HOUSE OF LORDS
European Union Committee

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The primary purpose of the House of Lords European Union Select Committee is to scrutinise EU law in draft before the Government take a position on it in the EU Council of Ministers. This scrutiny is frequently carried out through correspondence with Ministers. Such correspondence, including Ministerial replies and other materials, is published where appropriate.

This edition includes correspondence from 1 April – 30 June 2019

EU JUSTUCE SUB-COMMITTEE

CONTENTS

PROPOSAL FOR A COUNCIL REGULATION ON JURISDICTION AND THE RECOGNITION AND ENFORCEMENT OF JUDGMENTS IN MATRIMONIAL MATTERS AND THE MATTERS OF PARENTAL RESPONSIBILITY, AND ON INTERNATIONAL CHILD ABDUCTION (RECAST) (10767/16)

Letter from the Chairman to the Rt Hon David Gauke MP, Lord Chancellor and Secretary of State for Justice, Ministry of Justice

Thank you for your letter dated 27 March 2019. It was considered by the EU Justice Sub-Committee at its meeting of 30 April.

We reluctantly decided to clear the proposed Regulation from scrutiny given the stage that the negotiations of this matter have reached in the Council.

As you know, we have taken a keen interest in the ramifications of Brexit for this important area of EU cooperation, and we may return to these matters when necessary. In the meantime, the draft Regulation deals with an area of EU law that inevitably concerns the welfare of children and as such requires certainty. We are therefore concerned and disappointed to note your misgivings about the inconsistent approach to so-called privileged decisions enshrined in the text shortly to be agreed by the Council.

We do not expect a response to this letter.

30 April 2019

Letter from the Rt Hon David Gauke MP, Lord Chancellor and Secretary of State for Justice

Thank you for your letter of 30 April clearing this proposal from scrutiny.

When I wrote to you on 27 March I explained that the Romanian Presidency intended to refer the recitals and standard forms of this proposal to Coreper in April to allow the legal-linguists to consider these and the General Approach text which had been agreed in December 2018, before formal adoption of the Regulation in June.

I can confirm that, as anticipated, Coreper did agree the recitals and standard forms and therefore adoption remains scheduled for June, before the Presidency's term ends.

In your letter you expressed concern and disappointment about the different approach to the privileged decisions in relation to obtaining the views of children that I highlighted in the standard forms. While the Government shares the disappointment that there was no consistent approach in this regard, as I said in my previous letter, I do not consider any difference in interpretation in the forms will have a significant effect on the application of the new Regulation. The number of cases affected will be limited and such decisions will still be capable of enforcement in another Member State.

13 May 2019

Letter from the Chairman to the Rt Hon David Gauke MP, Lord Chancellor and Secretary of State for Justice

Thank you for your letter dated 13 May 2019. It was considered by the EU Justice Sub-Committee at its meeting of 4 June.

We have already cleared the proposed Regulation from scrutiny. We note your view that the inconsistent approach to privileged decisions enshrined in the final text will not have a "significant effect on the application of the new Regulation" and that you share our concern and disappointment with this outcome. We remind you that, in our letter dated 30 April, we said that "we may return to these matters when necessary".

We do not expect a response to this letter.

4 June 2019

COUNCIL DECISION AUTHORISING AUSTRIA, CYPRUS, CROATIA, LUXEMBOURG, PORTUGAL, ROMANIA AND THE UNITED KINGDOM TO ACCEPT, IN THE INTEREST OF THE EUROPEAN UNION, THE ACCESSION OF THE DOMINICAN REPUBLIC TO THE 1980 HAGUE CONVENTION ON THE CIVIL ASPECTS OF INTERNATIONAL CHILD ABDUCTION (10967/18)

Letter from the Rt Hon Sir Alan Duncan KCMG MP, Minister for Europe and the Americas, Foreign & Commonwealth Office

On 20 July 2018 the Foreign and Commonwealth Office submitted an Explanatory Memorandum on proposals for Council Decisions relating to the accession of the six states named above to the 1980 Hague Convention on the Civil Aspects of International Child Abduction. Following scrutiny, the UK agreed to opt-in to this proposal, including accepting the accession of the Dominican Republic to the Convention.

