EUROPEAN COMMISSION

European Commission policy on the management of competing interests of members of the expert panels on medical devices and *in vitro* diagnostic medical devices

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1. Introduction

As laid down in Regulation (EU) 2017/745[1] on medical devices (the MDR), Regulation (EU) 2017/746[2] on *in vitro* diagnostic medical devices (the IVDR) as well as Commission Implementing Decision (EU) 2019/1396[5], the European Commission is responsible for the supervision of the work of the expert panels on medical devices and *in vitro* diagnostic devices (hereinafter: "expert panels") in view of their various roles and tasks, namely:

• The provision of *ad hoc* advice in relation to the implementation of Articles 106, 55.3, 61.2 of the MDR[1] and Article 50.3 of the IVDR[2]

• The provision of scientific opinions/views in relation to the clinical/performance evaluation consultation procedure (CECP/PECP) for certain high-risk medical devices and specific *in vitro* diagnostic medical devices according to Article 54 of MDR and 48 of IVDR, respectively.

Table 1 of Annex I summarises the tasks of the expert panels according to the relevant provisions in the MDR[1] and IVDR[2].

Importantly, Article 107 of the MDR[1] states that members of the expert panels shall not have financial or other interests in the medical device industry which could affect their impartiality. Members of the expert panels shall act in the public interest and in an independent manner. They shall perform their tasks with impartiality and objectivity. Therefore, they shall declare any direct or indirect interests they may have in the medical device industry and update their declaration of interest whenever a relevant change occurs. The declarations of interests of the experts along with their curriculum vitae are made publicly available on the European Commission's website. Moreover, experts assigned to expert panels on a temporary basis must also declare any interests they may have in the issue in question.

Article 106.3 of the MDR[1] lays down that the Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest of expert panel members. Thus, the present conflict of interest management policy has been developed based on the applicable rules for Commission experts groups[3] and the European Medicines Agency (EMA) policy on the handling of competing interests of scientific committees' members and experts.[4] The effective implementation of this policy allows the timely exclusion of experts with conflicting or competing interests for certain companies or medical devices and in other cases restricts experts' participation in certain activities of the panels.

2. Objectives of the policy

The main objective of this policy is to ensure that permanently appointed expert panel members and temporarily assigned experts have no interests in the medical device industry which could affect their impartiality while securing the best expertise for the assessment of medical device dossiers according to the relevant provisions of the MDR[1] and IVDR[2].

It is important to underline that a high quality of scientific expertise is by nature based on prior experience and that having an interest does not necessarily mean having a conflict of interest. This policy aims at striking a balance between the cooling-off period for different types of declared interests and access to up-to-date expertise.

3. Definitions

3.1 Direct versus indirect interests

Art. 107 of the MDR[1] and Art. 12 of Commission Implementing Decision (EU) 2019/1396[5] consider different categories of interests or relevance for the purpose of this policy, i.e. direct and indirect interests in the medical device industry or in a notified body or any other organisation or sector, which could affect an expert's independence, impartiality and objectivity.

For the purpose of this **policy we refer to direct or indirect interest in a medical device company**, where **medical device company** is defined as:

- Any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices or in vitro diagnostic medical devices (IVDs).
- This includes companies to which activities relating to research, development, manufacturing, maintenance, marketing and/or distribution of medical devices / IVDs (which might also be carried out in house) are outsourced on a contractual basis.
- Notified Bodies (NBs), Clinical Research Organisations (CROs) or consultancy companies providing advice or services relating to the above activities or to activities linked with certification or other regulatory procedures, also fall under the definition of a medical device company.

Legal or natural persons, which do not fall within the scope of the above definition, are **also considered as medical device companies** for the purposes of this policy if they:

- control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device company),
- are controlled by or
- are under common control of a medical device company.

Independent researchers and research organisations including universities and learned societies are **excluded from the scope** of the present definition.

Direct interests in a medical device company:

- Employment
- Consultancy
- Strategic advisory role
- Financial interests

Indirect interests in a medical device company:

- Principal investigator
- Investigator
- Grant or other funding to the expert’s organisation/institution
- Close family member direct interest

Each of these interests is further defined below. However, it should be noted that some of the definitions cannot address all the various scenarios which may exist.

For the purpose of this policy **current** interest shall mean:

- At the application stage or for resubmissions: the **time of completion of the DOI** form.
- At the assessment stage before or during appointments as well as for temporary assignments to expert panels: **any time during the term of the mandate** of an expert panel member or as the **time of involvement in a specific expert panel activity**.

3.2 Direct interests

Employment with a medical device company shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a medical device company.

It should be noted that:
Employees of a NB, CRO or consultancy company (i.e. a professional business offering advice or services to medical device companies) by definition fall under 'employment with a medical device company'.

