Council of the European Union

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**'A' ITEM NOTE**

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| From: | General Secretariat of the Council |
| To: | Council |
| Subject: | Draft 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 **(first reading)**<br>- Adoption of the legislative act<br>- Statement |

## Statement by Hungary

Hungary recognizes and promotes equality between men and women in accordance with the Fundamental Law of Hungary, and the primary law, principles and values of the European Union, as well as the commitments and principles stemming from the international law. Furthermore, equality between women and men is enshrined in the Treaties of the European Union as a fundamental value. In line with these and its national legislation, Hungary interprets the concept of 'gender' as reference to 'sex', in the 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.