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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	11 August 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
Subject:	COMMISSION STAFF WORKING DOCUMENT EVALUATION Joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

Delegations will find attached document SEC(2020) 291 final.

Encl.: SEC(2020) 291 final

EUROPEAN COMMISSION

Brussels, 11.08.2020
SEC(2020) 291 final

REGULATORY SCRUTINY BOARD OPINION

Evaluation - Joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

{SWD(2020) 163 final}
{SWD(2020) 164 final}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares (2020)

Opinion

Title: Evaluation of the legislation on medicines for children and rare diseases

Overall 2nd opinion: POSITIVE

(A) Policy context

Developing new medicines takes time and is expensive. Drug companies are not willing to invest in developing products and bringing them to market unless they are confident that they can cover their investment costs and make a profit. This is an issue for rare diseases. Since 2000, the EU 'Orphan' Regulation has provided incentives to drug companies to make safe and effective medicines available for more diseases. Since 2007, the EU 'Paediatric' Regulation has done the same for medicines to treat children. Both aim to address market failings and ensure that these needs are met in the public interest.

In recent years, the Parliament and the Council have called on the Commission to examine the impacts of these Regulations. There is concern that too many important medicines are either unavailable or unaffordable.

This evaluation assesses how the Regulations have worked. It will feed into an impact assessment to analyse the need to revise the Regulations.

(B) Summary of findings

The Board notes improvements to the report.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

(1) The report is more reader friendly, but is still difficult to read for non-experts.

(2) There are no clear conclusions on the market-based approach of the Regulations.

(C) What to improve

(1) The report is restructured and shortened, but remains long. Some of the content of the main text could move to the annexes. The report remains difficult to read for non-experts. The executive summary should also be in plain language.

(2) The report could further clarify what success was supposed to look like for these

This opinion concerns a draft evaluation which may differ from the final version.

regulations in order to help the reader judge the achieved results. It could do more to illustrate issues with available case study evidence.

(3) The role of external factors and their influence is more prominent in the report, but could be made more explicit in the intervention logic diagram as well. The analysis of the role of external factors could be deeper.

(4) The conclusions could provide clearer lessons learnt regarding strengths and limitations of the market-based approach of these Regulations.

(D) Conclusion

The DG must take these recommendations into account before launching the interservice consultation.

Full title	Joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products
Reference number	PLAN/2017/2099
Submitted to RSB on	12 May 2020
Date of RSB meeting	Written procedure