Consultancy to a medical device company shall mean: any activity where the concerned expert provides advice (including training on a one to one basis) to a medical device company regardless of contractual arrangements or any form of remuneration.

For the purpose of this policy, "consultancy to a medical device company" is understood as an ad hoc/occasional activity typically not constituting the expert's main source of income. This can be for example the case of clinicians or academic researchers providing occasional consultancies to a medical device company.

However, if an expert's main activity and typically the expert's main source of income is the provision of advice to medical device companies, this activity should be considered as **"employment with a medical device company",** regardless on contractual arrangements.

Strategic advisory role for a medical device company shall mean: any activity where the expert is participating (with a right to vote/influence the outputs) in a(n) (scientific) advisory board, steering committee or executive committee with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of a medical device company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

For the purpose of this policy, "Strategic advisory role to a medical device company" is understood as an ad hoc/occasional activity typically not constituting the expert's main source of income. This can be for example the case of clinicians or academic researchers providing occasional advice to a medical device company.

However, if an expert's main activity and typically the expert's main source of income is the provision of advice to medical device companies, this activity is considered as **"employment with a medical device company",** regardless on contractual arrangements.

It should be noted that:

- Data monitoring committees (composed of independent external experts reviewing unblinded clinical investigation data independently of the sponsor / medical device company) fall outside the scope of this definition. Experts participating in these fora are considered as principal investigators (see below definition of principal investigator).
- Involvement of an expert in research work for a medical device company is considered an indirect interest.

Financial interests shall mean any economic stake in a medical device company including:

- Ownership or co-ownership, holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of such medical device company. The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the medical device sector) and they are independently managed (i.e. the individual has no influence on their financial management).
- Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a medical device company to the expert in a personal capacity. Payment for or reimbursement of expenses incurred for research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation and travel costs) are not considered as financial interests.
- Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medical device owned by the individual or of which the individual is directly a beneficiary.

3.3 Indirect interests

Principal investigator shall mean: an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre medical device industry instigated/sponsored clinical investigation / performance study for IVDs or the leading investigator of a monocentre medical device industry instigated/sponsored investigation / performance study for IVDs, or the coordinating (principal) investigator signing the clinical investigation report / performance study report for IVDs. This definition does not include a national coordinating investigator in a multinational investigation.

Investigator shall mean: an investigator involved in a medical device industry instigated/sponsored clinical investigation / performance study for IVDs at a specific clinical investigation site / performance study site. This can be the responsible lead investigator of the clinical investigation / performance study for IVDs at that specific site or a member of the clinical investigation team / performance study team for IVDs who performs critical investigation related procedures and makes important clinical investigation related decisions.

Grant or other funding to an organisation/institution shall mean: any funding from a medical device company to an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

Close family members' interests shall mean: current direct interests (i.e. employment, consultancy, strategic advisory role, financial interests) of close members of the family of the expert (i.e. siblings, children and parents) as well as a spouse or a partner, irrespective if they are living at the same address with the expert or not.

4. Management of conflicts of interest

4.1 Declared interests

The handling of declared interests is based on a two-step procedure. Following receipt of the DOI an interest level is assigned according to the below mentioned interest levels. Subsequently, the level of participation in the expert panel activities is determined taking into account the assigned interest level, the task at hand (Annex I), the envisaged role of the expert as well as the relevant interest code and resulting restrictions (Annex II).

Depending on the declared interest, **3 interest levels** can be identified:

- Direct interests declared (i.e. interest level D)
- Indirect interests declared (i.e. interest level I)
- No interests declared (i.e. interest level N)

Direct interests in the medical device industry lead to the highest level of restrictions and most stringent mitigating measures for involvement in expert panel activities.

Indirect interests in the medical device industry will be addressed through mitigating actions to reach a balance between limiting the involvement of an expert with an indirect interest and the need for the best available expertise.

Regarding the **nature** of the declared interest, **3 categories** and applicable timeframes are considered:

Category 1: Either current or past employment in an **executive role** within a medical device company or current or past employment within the last 5 years in a **lead role** in the development of a medical device, results in **exclusion of that expert** from expert panel activities.

Category 2: the following **declared interests** are considered **over when such interest is no longer present**, resulting in full involvement of the expert in activities of the panel(s):

- Financial interests
- Grant or other funding to an organisation/institution
- Interests of close family members

Category 3: for the remaining declared interests not listed in categories 1 and 2, it is assumed that the **declared interest is over following a 3 year cooling-off period.** The allowed involvements for expert panel members are defined in Annex II, Tables 2-4.

4.2 Other declarable interests

Involvement in academic clinical investigations / performance studies and in publicly funded research/development initiatives, as well as membership in an ethics committee should be declared. This will not result in the Commission restricting involvement in the expert panel activities, unless a specific interest is identified.

