Council of the European Union

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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
Subject:	Attendance of a third party at the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025 *- Approval*

1. At the meeting of the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025, the Presidency would like to invite representatives of the European Medicines Agency (EMA).

2. The meeting will focus on the examination of the proposal for a Critical Medicines Act. The representatives of the EMA are expected to give a contribution by presenting the status of their work on vulnerability assessments.

3. Specifically, the representatives of the EMA will only be present during the exchanges related to:

   - The Union List of critical medicinal products and vulnerability evaluations, as set out in the relevant provisions in the Pharma Package Council mandate, including the provisions on creation/adoption and update of the Union List (including handling of the category of other "medicinal products at risk") and the procedures for the vulnerability assessments by the Executive Steering Gorup on Shortages on Safety of Medicinal Products (MSSG), criteria for prioritisation of vulnerability assessments and the methodology for vulnerability assessments.

- The status and timeline for work on developing the procedure and criteria for prioritisation of vulnerability assessments and the methodology for vulnerability assessments (including the ongoing work in the MSSG WG on vulnerability assessment methodology).

4. The Presidency considers that this invitation is in the interest of the Council as the information provided by the EMA will complement the exchange of views on the above-mentioned topics.

5. In view of the above, the Permanent Representatives Committee is invited to approve the attendance of representatives of the EMA at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025.

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