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 101

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

Article 102

Cooperation

1 The competent authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.

2 Member States shall, with the support of the Commission, participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

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.

Article 104

Support by the Commission

The Commission shall support the functioning of the cooperation between national competent authorities. It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

Article 105

Tasks of the MDCG

Under this Regulation, the MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices;

(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States.

Article 106

Provision of scientific, technical and clinical opinions and advice

1 The Commission shall, by means of implementing acts and in consultation with the MDCG, make provision for expert panels to be designated for the assessment of the clinical evaluation in relevant medical fields as referred to in paragraph 9 of this Article and to provide views in accordance with Article 48(6) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, observing the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 7 of this Article.

2 Expert panels and expert laboratories may be designated in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.

3 Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The

Commission shall determine the number of members of each panel in accordance with the requisite needs.

The members of expert panels shall perform their tasks with impartiality and objectivity. They shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests, which shall be made publicly available.

The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

4 Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions.

5 The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the *Official Journal of the European Union* and on the Commission website following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.

6 The Commission, following consultation with the MDCG, may include advisors on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panel as needed. That list shall be published on the Commission website.

7 The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in:

— physico-chemical characterisation, or

— microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing

of specific devices, categories or groups of devices.

The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

8 Expert laboratories shall satisfy the following criteria:

a have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the devices for which they are designated;

b possess the necessary equipment to carry out the tasks assigned to them;

c have the necessary knowledge of international standards and best practices;

d have an appropriate administrative organisation and structure;

e ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks.

9 Expert panels appointed for clinical evaluation in relevant medical fields shall fulfil the tasks provided for in Article 54(1) and Article 61(2) and Section 5.1 of Annex IX or Section 6 of Annex X, as applicable.

10 Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:

a to provide scientific, technical and clinical assistance to the Commission and the MDCG in relation to the implementation of this Regulation;

b to contribute to the development and maintenance of appropriate guidance and CS for:

— clinical investigations,

— clinical evaluation and PMCF,
— performance studies,
— performance evaluation and post-market performance follow-up,
— physico-chemical characterisation, and
— microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing

for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;

c to develop and review clinical evaluation guidance and performance evaluation guidance for performance of conformity assessment in line with the state of the art with regard to clinical evaluation, performance evaluation, physico-chemical characterisation, and microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;

d to contribute to the development of standards at international level, ensuring that such standards reflect the state of the art;

e to provide opinions in response to consultations by manufacturers in accordance with Article 61(2), notified bodies and Member States in accordance with paragraphs 11 to 13 of this Article.

f to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;

g to provide views in accordance with Article 48(4) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices.

11 The Commission, shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, *inter alia*, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for clinical evaluation, with regard to physico-chemical characterisation, and with regard to microbiological, biocompatibility, mechanical, electrical, electronic and non-clinical toxicological testing.

12 When adopting its scientific opinion in accordance with paragraph 9, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.

The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 9 and 11 of this Article, ensuring consideration of aspects of confidentiality as set out in Article 109. The clinical evaluation guidance referred to in point (c) of paragraph 10 shall be published following consultation with the MDCG.

13 The Commission may require manufacturers and notified bodies to pay fees for the advice provided by expert panels and expert laboratories. The structure and the level of fees as well as the scale and structure of recoverable costs shall be adopted by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

14 The fees payable to the Commission in accordance with the procedure under paragraph 13 of this Article shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with point (c) of Section 5.1 of Annex IX

involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.

15 The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the tasks of expert panels and expert laboratories referred to in paragraph 10 of this Article.

Article 107

Conflict of interests

1 Members of the MDCG, its sub-groups, and members of expert panels and expert laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct or indirect interests they may have in the medical device industry and update that declaration whenever a relevant change occurs. The declaration of interests shall be made publicly available on the Commission website. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2 Experts and other third parties invited by the MDCG on a case-by-case basis shall declare any interests they may have in the issue in question.

Article 108

Device registers and databanks

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices, or the traceability of implantable devices, or all of such characteristics.

Status:
Point in time view as at 31/01/2020.

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