The ideas outlined below have six strands addressing the concerns referred to in para 2 raised by the stakeholders.

Increasing transparency

10. The EU is aware that transparency is a crucial element for building trust in Northern Ireland and there is clearly room for improvement. The Commission is working on setting up a website that would in a clear and comprehensive way show the EU legislation applicable in Northern Ireland (covering also dynamic alignment aspect). That will significantly contribute to greater transparency for the people of Northern Ireland.

11. In terms of stakeholders' engagement, we would also like to recall that the Commission launches public consultations for certain measures where Northern Ireland stakeholders can express their views. We could also envisage to include the information on pending public consultations for measures that have relevance for Northern Ireland, on this dedicated website.

12. Although this idea primarily addresses concerns of stakeholders, it is also important for Northern Ireland authorities to be able to easily refer and find the EU *acquis* applicable to and in the UK in respect of Northern Ireland.

The work of the JCWG

13. The JCWG as important platform for information sharing, consultation and exchanges with Northern Ireland authorities, specifically on (new) legislation relevant for the implementation of the Protocol. Operational arrangements are in place to facilitate the work of the JCWG. The Union acknowledges the importance of the JCWG, and we are committed to making it work better.

14. In agreement with our UK counterparts, we could set up structured groups with the participation of experts from respective authorities to discuss aspects of Union measures that are important for the implementation of the Protocol. This would create space for the technical cooperation that the day-to-day application of the Protocol requires.

15. Furthermore, the Rules of Procedure of the JCWG provide that the meetings of the group are confidential. However, we do see merits in lifting this confidentiality requirement for deliberations on specific legislative proposals (and in particular when expert explanations are given in the JCWG) and their impact on the Northern Ireland. The co-chairs of the JCWG may also decide to publish the summary of the minutes (which could include any explanations on specific measures).

16. The development of the work of the JCWG is relevant for the UK Government and Northern Ireland authorities to have a better understanding of the rules made applicable by the Protocol to and in the UK in respect of Northern Ireland. It builds on mechanisms already existing in the Protocol. While the EU is willing to engage and work constructively on these matters, we also believe that the UK

Government needs to play a crucial role to increase engagement with Northern Ireland's authorities on matters related to the implementation of the Protocol.

Fora for structured dialogue with Northern Ireland stakeholders

17. The structured dialogue would be established between stakeholders (including Northern Ireland civic society and business), the experts working in the Union institutions, bodies and agencies and their UK counterparts (including Northern Ireland authorities).

18. The purpose of having these formalised fora is to establish dedicated space for dialogue between Northern Ireland stakeholders and experts in certain fields (e.g. customs, sanitary and phytosanitary measures, and environment) to allow for the views of Northern Ireland stakeholders to be expressed in the areas relevant for the implementation of the Protocol. Those meetings could be structured around the meetings of the Specialised Committee and/or JCWG.

19. Creation of these dedicated fora has two main goals. First, it is important for Northern Ireland stakeholders to have a better understanding of the Union rules made applicable by the Protocol to and in the UK in respect of Northern Ireland. Secondly, it would allow the Union to be able to better understand the impact of certain aspects of the Protocol for Northern Ireland businesses and civic society.

Structured dialogue between stakeholders and co-chairs of the Joint Committee

20. The EU and the UK would establish a structured dialogue between the co-chairmen of the Joint Committee and representatives of business communities and of civil society organisations in Northern Ireland. These meetings would be set up on a regular basis.

21. These exchanges are already taking place – but going forward they could be organised in a more structured way. This primarily benefits the stakeholders in having their concerns heard.

Participation of the stakeholders at the Specialised Committee

22. The Specialised Committee is a high-level body that should be used as a platform to engage with wider Northern Ireland civic society and business. This primarily benefits the stakeholders and civic societies in having their concerns heard.

Stronger link between Northern Ireland Assembly and the EU-UK Parliamentary Partnership Assembly

23. Following the European Parliament's endorsement of its delegation to the EU-UK Parliamentary Partnership Assembly, further contacts with Parliament colleagues would be needed to see how the ideas of a Northern Ireland sub-structure could work.

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