



Council of the
European Union

084593/EU XXVII. GP
Eingelangt am 16/12/21

Brussels, 16 December 2021
(OR. en)

14938/21

Interinstitutional File:
2018/0018(COD)

CODEC 1632
PHARM 222
SAN 753
MI 941
COMPET 906
PE 121

INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	ADOPTION OF LEGISLATIVE ACTS FOLLOWING THE EUROPEAN PARLIAMENT'S SECOND READING Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - Outcome of the European Parliament's second reading (Strasbourg, 13 to 16 December 2021)

I. VOTE

On 13 December 2021, the President of the European Parliament declared the Council's position¹ at first reading approved without amendments.

The text of the European Parliament's legislative resolution is annexed to this note.

¹ 10531/3/21 REV 3.

II. ADOPTION OF LEGISLATIVE ACTS FOLLOWING THE EUROPEAN PARLIAMENT'S SECOND READING

Since the European Parliament has approved the Council's position at first reading without amendments, the act in question is deemed to have been adopted in the wording which corresponds to the Council's position at first reading, as provided for in Article 294(7)(a) of the TFEU.

After signature by the President of the European Parliament, the President of the Council and the Secretaries-General of the two Institutions, the act will be published in the *Official Journal of the European Union*.

P9_TA(2021)0484**Health technology assessment ***II**

European Parliament legislative resolution of 13 December 2021 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (10531/3/2021 – C9-0422/2021 – 2018/0018(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

- having regard to the Council position at first reading (10531/3/2021 – C9-0422/2021),
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Czech Chamber of Deputies, the German Bundestag, the French Senate and the Polish Sejm, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 23 May 2018 and of 27 April 2021²,
 - having regard to its position at first reading³ on the Commission proposal to Parliament and the Council (COM(2018)0051),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure,
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A9-0334/2021),
1. Approves the Council position at first reading;
 2. Notes that the act is adopted in accordance with the Council position;
 3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;

² OJ C 283, 10.8.2018, p. 28 and OJ C 286, 16.7.2021, p. 95.

³ OJ C 449, 23.12.2020, p. 638.

4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
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