Thursday 20 January 2022

P9_TA(2022)0006

European Medicines Agency ***I

European Parliament legislative resolution of 20 January 2022 on the proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020)0725 — C9-0365/2020 — 2020/0321(COD))

(Ordinary legislative procedure: first reading)

(2022/C 336/10)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2020)0725),

— having regard to Article 294(2) and Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0365/2020),

— having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

— having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Senate, 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 27 April 2021 ([1]),

— having regard to the opinion of the Committee of the Regions of 7 May 2021 ([2]),

— having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 10 November 2021 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rules 59 of its Rules of Procedure,

— having regard to the opinion of the Committee on Industry, Research and Energy,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0216/2021),

1. Adopts its position at first reading hereinafter set out ([3]);

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2020)0321

Position of the European Parliament adopted at first reading on 20 January 2022 with a view to the adoption of Regulation (EU) 2022/… of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2022/123.)

([1]) OJ C 286, 16.7.2021, p. 109.
([2]) OJ C 300, 27.7.2021, p. 87.
([3]) This position replaces the amendments adopted on 8 July 2021 (Texts adopted, P9_TA(2021)0351).