I wanted to inform you that a European Council Decision authorising the UK to accept the accession of the Dominican Republic was issued on 21 February 2019. The UK is now obliged to deposit a declaration of acceptance of the accession by 21 February 2020 and we are currently working through this process.

16 April 2019

PROPOSAL FOR A REGULATION LAYING DOWN RULES ON THE EXERCISE OF COPYRIGHT AND RELATED RIGHTS APPLICABLE TO CERTAIN ONLINE TRANSMISSIONS OF BROADCASTING ORGANISATIONS AND RETRANSMISSION OF TELEVISION AND RADIO PROGRAMMES (12258/16)

Letter from the Chairman to Chris Skidmore MP, Minister of State for Universities, Science, Research and Innovation Department for Business, Energy and Industrial Strategy

Thank you for your letter dated 6 March 2019 which was considered by the EU Justice Sub-Committee at its meeting of 2 April.

We decided to clear this matter from scrutiny and take this opportunity also to clear 12281/16 and 12283/16, which were related to this proposed regulation.

We do not expect a response to this letter.

2 April 2019

AMENDED PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON CERTAIN ASPECTS CONCERNING CONTRACTS FOR THE SALES OF GOODS, AMENDING REGULATION (EC) NO 2006/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AND DIRECTIVE 2009/22/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AND REPEALING DIRECTIVE 1999/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (13927/17)

Letter from Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility, Department for Business, Energy & Industrial Strategy

Thank you for your letter of the 6th February 2019 and for granting a scrutiny waiver.

Following the negotiations between the Council of the EU and the EU Parliament to reach a final version of the text, the Council of the EU adopted the final version on 15th April 2019.

1) Developments since my last letter dated 17 January

i) Time limits for a remedy

My last letter dated 17th January 2019 represents the position of the final text. We have successfully negotiated for the UK to maintain only a limitation period, without the need to introduce also a liability period. Further, no change should be required to the UK's existing fixed limitation periods where digital elements in smart goods are supplied by a single act or by a series of individual acts.

However, in the specific case of smart goods where the digital content or digital services are supplied on a continuous basis over a period of time, the Sale of Goods Directive requires that consumers should be able to seek remedies for any lack of conformity that occurs or becomes apparent throughout the period of continuous supply. It is unclear exactly how this provision would work in practice, but there is a possibility that the UK's existing fixed time limit periods for breach of contract claims (i.e. 6 years in England and Wales and 5 years in Scotland) would not be sufficient where continuous supply extended over a very long period, especially where there was a delay between a fault occurring and that fault becoming apparent to the consumer. The existing UK limitation provisions would, therefore, need to be amended to reflect the time limit requirements for cases of continuous supply.

ii) Treatment of goods with embedded digital elements (smart goods)

In my last letter I explained how the text has developed to accommodate smart goods within the scope of this directive rather than the associated directive for the supply of digital content. Specifically, as part of their general obligations, the trader is obliged to ensure that the consumer is informed of and provided with updates to any digital elements within a good, so that the good remains in conformity. Since then, and to reflect that updates are in some cases provided by the manufacturer or another third party, an amendment was agreed in trilogue negotiations to clarify that traders shall be entitled to pursue remedies against those in the supply chain who may have omitted to provide the consumer with digital updates necessary for maintaining conformity with the contract.

The statutory requirement for retailers to provide security updates to digital content that is within smart goods would be new for UK consumer law. If we were to implement the directive, then we would consult closely with business and consumer representatives to do it in a proportionate and pragmatic way, including by seeking consistency with wider government regulation of smart goods.

iii) Commercial guarantees

The Directive requires, where a commercial guarantee is provided, the consumer should be given a commercial guarantee statement including certain information, such as who the guarantor is, the goods to which the guarantee applies and the terms of the guarantee. There is a new requirement that, if a producer offers a commercial guarantee of durability, then they are liable directly to the consumer for the period of the guarantee to provide repair or replacement if there is a fault. This is in addition to the trader's liability to repair or replace goods as part of the general remedy regime. "Durability" is defined as the ability of the goods to maintain their required functions and performance through normal use.

