



HOUSE OF LORDS

European Union Committee

House of Lords
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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 15 October 2019 – 31 January 2020

EU HOME AFFAIRS SUB-COMMITTEE

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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN
PARLIAMENT SUMMARY OF THE ANNUAL IMPLEMENTATION REPORTS FOR THE
OPERATIONAL PROGRAMMES CO-FINANCED BY THE FUND FOR EUROPEAN AID
TO THE MOST DEPRIVED IN 2017 (10602/19)

**Letter from the Chairman to Victoria Atkins MP, Parliamentary Under Secretary of
State for Crime, Safeguarding and Vulnerability, Home Office**

Thank you for your letter dated 27 September 2019 on the above report.

We have decided to retain the file under scrutiny, and would be grateful if you could write again when the European Commission has decided whether to approve the proposed programme. In the event of 'no deal', please write to confirm whether the Government intends to provide alternative funding to ensure that the project can still go ahead.

I look forward to your response to this letter by the end of November 2019.

1 October 2019

**Letter to the Chairman from Sir Philip Rutnam KCB, Permanent Secretary, Home
Office**

Thank you for your letter of 23 October 2019, regarding the Fund for European Aid to the Most Deprived (FEAD).

It has become apparent that due to European Commission accounting rules, the amount of funding the UK can now access for a programme focused on social inclusion and mental health support would not allow us to deliver a comprehensive programme in the way it was originally envisaged. Regrettably, the decision has therefore been taken to withdraw from the FEAD application process.

The department will, of course, continue its work to support some of the most vulnerable children and young people in our society. For instance, we will continue to provide Independent Child Trafficking Guardians (ICTGs) as an additional source of support and advice for trafficked children and someone to advocate on their behalf.

Ministers and I would like to take this opportunity to thank you, and the European Union Committee, for your interest in this fund. This Government has a proud history of helping the most vulnerable and is absolutely committed to ensuring that victims of trafficking, unaccompanied asylum-seeking children and refugees get the support they need

23 October 2019

PROPOSAL FOR A COUNCIL DECISION ON THE POSITION TO BE TAKEN ON
BEHALF OF THE EU IN THE COUNCIL OF THE INTERNATIONAL CIVIL AVIATION
ORGANIZATION, IN RESPECT OF THE REVISION OF CHAPTER 9 ('FACILITATION')
TO THE CONVENTION ON INTERNATIONAL CIVIL AVIATION WITH REGARD TO
STANDARDS AND RECOMMENDED PRACTICES ON PASSENGER NAME RECORD
DATA (12197/19)

**Letter from the Chairman to the Rt Hon Brandon Lewis MP, Minister of State for
Security, and Deputy for EU Exit and No Deal Preparation, Home Office**

Thank you for your EM dated 27 September 2019 on the above proposal, which the EU Home Affairs Sub-Committee considered at its meeting on 23 October.

Please confirm the Government's opt-in decision and the reasons behind this decision. In particular, please provide a more detailed explanation of the Government's position on the suggestion that the deletion of PNR data should be ensured in accordance with the legal requirements of the source

country. We would also like to know what, if any, changes were made to the draft text during Working Parties.

The Committee also takes this opportunity to note the importance of UK participation in EU PNR data-sharing arrangements to our national security. The UK led the way on the development of PNR legislation at EU-level – measures which facilitate the collection and real-time sharing of data to prevent, detect and investigate terrorism and other forms of serious crime, while maintaining robust data protection safeguards.

A commitment to seek reciprocal arrangements with the EU for the timely, effective and efficient exchange of PNR data was included in both the 2018 and 2019 Political Declarations. Please provide further detail on the proposed framework for this aspect of the future relationship, and explain how the Government intends to avoid a significant capability gap with regard to PNR data if the UK crashes out of the EU in a ‘no deal’ scenario.

I look forward to your response to this letter within 10 working days.

