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GUIDELINES ON MEDICAL DEVICES

Committees/Working Groups contributing to the implementation of the Medical Device Directives

Note

This guideline is giving information on the practical working structures in implementation of the medical device directives. It is not legally binding but has been jointly drafted by various interested parties including Competent Authorities, the European Commission services and industry. As such it can be taken as reflecting positions taken by those stakeholders in the medical device sector and it is anticipated that they will be followed within the Member States and help ensure uniform application of relevant provisions of the Directive.

INTRODUCTION

A number of Committees and Working Groups play a role in the implementation of the medical device directives (Directives 93/42/EEC on medical devices, 90/385/EEC on active implantable medical devices and 98/79/EC on *in vitro* medical devices). This document gives an overview of the existing groups and their functions, participation in these groups and their working practices. These groups either have a legally defined role in the implementation, such as the Committee on Medical Devices, or they contribute to the harmonized implementation and application of the Directives and support the Commission in the development of new policies and initiatives in relation to medical devices.

1. EXISTING GROUPS AND THEIR FUNCTIONS

1.1. Committees

1.1.1. Committee on Medical Devices

The "Committee on Medical Devices" has specific regulatory powers as set out in the medical device directives, including for example changing classification rules, implementation of Eudamed, adoption of Community health monitoring measures or amendments of non-essential elements relating to the clinical investigation requirements. Measures taken by the Committee are legally binding. An example of such measure is the Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements. The Committee has its own rules of procedure and is composed of Member States representatives.

1.1.2. Committee under Directive 98/34/EC

The Directives on medical devices also make reference to the Committee set up under Directive 98/34/EC, dealing with standardization. This is related to the procedures relating to mandates for standardization and to be used when challenging harmonized standards, either as such or in the context of safeguard clauses.
(http://ec.europa.eu/enterprise/standards_policy/general_framework/index.htm)

1.1.3. Scientific Committees

The Commission is assisted by Scientific Committees and in relation to medical devices in particular by the "**Scientific Committee on emerging and newly identified health risks (SCENIHR)"** which provides for independent scientific expertise.
(http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm).

1.2. Working Groups[1]

The Commission and Member States are supported in the implementation of the Directives of medical devices by a number of Working Groups. These Working Groups have, *inter alia*, developed a number of guidance documents, the so-called MEDDEV's, which are available on the Commission Website.

[1] The term "Working Group" is used here as an umbrella term for all types of groups, also those that are called differently, such as Competent Authority Group, expert group etc.

Similarly, the Commission has started to publish “consensus statements” on its website on issues on which MDEG reached consensus.

These documents do not have regulatory power and can not set legally binding rules. But they have been jointly drafted by various interested parties including Competent Authorities, the European Commission services and industry. As such they can be taken as reflecting positions taken by those stakeholders in the medical device sector and it is anticipated that they will be followed within the Member States and help ensure uniform application of relevant provisions of the Directive.

1.2.1. General coordination/Policy and Strategy related Groups

A broad forum for coordination encompassing all stakeholders is the Commission's Medical Devices Experts Group (MDEG), in which national competent authorities, representatives of the European standards bodies, Notified Bodies, European trade federations, representing also Small and Medium Enterprises, and, as the case may be, of other stakeholders, such as patient organisations participate. MDEG aims at discussion and coordination of strategic issues and of issues relating to implementation and enforcement of the medical device Directives, as well as the coordination of and overseeing the work of other Working Groups.

Member State representatives meet in the so-called Competent Authority (CA) meetings. These are organized by Member States on the occasion of their respective rotating Council Presidency. Competent Authorities only also meet in the closed sessions of the Medical Devices Experts Group (MDEG/CA).

1.2.2. Standing Working Groups

There are a number of Working Groups that address issues of implementation that require constant coordination between Member States. These are in particular the Compliance and Enforcement Group (COEN) and Notified Bodies Operational Group (NBOG), which coordinate the implementation of Member States competencies under the Directive on medical devices. These groups are under the oversight of the Competent Authorities.

Similarly, the Medical Device Vigilance Experts group, the Medical Device Borderline and Classification Group, the Working Group on Clinical Investigation and Evaluation and the IVD Technical Group are working groups dealing with the coordination of general implementation.

1.2.3. Special Issue Working Groups

The MDEG has in addition set up several working groups, dealing with issues such as European Database on Medical Devices (EUDAMED), New and Emerging Technologies, etc.

1.3. Notified Bodies Group

The Commission services have set up the Notified Bodies group (NB-MED) in order to ensure close cooperation between Notified Bodies active in the medical device field.

Such cooperation is needed for a consistent application of the conformity assessment procedures.

2. PARTICIPATION

Participation in the Committee on Medical Devices is restricted to Member State representatives.

The Competent Authority meetings, the Compliance and Enforcement Group (COEN) and Notified Bodies Operational Group (NBOG) are also restricted to representatives of the Member States, respectively the Competent Authorities/Designating Authorities.

The other Working Groups are generally open to all invited stakeholders, unless the meeting is clearly specified as a closed meeting. Stakeholders include in particular industry representatives, patient and user representatives, and representatives of Notified Bodies. In order to ensure balanced participation and representation and to maintain a workable meeting size, participation is however restricted to European umbrella organizations. Therefore, neither representatives of single manufacturers, patients or users, nor national trade associations can generally participate in these meetings.

3. FREQUENCY OF MEETINGS

The Committee on Medical Devices only meets when necessary, there is no regular meeting frequency. The MDEG as well as the CA meetings take place twice a year. The meeting frequency of the other Working Groups depends on the need, but usually each Working Groups will meet between 2 and 4 times a year.

4. WORKING PRACTICES

In the interests of having efficient and effective meetings the Working Groups aim to work in accordance with the following work practices:

- Each Group will have clear 'terms of reference', endorsed by MDEG/CA,
- Each Group will have a yearly working program and produce annual activity reports,
- Meetings will be forecasted early in advance,
- If there are insufficient items for the agenda a meeting will be cancelled or postponed,
- A preliminary draft agenda should be set at least one month prior to the meeting,
- Reports or updates should be submitted in writing prior to the meeting for discussion at the meeting,
- CIRCA will be further utilised to coordinate meetings and circulate documents,
- All papers should be submitted no later than two weeks before a meeting,
- The Commission, and, where applicable, in conjunction with the Chair, will make all documents available on CIRCA at least two weeks prior to a meeting,
- Draft notes/operational conclusions should be produced, in principle, within one month following a meeting.

5. OVERVIEW OF THE COMMITTEE AND WORKING GROUP STRUCTURE

Committee on Medical Devices
Committee 98/34
Scientific Committee

Policy and Strategy/General Coordination					
CA Meetings		**MDEG (partly Authorities only)**			
Standing Working Groups					
COEN	**NBOG**	**Vigilance**	**Classification and Borderline**	**Clinical Investigation and Evaluation (CIE)**	**IVD Technical Group**
Special Issue Working Groups (WG)					
EUDAMED WG	New and Emerging Medical Device Technologies (NET)	E-labelling WG	Software WG	MRA WG (inactive)	PVC-DEHP WG (inactive)	BSE/TSE WG (inactive)
NB-MED					

	Member States
	All Stakeholders (but in some cases closed sessions possible)