This requirement on producers would be an addition to UK consumer legislation, although producers are already free to offer repair/replacement directly to consumers on a contractual basis. It is currently unclear how a new statutory requirement on producers would interact, in practice, with the existing statutory remedy regime, which imposes obligations on traders. This requirement was not in the Council's General Approach but was a high priority for the European Parliament. It was agreed late in the trilogue negotiation between the institutions.

iv) Obligation for consumers to notify a defect

The trilogue negotiations resulted in a power for Member States, if they so wish, to require that consumers must notify traders within two months of discovering a defect if they are to benefit from their rights. No provision like this currently exists in UK law. The text also allows Member States to determine whether and to what extent a contribution of the consumer to a lack of conformity affects the right to remedies.

v) A new right to withhold outstanding payment

The trilogue negotiations resulted in a new EU right for consumers to withhold payment of any outstanding part of the price until the trader has fulfilled their obligations under the directive. Member States may determine the conditions and modalities for the exercise of this right. This is a positive outcome for the UK because the right to withhold payment already exists in our domestic common law and can, therefore, be maintained.

2) Transposition and Next Steps

In light of the developments listed above, we anticipate that the transposition deadline will be in May or June 2021. This would fall after the end of the implementation period provided for by the Withdrawal Agreement between the UK and the EU (which has an end date of 31 December 2020). If circumstances change so that the UK is required or chooses to transpose the Directive, then the government will work closely with stakeholders to ensure this is done in the most sensible and proportionate way.

8 May 2019

Letter from the Chairman to Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility

Thank you for your letter dated 8 May 2019 which was considered by the EU Justice Sub-Committee at its meeting of 4 June.

We decided to clear the agreed Directive from scrutiny. We are grateful for your detailed update on the final text agreed by the Council in April. We do not expect a response to this letter.

4 June 2019

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON CERTAIN ASPECTS CONCERNING CONTRACTS FOR THE SUPPLY OF DIGITAL CONTENT (15251/15)

Letter from Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility, Department for Business, Energy & Industrial Strategy

Thank you for your report of the 5th February 2019 and for granting a scrutiny waiver. Following the negotiations between the Council of the EU and the EU Parliament to reach a final version of the text, the Council of the EU adopted the final version on 15th April 2019.

Developments since my last letter dated 17 January

i) *Time periods for consumer remedies*

My last letter dated 17th January 2019 represents the position of the final text. We have successfully negotiated for the UK to maintain only a limitation period, without the need to introduce also a liability period, as previous iterations of the text had required. Further, no change should be required to the UK's existing fixed limitation periods where digital content or digital services are supplied by a single act or by a series of individual acts.

However, in the specific case of digital content or digital services supplied on a continuous basis over a period of time, the DCD requires that consumers should be able to seek remedies for any lack of conformity that occurs or becomes apparent throughout the period of continuous supply. It is unclear exactly how this provision would work in practice, but there is a possibility that the UK's existing fixed time limit periods for breach of contract claims (i.e. 6 years in England and Wales and 5 years in Scotland) would not be sufficient where continuous supply extended over a very long period, especially where there was a delay between a fault occurring and that fault becoming apparent to the consumer. The existing UK limitation provisions might, therefore, need to be amended to reflect the time limit requirements for cases of continuous supply.

ii) *Compensating traders for the termination of long-term contracts*

My last letter summarised a discussion about whether the Directive should require that a consumer's early termination of a long{erm contract (running longer than one year) should be free of charge, or whether the consumer should provide the trader with compensation proportionate to any promotional advantage they may have received as a result of committing to that longer contract (e.9. a discounted price or additional services). Eventually it was decided to delete the article entirely, leaving it to Member States to decide the extent to which early termination situations should be regulated. This is a welcome development, for the reasons outlined in my last letter.

iii) *Transposition deadline*

In light of the above developments, we anticipate that the transposition deadline will be in May or June 2021. This would fall after the end of the implementation period provided for by the Withdrawal Agreement between the UK and the EU (which has an end date of 31 December 2020). If circumstances change so that the UK is required or chooses to transpose the Directive, then the government will work closely with stakeholders to ensure this is done in the most sensible and proportionate way.