23 October 2019

SUBMISSION OF UK REPORT ON THE ASSESSMENT OF EU PAEDIATRIC REGULATIONS IN THE UK, INCLUDING THE IMPLICATIONS OF EU EXIT

Letter to the Chairman from Baroness Blackwood, Parliamentary Under Secretary of State at the Department of Health and Social Care

I hereby submit the UK report on the assessment of EU Paediatric Regulations in the UK (Annex A) and associated cost-benefit analysis (Annex B)¹. This is done in response to the Commons European Scrutiny Committee’s report [document number: (39173), [13779/17](#), COM(17) 626] from their meeting of 10 January 2018.

An Explanatory Memorandum² (EM) summarising the European Commission’s report³ on the impact of the EU Paediatric Regulation ten years after its implementation, in line with its Article 50(3), was laid before Parliament for scrutiny in November 2017. The report provided an analysis of the Paediatric Regulation’s⁴ achievements against its objectives over the 10 year period since it came into force in the European Union.

This EM was cleared by the Lords EU Scrutiny Committee without comment on 16th November 2017. The Commons European Scrutiny Committee considered the EM at their meeting of 10 January 2018 and did not clear it from scrutiny, considering it necessary for the UK to be aware of the level of paediatric medicines development domestically. The Committee asked the former Parliamentary Under-Secretary of State for Health (Lord O’Shaughnessy) that he:

- *Commits to the immediate launch of a UK-specific analysis to be completed well in advance of the UK’s withdrawal from the EU;*
- *Explains how third countries currently engage with the EU on the development of paediatric medicine and confirm whether or not that level of engagement would be satisfactory post-Brexit or if the UK will be seeking closer engagement; and*
- *Explains the impact of the UK diverging from EU rules in the areas of both paediatric and orphan medicines*

¹

http://europeanmemoranda.cabinetoffice.gov.uk/files/2019/11/191105_Letters_to_European_Scrutiny_Committee_Chairs_re_Annex_A_and_B_on_the_Assessment_and_Cost-benefit_analysis_of_the_EU_Paediatric_Regulations_in_the_UK.pdf

²http://europeanmemoranda.cabinetoffice.gov.uk/files/2017/11/171116_Signed_Explanatory_Memorandum_on_State_of_Paediatric_Medicines_Regulation_in_the_EU_ref_ST-13779-2017-INIT-EN.pdf

³ https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/2017_childrensmedicines_report_en.pdf

⁴ Regulation (EC) No 1901/2006 of the European Parliament and of the Council

In response on 6 February 2018⁵ the former Minister made a commitment that the Medicines and Healthcare products and Regulatory Agency (MHRA) and the Department for Health and Social Care (DHSC) will undertake a discrete piece of analysis of the specific impact of the Paediatric Regulation on the UK. This analysis was also to include the current level of paediatric medicine development domestically; the possible post-EU policy impacts on paediatric medicines development; and the options the UK could take on paediatric regulations post EU-exit.

MHRA and DHSC have shared this analysis with DHSC Ministers. Key conclusions are that:

- the EU and UK experiences are similar and that the Paediatric Regulation has had a positive impact overall, including through an increase in the number of paediatric medicines and medicines with paediatric indications.
- some of the incentives offered in the Regulation have had a low uptake although a complete assessment of this would only be possible after a longer period of time.
- there is insufficient data to conclude that the benefits of the regulation on EU-level, namely increased access to paediatric medicines, outweighs the significant costs of providing these incentives in the UK.

For the reasons set out above, it is recommended that the impact of the Paediatrics Regulation should continue to be monitored and that a further review carried out if required. We also emphasise our commitment to maintaining close cooperation and collaboration with the EU and other nations on regulatory approaches to development of paediatric medicines.

I have noted the outcomes of the analysis and I hope the Commons EU Scrutiny Committee are content that the report addresses their questions.

5 November 2019

⁵ [Letter](#) dated 6 February 2018 from the Lord O'Shaughnessy to Sir William Cash MP.