

Message 013

Communication from the Commission - TRIS/(2025) 1602

Directive (EU) 2015/1535

Notification: 2025/0290/BE

Acceptance by the Commission of the invocation of urgency (article 6, paragraph 7, of Directive (EU) 2015/1535) and closure of the procedure for the provision of information.

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1. MSG 013 IND 2025 0290 BE EN 11-06-2025 23-06-2025 COM URGENCY 11-06-2025

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2025/0290/BE - C10P - Pharmaceuticals

5. article 6, paragraph 7, of Directive (EU) 2015/1535

6. On 10 June 2025, the Belgian authorities notified under reference 2025/290/BE the draft “Decision extending the submission of the export of the medicinal products Zypadhera 405 mg prolonged release suspension for injection (pdr. + solv.) i.m. vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for injection (pdr. + solv.) i.m. vial 300 mg + 3 ml and Zypadhera 210 mg + 3 ml intended for the Belgian market for a prior authorisation” and requested the urgent adoption procedure provided for in Article 6 (7) of Directive (EU) 2015/1535.

Following examination of the draft, the Commission is of the opinion that the claim for urgent adoption is justified.

The fact that the Commission accepts the urgency of this case in no way prejudices its assessment of the compatibility of the notified measure with European Union law.

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