8 May 2019

Letter from the Chairman to Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility

Thank you for your letter dated 8 May 2019 which was considered by the EU Justice Sub-Committee at its meeting of 4 June.

We decided to clear the Directive from scrutiny.

In so doing, we note: (i) the Council's agreement of the Directive; (ii) the Government's concerns regarding the potential impact of this Directive, if it is ever implemented here, on the UK's respective limitation periods (5 years in Scotland, 6 years in England and Wales); and, (iii) the removal of the contentious provision which dealt with compensating traders for the termination of long-term contracts.

We do not expect a reply to this letter.

4 June 2019

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE A NEW DEAL FOR CONSUMERS (7875/18)

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING COUNCIL DIRECTIVE 93/13/EEC OF 5 APRIL 1993, DIRECTIVE 98/6/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, DIRECTIVE 2005/29/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AND DIRECTIVE 2011/83/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS BETTER ENFORCEMENT AND MODERNISATION OF EU CONSUMER PROTECTION RULES (7876/18)

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON REPRESENTATIVE ACTIONS FOR THE PROTECTION OF THE COLLECTIVE INTERESTS OF CONSUMERS, AND REPEALING DIRECTIVE 2009/22/EC (7877/18)

Letter from Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility, Department for Business, Energy & Industrial Strategy

Thank you for your letter dated 13 February, in reply to my letter of 31 January. I am writing to update you that the Omnibus Directive received a Council General Approach at a COREPER meeting

on 1 March and the subsequent formal negotiations between the Council of the European Union and the European Parliament have also now concluded. I am also writing to request a waiver to vote in favour once the text is tabled for final approval at an upcoming Council meeting.

I am pleased to say that the UK was able to achieve our three negotiating objectives, that were anchored around a desire not see UK consumer protection reduced or limited. We were therefore able to support the text when it went COREPER for a Council General Approach mandate. During the trilogues phase our priority was to ensure that these negotiating objectives were still met in the final compromise text. I am glad to say that this was achieved. The UK therefore supported the text at final endorsement stage in COREPER on 29 March, whilst noting our Parliamentary scrutiny reserve, which I am now requesting you to lift. The European Parliament adopted the file on 16 April, and it is now going through the jurist-linguist process before being tabled as an I point at the next possible Council meeting for final approval. I expect this to be in June but there is a possibility it could be at the end of May.

I have briefly summarised below the UK's three main negotiating objectives on the file and what the outcome was. I have also summarised some amendments of interest that were added to the Directive during the formal negotiations with the European Parliament.

UK Negotiating Objectives

i) Preserving UK consumers existing right to withdraw from a contract

The original draft Directive proposed amending the operation of the existing EU right of withdrawal that allows consumers to cancel a distance (including online) or off-premises contract within 14 days, without having to give a reason. The Commission had argued that the right puts disproportionate burdens on business and is open to abuse (e.g. a consumer purchases a dress online and uses it before sending it back and asking for a refund). They were therefore proposing to make amendments to remove the obligation for the trader to accept the right of withdrawal when a consumer has 'handled' a good more than necessary, and to reimburse the consumer before they have received the returned goods and have had a chance to inspect them. This would have resulted in a reduction of UK consumer protection and could have put consumers in a weak position which is why the UK opposed the amendment. The proposed changes could have been open to abuse by traders arguing over whether a good has been handled more than necessary allowing them to retain the consumer's money. Furthermore, the Commission did not provide enough evidence to justify this change, with a small sample size of businesses (99 SMEs, 17 large companies) being consulted and a lack of monetized evidence of detriment to traders.

The UK position was generally shared by other Member States which resulted in the amendment being removed from the text that received Council General Approach. As the European Parliament was also opposed to the amendment it is not present in the final compromise text.

ii) Preserving the UK's existing rules on secondary ticketing

The original draft Directive contained amendments to require online marketplaces to provide information to consumers on the main parameters determining the ranking of offers on the marketplace, whether the third party selling through the marketplace is a trader or private individual, whether EU consumer law rights will apply to the contract as a result and who will bear responsibility for enforcing them. While I was supportive of the principles behind these requirements, which are part of the final text, I was concerned that they were originally proposed to be "maximum harmonisation", i.e. without allowing flexibility for Member States to go beyond these requirements. This would have presented a significant risk of the UK having to scale back or remove our existing rule on the information required from secondary ticketing websites about tickets re-sold online and limited the scope for the UK to take further action domestically to protect consumers in this area.

