REGULATORY FOCUS

The Medical Device Coordination Group: a new Authority Under EU Device Regulations

By Robert D. Cumming and Nancy W. Mathewson, Esq.

This article discusses the organization and functions of the Medical Device Coordination Group (MDCG) established under the new EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR). The article explains how both groups will be important players in the conformity assessment body 'notification' process and in determining how notified bodies assess and certify devices and in serving as a reviewing body for making regulatory and jurisdictional decisions for the European Commission.

European Commission Device Directives and the new Regulations

The European Parliament and the Council of the European Union issued 'new approach directives' in the early to mid-1990s for active implantable medical devices (*Directive 1990/385/EEC*), medical devices (*Directive 1993/42/EEC*) and *in vitro* diagnostic devices (*Directive 1998/79/EEC*). *Directive 2007/47/EC*, issued by the European Parliament and Council, amended the active implantable device directive, medical device directive, and a directive concerning placing biocidal products on the market (*Directive 98/8/EC*).

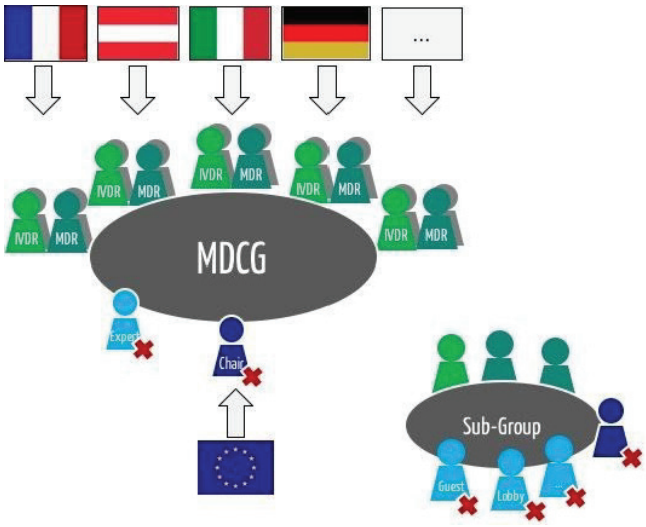
In April 2017, without amendments, the European Parliament and Council of the EU approved final versions of the *Medical Device Regulation (MDR EU 2017/745*) and *In Vitro Diagnostic Medical Device Regulation (IVDR EU 2017/746*).{1,2} Following revisions, the *Medical Devices Directive (1993/42/EEC*) and the *Active Implantable Medical Devices Directive (190/384/EEC*) were combined to form the MDR. The *In Vitro Diagnostic Medical Devices Directive (1998/79/EEC*), following revision, became the IVDR. The two regulations, entering into force on 26 May 2017, are effective across the EU and the European Economic Area. Application of the *MDR* and *IVDR* will become mandatory (i.e., date of application) following three-year (26 May 2020) and five-year (26 May 2022) transition periods, respectively.

The Medical Device Coordination Group

Article 103 of the *MDR* and *Article 98* of the *IVDR* require the European Commission (Commission) to establish a corresponding Medical Device Coordination Group (MDCG). The MDCG, characterized as a centralized organization of qualified individuals with medical device and *in vitro* device experience, will function at the request of the commission to develop common specifications, draft guidance documents, oversee and approve applications by conformity assessment bodies, and resolve regulatory or other product lifecycle issues. The MDCG will work cooperatively to ensure consistent cross-border decisions and enforcement. **Table 1** summarizes the diverse range of MDCG tasks.

Each of the 28 member states must appoint one individual expert and one alternate expert to represent the competent authority of their member state and serve a renewable three-year term on each MDCG. If qualified, an individual may serve in the same or alternate capacity on both MDCGs. A non-voting representative of the commission will chair each MDCG. The MDCG is required to meet at regular intervals and at the request of the commission or a member state. **Figure 1** illustrates the membership structure of the MDCG.{3}

Figure 1. Illustration from Johner Institut.



Each member state is to appoint two individuals qualified through professional training or experience to serve as members of the *IVDR* and MDR Medical Device Coordination Group. Each MDCG will be chaired by a non-voting representative of the commission. As needed, the MDCG may appoint a subgroup to address a particular regulatory or classification issue that the MDCG itself does not feel qualified to resolve. Experts, guests, and lobbyists invited to attend a MDCG or convened subgroup meeting are non-voting participants.

Each MDCG has significant responsibilities spanning the product lifecycle and providing oversight of notified bodies. Each MDCG is also charged with refining conformity assessment procedures and developing standards for use in the determination of product safety and performance. Each MDCG must contribute to the assessment of notified bodies, resolve regulatory issues, and develop guidance documents for medical devices and diagnostics. Additional responsibilities include developing guidance for post-market surveillance activities and providing support to competent authorities in the coordination and harmonization of issues related to the classification and regulation of a product, or category or group of products (*Article 105* of *MDR*, *Article 99* of *IVDR*).

Expert Consultation Panels

The MDCG is authorized to appoint impartial and objective expert consultation panels to resolve issues raised by a manufacturer or a competent authority regarding classification of a product, as well as identifying premarket clinical requirements or marketing requirements. In addition, the MDCG can appoint laboratories to provide scientific, technical or clinical advice, or laboratory expertise for implementing each regulation.

