Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 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 (Text with EEA relevance)

CHAPTER VIII

COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS

Article 103

Medical Device Coordination Group

1 A Medical Device Coordination Group (‘MDCG’) is hereby established.

2 Each Member State shall appoint to the MDCG, for a three-year term which may be renewed, one member and one alternate each with expertise in the field of medical devices, and one member and one alternate with expertise in the field of *in vitro* diagnostic medical devices. A Member State may choose to appoint only one member and one alternate, each with expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

The alternates shall represent and vote for the members in their absence.

3 The MDCG shall meet at regular intervals and, where the situation requires, upon request by the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of medical devices, or by the members appointed for their expertise in the field of *in vitro* diagnostic medical devices, or by the members appointed for their expertise in both fields, or their alternates, as appropriate.

4 The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the MDCG's position.

5 The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6 The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.

7 The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to such sub-groups in the capacity of observers.

8 The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

— the adoption of opinions or recommendations or other positions, including in cases of urgency;

— the delegation of tasks to reporting and co-reporting members;

— the implementation of Article 107 regarding conflict of interests;

— the functioning of sub-groups.

9 The MDCG shall have the tasks laid down in Article 105 of this Regulation and Article 99 of Regulation (EU) 2017/746.

Status:
Point in time view as at 05/04/2017. This version of this provision has been superseded.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 103.