Council of the European Union

Brussels, 21 September 2026
(OR. en)

12262/26
ADD 1

Interinstitutional File:
2023/0131 (COD)

SAN 618
PHARM 142
MI 813
COMPET 992
VETER 133
ENV 991
RECH 331
PI 94
CODEC 1513

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 **(first reading)** - Adoption of the Council's position at first reading and of the statement of the Council's reasons = Statements

Bulgaria has requested that the following statement be entered in the Council minutes

Bulgaria supports a balanced and sustainable legislation towards a coherent EU regulatory framework, ultimately ensuring timely access for patients to medicinal products that are safe, effective and affordable.

The references to ‘gender-based equity’ are to be understood strictly as a biological (women and men) category, ensuring equal rights, opportunities, representation and participation of men and women in clinical trials and robust sex-specific data, without implications for concepts of ‘gender’ as a social construct that exceeds the constitutional framework of the Republic of Bulgaria.

In this context, Bulgaria interprets the use of gender-related terminology in light of our constitutional binary model (women and men) and recognises, interprets and applies the translation of the term ‘gender’ for the purposes of translation and implementation of EU law, exclusively and strictly as ‘sex’.

Malta has requested that the following statement be entered in the Council minutes

Malta welcomes the adoption of the revised pharmaceutical legislation which represents a significant improvement when compared to the current framework.

The legal obligations to supply innovative products to all Member States on the fulfilment of certain conditions, which have been included in both the directive and the regulation, are clearly a step in the right direction. The effectiveness of these obligations in practice is, however, yet to be seen, considering the complex triggers and that the sanctions for the non-fulfilment of these obligations are rather weak. The proposed extension of the SPC through the biotech act may also further weaken this obligation if retained within final text.

However, Malta would like to recall that the EU is built on the principles of equality amongst the Member States and on solidarity. These principles are entrenched in the Treaty of the European Union, more specifically in Article 4 and Article 2 respectively.

The revised framework falls short in providing the conditions for equal access to medicines to the populations of all Member States.

This fragmentation also trickles down to the implementation of the framework, such as the European Medicines Verification System, which further fragments the market and introduces additional barriers and costs, in particular on smaller markets.

Malta has persistently argued in favour of eliminating barriers within the internal market for patients at all levels, including within the European Council, and it regrets that the new framework is built on 27 distinct markets, rather than on the EU single market. Most of the existing barriers for patients have been retained, and new barriers have been introduced. Article 120(1a) of the regulation is a case in point. We would have liked to see a more European approach across the board, including when it comes the shortages chapter, where the focus should have been that the EU is adequately supplied, and not on the individual markets of the Member States.

It is therefore difficult for Malta to endorse a framework that does not address, fully and equally, all the barriers being faced by all the 27 Member States. However, considering the improvements on the current framework, Malta opts to abstain on the Regulation.