Manufacturers of Class III implantable devices and Class IIb active devices intended to administer a medicinal product are encouraged to request consultation by a panel to review the clinical development strategy and proposed clinical investigation plan. Notified bodies reviewing a clinical evaluation assessment report for Class III and Class IIb active devices are encouraged to request the commission and MDCG to appoint an expert panel to review the report. Upon completion of any panel review, the panel must report to the competent authorities on the successful review completion and Conformité Européene (CE) marking following a conformity assessment procedure involving an expert panel.

Table 1. Tasks of the MDCG under the MDR and IVDR

Task Description	MDR EU 2017/745	IVDR EU 2017/746
Assessment of applicant conformity assessment bodies	X	X
Advise commission in matters concerning the coordination group of notified bodies	X	X
Guidance development to ensure regulation harmonization	X	X
Guidance development for designating and monitoring notified bodies	X	X
Guidance development for application of general safety and performance requirements	X	X
Guidance development for conduct of clinical evaluations and investigations	X	X
Guidance development for vigilance activities	X	X
Monitoring of technical progress and assessing adequacy of general safety and performance requirements of regulation	X	X
Contribute to development of device and common specification standards, scientific guidelines and clinical investigation guidelines for implantable devices and Class III devices	X	X
Assist member state competent authorities in classification and regulatory status determinations, clinical investigation and market surveillance	X	X
Work with commission to set up a unique device identification database	X	X
Work with commission to set up an electronic system for registration of economic operators	X	X
Contribute to harmonized administrative practice	X	X
Request scientific advice from expert panels about safety and performance of any IVD		X

Marketed Products

Manufacturers with products on the common market also will be affected by decisions and guidance documents (e.g., clinical evaluation guidance, vigilance activities, etc.) issued by the MDCG, including new requirements for annual surveillance activity plans as required for all devices marketed in the EU. Neither regulation specifies a release date for MDCG or commission guidance documents. Because CE marking requirements must include the existence of a market surveillance plan, the CE means that these guidance documents will be available well before the application date.

Borderline Products

According to *MDR* and *IVDR* provisions, it is the responsibility of each member state to determine - on a case-by-case basis - whether a product is or is not within the scope of the regulation. For consistency across all member states, borderline cases in which it is unclear or in dispute as to whether the product has a device, medicinal or biologic primary mode of action are subject to review by the commission. The regulation further clarifies that the European Medicines Agency (EMA), the European Chemicals Agency, and the European Food Safety Authority, as relevant, should be consulted for borderline cases containing human tissues or cells, biocidal products, or food products.

Article 4.1 of the *MDR* states that "… upon a duly substantiated request of a member state, the commission shall, after consulting with the Medical Device Coordination Group … determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device.'" *Article 3.1* of the *IVDR* has a similar statement for the determination of the regulatory status of *in vitro* diagnostic medical devices. In either case, a request for determination of classification or regulatory scope by the MDCG can originate from the commission or member state. When the MDCG deliberates on the regulatory status of a product, during its review of the MDCG decision the commission is required to ensure the MDCG included consultation with the EMA or other relevant competent authority as appropriate.

Therefore, the MDCG will play an important role for manufacturers seeking clarification as to the regulatory status or requirements for a borderline case or combination product. Borderline or combination product classification discussions will typically first occur between the manufacturer and their member state competent authority. If the competent authority cannot provide a classification, or if the manufacturer does not agree with the classification, the manufacturer may submit a request for classification to the European Commission. The commission reviews the dossier and makes a determination or most likely, assigns the MDCG responsibility for reaching a consensus opinion as to how the product should be regulated and subjected to premarket review. Having either made its decision or accepted the opinion of the panel, the MDCG reports review outcomes to the commission, the manufacturer, any involved notified body, and the member state competent authority.

Under *MDR*, disputes between the manufacturer and a notified body regarding the classification of a device are first referred to the competent authority of the member state in which the manufacturer is registered. If the notified body is in a member state other than the one in which the manufacturer is registered, the competent authority from the manufacturer's member state must consult with the competent authority of the member state that designated the notified body.

Prior to the *MDR* and the regulation calling for the formation of the MDCG, and in the event that a manufacturer could not determine whether a product had a medicinal, physical or perhaps cosmetic primary mode of action, or neither, the commission published a manual to help the manufacturer determine the classification of a "borderline product." A borderline product also could include a product that is a combination of two or more product types. The Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices was published by the Working Group on Borderline and Classification for Consultation.{4} This group was chaired by the commission and composed of representatives of all EU member states, the European Free Trade Association and other stakeholders. Under new EU device regulations, it is likely the MDCG and any assigned expert panel will continue to use the manual as a guide to assist in the determination process.

Summary

EU device regulations harmonize pre- and post-market procedural requirements for regulated devices and expand the responsibilities of notified bodies. They also increase manufacturer responsibilities for post-market vigilance and safety reporting and define market surveillance responsibilities for competent authorities to ensure marketed devices comply with pan-European safety and performance requirements. The MDCG—an important new jurisdictional component serving as an agent for the European

Commission—will provide important guidance and timely oversight management as needed to manufacturers, notified bodies, and national competent authorities.

References

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About the Authors

Robert D. Cumming is the regulatory manager in the medical devices and diagnostics group at PPD, and has more than 30 years of experience in high-risk medical device research and development, preclinical and clinical evaluations, and international regulatory affairs. He can be contacted at Robert.Cumming@ppdi.com.

Nancy W. Mathewson, Esq., is the director of regulatory affairs for the medical devices and diagnostics group at PPD, and has more than 30 years of experience in the medical device and pharmaceutical industries. She can be contacted at Nancy.Mathewson@ppdi.com.

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