To mitigate against the risk set out above I pushed for an amendment to the proposal that would allow Member States discretion to make national laws that go beyond the requirements of this Directive regarding the pre-contract information that must be given to consumers by online marketplaces.

The UK was able to achieve a concession, in the form of recital 29 to the Omnibus Directive and new article 6a (2) inserted into the Consumer Rights Directive. Read together, these give Member States discretion to maintain or introduce additional information requirements on online marketplaces that

are proportionate, non-discriminatory and justified on grounds of achieving a higher level of consumer protection. As the European Parliament had a similar provision in their text it was included in the final compromise text.

iii) Allowing flexibility for breaches of consumer law

The original draft Directive proposed adding to rules on penalties in existing EU consumer law, with a new clause to replace existing, less detailed provisions in the Price Indication Directive (PID), the Unfair Commercial Practices Directive (UCPD), the Consumer Rights Directive (CRD) and to insert this new clause into the Unfair Contract Terms Directive (UCTD) to introduce requirements for penalties into that Directive. The clause originally proposed was identical across the four directives and went beyond the existing provisions[1] to require MS to ensure that:

1. courts or authorities, when deciding whether to impose penalties, have due regard to a list of non-exhaustive criteria;
2. penalties for widespread infringements (including those with a Union dimension) include the possibility to impose a fine, the maximum amount of which must be set at least at 4% of trader's annual turnover; i.e. any cap on fines cannot be less than 4%.

I was not opposed to the original proposal, however I as I highlighted in my letter of 31 January I would be opposed to any move towards maximum harmonisation. In other words, I would be content as long as the maximum fine was *at least* 4%, and the criteria remain *non-exhaustive*.

Most Member States shared the UK's desire for the rules on penalties to be clearly set at minimum harmonisation and this was therefore reflected in the Council General Approach. The European Parliament was generally aligned with this position but did have a couple of amendments which were cause for concern. Firstly, they proposed amending the rules on fines which would have made the fine a maximum 10 million EUR or at least 4% of the trader's annual turnover, whichever was higher. The majority of Member States (inc. UK) pushed back against setting the cap on fines (in the absence of turnover information) at *at least* 10 million Euros, however a compromise was suggested by the Romanian Presidency, as set out below.

In the text approved by COREPER, there are minor variations between the new provision on penalties in the UCTD, CRD and UCPD (to adapt them to the Directive into which they are inserted) but in general the provision goes beyond the existing law to require MS to ensure that:

- Certain, specified non-exhaustive and indicative criteria are taken into account when deciding on the imposition of penalties.
- When penalties are to be imposed in accordance with Article 21 of the CPC Regulation[2], they may include fines and the maximum amount of the fine must be at least:
    - 4 % of the trader's annual turnover in the relevant member state(s), or
    - where information on turnover is not available, 2 million euros.

The clause on penalties inserted into the Price Indication Directive does not contain the second requirement above (on fines).

Secondly, the European Parliament proposed adding a rule that would require Member States to direct the revenues from fines towards a fund intended to enhance the protection of consumers. There was almost unanimous opposition to this amendment, including from the UK, as it should always be left to the discretion of Member States where revenues are allocated. Although this requirement was deleted, a Recital was added as a compromise asking Member States to consider enhancing consumer protection (as well as other protected public interests) when allocating revenues

[1] i.e. the existing provisions in the Price Indication Directive, the Unfair Commercial Practices Directive and the Consumer Rights Directive.

