



C/2023/1076

15.12.2023

P9\_TA(2023)0122

## **Specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland**

**European Parliament legislative resolution of 9 May 2023 on the proposal for a regulation of the European Parliament and of the Council on specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland (COM(2023)0122 — C9-0033/2023 — 2023/0064(COD))**

**(Ordinary legislative procedure: first reading)**

(C/2023/1076)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0122),
  - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0033/2023),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Article 294(3) and Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 27 April 2023 <sup>(1)</sup>,
  - after consulting the Committee of the Regions,
  - having regard to the undertaking given by the Council representative by letter of 19 April 2023 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 and 40 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0167/2023),
1. Adopts its position at first reading hereinafter set out;
  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.

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**P9\_TC1-COD(2023)0064**

**Position of the European Parliament adopted at first reading on 9 May 2023 with a view to the adoption of Regulation (EU) 2023/... of the European Parliament and of the Council on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2023/1182.)*

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<sup>(1)</sup> Not yet published in the Official Journal.