



Brussels, 29 October 2021  
(OR. en)

13233/21

---

**Interinstitutional File:**  
**2018/0018(COD)**

---

**CODEC 1369**  
**PHARM 182**  
**SAN 630**  
**MI 774**  
**COMPET 741**

**'I/A' ITEM NOTE**

---

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU ( <b>first reading</b> ) - Adoption of the Council's position at first reading and of the statement of the Council's reasons

---

1. On 1 February 2018 the Commission sent its proposal<sup>1</sup>, based on Article 114 TFEU, to the Council.
2. The European Economic and Social Committee delivered its opinions on 23 May 2018<sup>2</sup> and on 27 April 2021<sup>3</sup>.
3. The Committee of the Regions was consulted and decided not to issue an opinion.
4. The European Parliament adopted its position at first reading on 14 February 2019<sup>4</sup>.

---

<sup>1</sup> 5844/18  
<sup>2</sup> OJ C 283, 10.8.2018, p. 28–34  
<sup>3</sup> OJ C 286, 16.7.2021, p. 95–101  
<sup>4</sup> 6462/19

5. On 30 June 2021, the Permanent Representatives Committee confirmed the final compromise text on the above draft Regulation<sup>5</sup>.
  6. The Permanent Representatives Committee is asked to suggest that the Council adopt its position at first reading, as set out in document 10531/21, and the statement of reasons, as set out in document 10531/21 ADD 1 + COR 1, as an 'A' item at a forthcoming meeting, with Bulgaria and Poland abstaining.
  7. The statements for the minutes of the Council meeting are set out in the Addendum 1 to this note.
- 

---

<sup>5</sup> In accordance with the letter of 16 July 2021 sent by the Chair of the European Parliament's Committee on the Environment, Public Health and Food Safety to the Chair of COREPER, the European Parliament should, at second reading, approve the Council's position at first reading without amendment.