[2] Article 21 of the CPC Regulation (Regulation 2017/2394) sets out that the relevant competent authorities, taking co-ordinated enforcement action in response to a widespread infringement or widespread infringement with a Union dimension, shall impose penalties on the trader responsible as appropriate. Whether an infringement is "widespread" depends on the number of Member States involved and, for it to have a "Union dimension", the affected consumers must account for at least two-thirds of the EU population See the definitions of different types of infringement in Article 3(3) and 3(4) of the CPC Regulation.

from fines. Although I am not completely satisfied with the above compromises, I am content overall that the UK negotiating objective was achieved.

European Parliament Amendments

During the trilogue process some new provisions were added to the Directive which I have summarised below.

Consumer reviews

The European Parliament proposed an addition in relation to consumer reviews to the existing Unfair Commercial Practices Directive. They felt this was necessary as in their view consumers increasingly rely on consumer reviews when they make purchasing decisions. They suggested an amendment that, where a trader provides access to consumer reviews, would explicitly make information about *whether* and *how* a trader verifies these reviews amount to "material information". This for example could include information about the trader's process to check that reviews posted come from consumers who have actually used or bought the product in question.

This means that failure to provide information about whether or how the trader verifies consumer reviews, where this causes the consumer to take a different transactional decision, would be prohibited as an unfair commercial practice. In addition to this the EP proposed two further amendments to the UCPD to prohibit two specific commercial practices:

- stating that reviews are from consumers who have actually used or bought the product without taking reasonable and proportionate steps to check that this is correct, or
- submitting, or commissioning another person to submit, false or misleading consumer reviews or endorsements, in order to promote products

Although the UK, amongst other Member States expressed reservations about how these amendments would work in practice, the Parliament's position was retained in the final compromise text.

Secondary ticketing

A further amendment was tabled by the European Parliament to the Unfair Commercial Practices Directive to prohibit the practice of re-selling event tickets to consumers if the trader acquired them by using automated software (e.g. bots) to circumvent limits or other rules on ticket purchases. While I was not opposed to the principle behind this amendment since the UK has already implemented domestic legislation in this area,[3] I did have some concerns with the original drafting. The UK therefore did not oppose this amendment but did suggest drafting changes, some of which were accepted. We also managed to secure, in recital 50, wording clarifying that Member States retain discretion to take further action in this area to protect the legitimate interests of consumers and secure cultural policy and broad access of all individuals to cultural and sports events.

Personalised pricing

The European Parliament proposed an addition to the Consumer Rights Directive that adds to the information that traders are required to give to consumers, before entering into a distance (e.g. online) or off premises contract, to require traders to inform consumers when a price has been personalised based on automated decision making. The EP posited that traders often personalise their prices for specific consumers or specific categories of consumers based on automated decision making and profiling of consumer behaviour allowing traders to assess the consumer's purchasing power. This is an area that my Department has been looking at closely as part of our ongoing work following the Consumer Green Paper that was published in April last year.

Although there have been studies at a national and international level trying to assess to what degree personalisation (both price and search) is occurring, the evidence to date is very limited. Unfortunately, the UK was one of only a few Member States who expressed reservations and the amendment was therefore included in the final compromise text.

15 May 2019

[3] The Breaching of Limits on Ticket Sales Regulations 2018 (2018/735)

Letter from the Chairman to Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility

Thank you for your letter dated 15 May 2019. It was considered by the EU Justice Sub-Committee at its meeting of 18 June.

We decided to clear from scrutiny the proposed Omnibus Directive (document: 7876/18) and retain under scrutiny the Commission's Communication (document: 7875/18) and the proposed Directive on representative actions (document: 7877/18).

We are grateful for your detailed summary of the final text of the so-called Omnibus Directive to be agreed by the Council shortly. In previous correspondence, we expressed our support for your negotiating objectives, and we welcome your confirmation that these have been achieved. We also note that, should the Directive come into effect in this country, the final text will satisfy our desire to avoid any reduction in the consumer protection standards currently applicable in the UK.

Whilst we do not expect a response to this letter we look forward to considering further updates on the two related documents we retain under scrutiny in due course.

18 June 2019

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EC) NO 469/2009 CONCERNING THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS (9485/18)

Letter from Chris Skidmore MP, Minister of State for Universities, Science, Research and Innovation, Department for Business, Energy & Industrial Strategy

Thank you for your letter of 21 March 2019 regarding the above proposal for a Supplementary Protection Certificate (SPC) manufacturing waiver. I am writing to answer the further questions that you raised in your letter, and also to request that this proposal be cleared from scrutiny ahead of the likely upcoming vote in Council.

