Statement of the Council's reasons: Position (EU) No 2/2017 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(2017/C 116/02)

I. INTRODUCTION

1. The Commission adopted its proposals for a new Regulation replacing the current Directives 90/385/EEC ([1]) and 93/42/EEC ([2]) on medical devices on 26 September 2012 together with a proposal for a new Regulation replacing the current Directive 98/79/EC ([3]) on *in vitro* diagnostic medical devices and submitted them to the Council and to the European Parliament. These two proposals are closely interlinked, to a large extent contain the same provisions and have throughout the Council's examination and the negotiations with the other Institutions been treated together.

2. The legal basis for the two proposals is Article 114 and point c) of Article 168(4) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

3. In accordance with Protocol No 2 annexed to the Treaties, the Member States' national parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity. None of the national parliaments objected to the proposals ([4]).

4. The European Data Protection Supervisor was consulted by the Commission and issued an opinion on 8 February 2013 ([5]).

5. Invited by the Council, the European Economic and Social Committee issued its opinion on the Proposals on 14 February 2013 ([6]). The Committee of the Regions decided not to deliver any opinion given the low impact of the measures proposed on the local or regional authorities.

6. On 2 April 2014, the European Parliament adopted its legislative resolutions ([7]) on the two proposals and thus concluded its first reading. Following the elections, the Committee on the Environment, Public Health and Food Security of the European Parliament ('the ENVI Committee') on 5 November 2014 mandated the Rapporteurs to enter into negotiations with the Council in order to reach an agreement on these proposals.

7. On 5 October 2015, the Council reached General Approaches on the draft Regulation on medical devices ([8]) and on the draft Regulation on *in vitro* diagnostic medical devices ([9]).

8. In October 2015, negotiations with the European Parliament were started. At the tenth informal trilogue held on 25 May 2016 the Council representatives and the representatives of the European Parliament reached an agreement on compromise texts for both Regulations.

([1]) OJ L 189, 20.7.1990, p. 17.
([2]) OJ L 169, 12.7.1993, p. 1.
([3]) OJ L 331, 7.12.1998, p. 1.
([4]) http://www.ipex.eu/
([5]) 5590/13.
([6]) Opinion available in document INT/665-666-667 - CES2185-2012_00_00_TRA_AC - 2012/0266 (COD) and 2012/0267 (COD) of 14 February 2013.
([7]) The EP adopted its amendments to the two proposals already at the Plenary on 22 October 2013. They are set out in documents 14936/13 and 14937/13.
([8]) 12040/1/15 REV 1 + ADD 1.
([9]) 12042/15 + ADD 1.

9. On 15 June 2016, the Permanent Representatives Committee held a final discussion on the two proposals and agreed on the compromise text for the draft Regulation on medical devices ([1]) and on the compromise text for the draft Regulation on *in vitro* diagnostic medical devices ([2]). As these compromise texts had been adjusted compared to the texts resulting from the final informal trilogue on some points ([3]) important to the Commission, the Commission representative could also fully support them.

10. On the same day those texts were supported by all Members in a vote in the ENVI Committee.

11. On 20 September 2016, the Council reached political agreement on the two compromise texts ([4]).

12. After the political agreement, it became apparent that the transitional provisions, in particular, could have led to uncertainty as regards their interpretation and thus possibly to unforeseen consequences for industry, patients and regulators. At the initiative of several Member States, and in line with suggestions from some Members of the European Parliament, it was therefore decided to clarify the intention of the political agreement in this regard. The resulting technical clarifications to the two compromise texts were informally agreed by all Member States and the European Parliament and were inserted in the texts during the legal-linguistic finalisation. The technical clarifications to the draft Regulation on medical devices are set out in:

— the second and third sentences in Recital (98);

— Recital (99);

— Article 120(3);

— the first and second paragraphs of Article 122;

— the last paragraph of point (d) of Article 123(3);

and in

— point (i) of Article 123(3).

13. Taking into account the agreed compromise texts referred to in Points 9 and 10 and following legal-linguistic revision, the Council adopted its position at first reading on 7 March 2017, in accordance with the ordinary legislative procedure laid down in Article 294 of the Treaty on the Functioning of the European Union.

II. **OBJECTIVE**

14. The new Regulations aim at modernising the existing legislative framework for the marketing of medical devices and to overcome legal gaps, thereby supporting innovation and the competitiveness of the medical device industry. They should further strengthen patient safety, notably through the introduction of more stringent procedures for conformity assessment and for post market surveillance and through requirements on manufacturers to generate clinical data providing evidence on safety, performance and any undesirable side-effects. They should also allow rapid and cost-efficient market access for innovative medical devices.

III. **ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING**

15. The Council considers that Directives 90/385/EEC, 93/42/EEC and 98/79/EC are no longer sufficient to regulate the medical device sector. It is desirable to maintain a joint Union legislative framework for medical devices and *in vitro* diagnostic medical devices and the two Regulations on medical devices and on *in vitro* diagnostic medical devices should therefore only differ where differences are justified by the nature of these two categories of devices and their intended purposes.

([1]) 9364/3/16 REV 3. (In this text changes to the Commission proposal are indicated. A 'clean' text is available in all languages in document 10617/16.)
([2]) 9365/3/16 REV 3. (In this text changes to the Commission proposal are indicated. A 'clean' text is available in all languages in document 10618/16.)
([3]) 10035/16.
([4]) 11662/16 PHARM 50 SAN 308 MI 531 COMPET 449 CODEC 1152 + COR 1 and 11663/16 PHARM 51 SAN 309 MI 532 COMPET 450 CODEC 1153

16. The Council has in the preparation of its positions at first reading, as one of its priorities, concentrated on strengthening the rules regarding notified bodies in order to ascertain that notified bodies are designated and operate under harmonised conditions throughout the Union. The new Regulations not only strengthen the monitoring of notified bodies by Member State authorities but also strengthen the competences of notified bodies *vis-à-vis* economic operators.

17. The provisions regarding registration of devices and economic operators, in particular those governing the Unique Device Identification system have been complemented and clarified. They should lead to the establishment of a more functional system related to identification and traceability of devices, while maintaining alignment with international principles and practices in this field.

18. The classification system for medical devices, and, even further, the classification system for *in vitro* diagnostic medical devices have been adapted to correspond to the rapid increase in scientific, medical and technical knowledge and to the resulting development of more and more advanced devices.

19. The provisions on conformity assessment have been clarified but continue to be based on the existing well-established system. Thereby, the provisions on assessment of high-risk devices have been considerably strengthened with a view to patient safety.

20. The requirements on collection of data in clinical investigations on medical devices and performance studies on *in vitro* diagnostic medical devices have been considerably strengthened and aligned to those applicable for clinical trials on medicinal products for human use.

21. The provisions on vigilance and market surveillance have been strengthened and new requirements on economic operators regarding post-market surveillance, notably clinical follow-up, introduced.

IV. **CONCLUSION**

22. The Council's position at first reading reflects the compromise agreed between the Council and the European Parliament, with the support of the Commission.

23. In two letters dated 16 June 2016, the Chair of the ENVI Committee informed the Chair of the Permanent Representatives Committee (Part 1) that should the Council formally transmit to the European Parliament the two compromise texts thus agreed, subject to legal-linguistic finalisation, as its positions at first reading, he would, together with the two Rapporteurs, recommend to the Plenary that the Council's positions be accepted without amendments at Parliament's second reading.

24. The position of the Council takes full account of the Commission proposal and the amendments proposed by the European Parliament at first reading. The Council therefore believes that its position at first reading represents a balanced compromise that will benefit patients, health care providers and economic operators in the sector.