You asked whether the legislation will be replicated in the UK after it leaves the EU, or whether there are plans to diverge from these EU rules. If the Government did decide to diverge from these EU rules, you also asked what the impact would be on the UK's medicines industry.

If the manufacturing waiver proposal comes into force during the time-limited implementation period which forms part of the proposed UK-EU Withdrawal Agreement, it will apply to the UK during the implementation period. In this case, the UK will need to take a decision on whether or how an SPC manufacturing waiver should continue to apply to the UK after the end of the implementation period. This decision may also depend on what is agreed in the future economic partnership with the EU.

If Parliament does not approve the Withdrawal Agreement there will be no implementation period. Any future decision on whether or how an SPC manufacturing waiver should apply to the UK will take account of relevant interests and information, including any possible impacts on the UK's medicines industry. This will require further consideration in due course. In relation to this point, I note that I expect to be able to submit the Intellectual Property Office's final impact assessment of the Commission's original proposal to the committee shortly. This shows that there are a number of factors to take into consideration.

3 April 2019

Letter from the Chairman to Chris Skidmore MP, Minister of State for Universities, Science, Research and Innovation

Thank you for the letter dated 3 April 2019. It was considered by the EU Justice Sub-Committee at its meeting of 30 April.

We decided to retain the proposal under scrutiny.

In light of the fact that the Council is on the verge of agreeing this proposal, our recent correspondence has focussed on your plans for this legislation after Brexit; particularly, given your

concerns with the final draft and conclusion that the text is "not balanced or proportionate", the question of whether you intend to replicate the Regulation's rules or will choose to diverge.

Your response focusses on the ramifications of Parliament's acceptance or rejection of the Withdrawal Agreement but does not engage with our question regarding the impact on the UK's medicines industry of any decision to diverge from the Regulation's rules after we have left the EU. Instead, you look forward to sharing with us the UK Intellectual Property Office's (UKIPO) impact assessment of this proposal which you anticipate will illustrate the factors that you will have to take into account when considering whether or not to replicate these rules after Brexit.

We look forward, therefore, to considering the Government's analysis of the UKIPO's impact assessment of this proposed Regulation in due course.

30 April 2019

Letter from Chris Skidmore MP, Minister of State for Universities, Science, Research and Innovation

Further to your letter of 30 April 2019 regarding the above proposal, please find enclosed the final impact assessment of the Commission's original proposal for an SPC export waiver prepared by my officials at the Intellectual Property Office. I note that the committee has indicated in earlier correspondence that it has waived the scrutiny reserve ahead of the upcoming final vote in Council, whilst retaining this file under scrutiny.

Overall, the impact assessment suggests that the original export waiver proposal would be likely to result in a net gain in UK exports. This is consistent with the Intellectual Property Office's provisional assessment as set out in previous correspondence with the committee. However, there are some key evidence gaps relating to the true impact on originator pharmaceutical companies and there is considerable uncertainty about the size of any gain. This is shown in the wide range of possible impacts in the impact assessment.

The impact assessment estimates the impact of the Commission's original export waiver proposal on the UK. It does not consider developments of the proposal since then, such as the extension of the original proposal to allow stockpiling of SPC-protected medicines in the EU ready for entry into EU markets immediately after SPC expiry.

A reliable assessment of the impact of stockpiling has not been possible as the data required to make such an assessment is not available. For example, we do not consider the Commission's estimates to be robust and data that would be needed to quantify the impact of stockpiling is not publicly available. Additionally, there is a lack of evidence about how much faster a stockpiling waiver would allow generics to enter the market.

The Commission's original impact assessment also lacked an adequate assessment of the effects of a stockpiling provision. This lack of a robust analysis of the impact of stockpiling in the Commission's impact assessment was one of the UK's major concerns about the inclusion of stockpiling within the scope of the waiver and is one of the key reasons for the UK currently being minded to vote against the final proposal in Council. The final vote in Council is expected to take place on 14 May 2019.

Your letter referred to the question of whether the UK intends to replicate the proposed Regulation's rules or whether the UK will choose to diverge from the Regulation after EU exit, and to the possible impacts on the UK's medicines industry.

As indicated in my previous letter, if the proposed Regulation comes into force during the time-limited implementation period which forms part of the proposed UK-EU Withdrawal Agreement, it will apply to the UK during the implementation period. In the event of a no deal exit, if the proposal has come into force by exit day, the waiver legislation would be retained as functioning domestic law under the Withdrawal Act.

Any future decision on whether or how an SPC manufacturing waiver should apply to the UK will take account of relevant interests and information. This includes the information provided by the enclosed impact assessment, the future relationship with the EU, and information relating to the UK's medicines industry after EU exit. This will require further consideration in due course. Consequently

at this stage it is not possible to assess the impact on the UK's medicines industry of any potential future decision to diverge.

13 May 2019

Letter from Chris Skidmore MP, Minister of State for Universities, Science, Research and Innovation

Further to my letter of 13 May 2019 regarding the above proposal, I am writing to update the Committee on the outcome of the vote in Council.

The UK voted against the proposed regulation in Council, consistent with the intention set out in previous correspondence with the Committee. No formal explanation of vote was tabled. Although a number of other Member States also voted against or abstained, there was sufficient support for the proposal for it to be approved by Council.

The proposed regulation will now be signed before being published in the Official Journal of the EU. It is expected to enter into force by 1 July 2019.

I would be grateful if you could now therefore release this file from scrutiny.

5 June 2019

Letter from the Chairman to Chris Skidmore MP, Minister of State for Universities, Science, Research and Innovation

Thank you for your letters dated 13 May and 5 June 2019. They were both considered by the EU Justice Sub-Committee at its meeting of 18 June.

We decided to clear this matter from scrutiny.

We are grateful for sight of the UKIPO's impact assessment of this proposal and understand that it does not take account of any changes to the text since it was published in 2018. With regard to the application of the Regulation to the UK immediately after Brexit, and given that it will come into effect in July, we note that its rules will either apply here during the proposed transition period by virtue of the Withdrawal Agreement or, in the event of a no deal, that it will be retained here as "functioning domestic law under the Withdrawal Act".

We also take this opportunity to welcome your promise to consult with all relevant stakeholders on any decision to mimic these EU rules in the future.

We do not expect a response to this letter.

18 June 2019

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON COOPERATION BETWEEN NATIONAL AUTHORITIES RESPONSIBLE FOR THE ENFORCEMENT OF CONSUMER PROTECTION LAWS (TEXT WITH EEA RELEVANCE) (9565/16)

Letter from Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility, Department for Business, Energy & Industrial Strategy

The Committee has retained this Regulation under scrutiny, and I would like to provide an update.

The Regulation came into force in January 2018 and it will apply in Member States from 17th January 2020. Under the terms of the Withdrawal Agreement, the Regulation will apply to the UK. My department is therefore preparing so that the provisions of the new Regulation are operative in national law where they are not already. To enable us to do this on time, the government will shortly publish a consultation to gather stakeholders' views on how to do this most effectively.

I am pleased that the House of Lords debated the Committee's report "Brexit: will consumers be protected?" in January 2019. The terms of any enforcement cooperation between the UK and the EU

(beyond any implementation period following the UK's EU withdrawal) will be subject to the future partnership negotiations. The government has been clear that we will retain high standards of consumer protection in the UK. As part of that, we are aiming for continued cross-border cooperation on consumer issues as part of the new relationship with the EU.

13 May 2019

Letter from the Chairman to Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility

Thank you for your letter dated 13 May 2019 which was considered by the EU Justice Sub-Committee at its meeting of 4 June.

We decided to retain the Regulation under scrutiny.

Whilst we are grateful for the confirmation that the Regulation will come into effect in EU Member States in January 2020, the ongoing uncertainty over the Withdrawal Agreement, the transition period, and the Government's ability to secure the UK's post-Brexit participation in this important legislation remain.

We look forward to considering further updates on this matter in due course

4 June 2019