Attendance at courses and conferences funded by the medical device industry (including attendance at accredited courses or conferences with respect to continuing development of experts CPD/CME acquisition) do not need to be declared. However, in case the expert receives payment by medical device industry going beyond reimbursement of reasonable expenses (i.e. accommodation and travel costs) directly related to a conference/seminar attendance, this needs to be declared and this will be incompatible with involvement in the expert panel activities.

For transparency reasons it is advisable that experts also include declarations of interests related to:

- Academic clinical investigations / IVD performance studies and publicly funded research/development initiatives involving medical devices
- Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, funded in full or in part from unrestricted grants from several medical device companies (not from one single company), with or without involvement of industry participants and providing general advice (on development programmes, clinical study design, strategy, etc.) to several medical device companies (not one particular company) in a specific medical area
- Employment in an organisation/institution, where colleagues provide consultancy advice to medical device companies, but the expert is not directly involved in the provision of such advice. Examples include employees of European Union Reference Laboratories (EURLs) and Expert Laboratories (as stated in the relevant EU Regulations 2017/746 & 2017/745, respectively), National Reference Laboratories (and other laboratories performing testing on behalf of the EURLs), staff members of academic departments, etc.
- Continuous systematic attendances to congresses covered by the same medical device company
- Membership of an ethics committee
- Expert opinion or testimony in judicial proceedings against or by a medical device company relating to a medical device
- Testimonials in patient organisations
- Participation as a patient in a clinical investigation.

Experts' declarations related to the above three interests will be assessed on a case by case basis and specific measures might be decided and imposed by the Commission.

4.3 Restricting involvement in the expert panel activities

Levels of restriction and timeframes

Involvement of the individual experts in activities of the panels is restricted based on 3 factors:

- the nature of the declared interest,
- the timeframe during which this interest occurred, as well as
- the envisaged role and activities in the expert panel

The following step-wise methodology applies: first the nature of the declared interest within the frame of the expert panel activity will be assessed, before determining the type and length of any applicable restrictions.

As a general rule, **current employment** with a medical device company or **current financial interests** in **medical device industry** are **incompatible** with involvement in expert panel activities.

Applicable mitigating measures **for current or past interests** depend on the type of interest, e.g. employment, consultancy, strategic advisory role or (principal) investigators, the envisaged role of the expert, e.g. chairperson, rapporteur or co-rapporteur, reviewing member (as appointed panel member or temporarily assigned expert) as well as the specific task to be covered by the expert panel (Annex I, Table 1). For example, the requirements are stricter for chairpersons as well as for rapporteurs / co-rapporteurs of the expert panels.

It should however be noted that the cumulative effect of several restrictions stemming from different interests, e.g. multiple consultancies and/or strategic advice activities might limit an expert's usability to a degree of making him/her unsuitable for participation in expert panels activities.

The timeframe to be considered depending on the declared direct or indirect interest is either current, or within the past 3 years or in certain cases for a longer period (e.g. more than 5 years for past employment in lead role). However, individuals can always declare any interests beyond the specified periods. Experts can also restrict on their own initiative their involvement in expert panel activities as a result of such declaration.

5. Appointment to the expert panels on medical devices and *in vitro* diagnostic medical devices or inclusion in the central list of available experts

At the application stage, prior their first appointment and during their mandate in an expert panel, applicants or experts must submit the following documents:

- <u>At the application stage:</u>

- Application form
- Proof of citizenship
- Public declaration of interests (DOI)
- Curriculum Vitae (CV)

- <u>At the appointment stage:</u>

- (Updated) public declaration of interests (DOI)
- Declaration on confidentiality and commitment

- <u>During the term of their mandate:</u>

Experts must update their declarations of interest (DOI)

- whenever a change of circumstances so requires (e.g. new interests or changes in interests since the last DOI)
- prior to commencement of a panel task in case there is a change of circumstances relevant in regard to the specific task. In particular, **advisors must signal any potential conflict of interest** in relation to a specific task, which was not or could not have been identified by the Secretariat for whatever reason.

6. Practical operation of the policy

Depending on the tasks of the expert panels described in Annex I (Table 1), the application of the principles laid down in this policy in terms of allowable interests are summarised in the following three tables (Tables 2 – 4, Annex II):

- **Table 2** ***"Expert panel members' allowed involvement in ad hoc advice".*** It applies to expert panels tasks related to the provision of *ad hoc* advice – see tasks A1 – A7 of Table 1.

- **Table 3** ***"Expert panel members' allowed involvement in ad hoc advice on CDS/CIPR".*** It applies to expert panel tasks related to *ad hoc* opinions on manufacturers' clinical development strategies (CDS) or clinical investigation proposals (CIPR) - see task A8 of Table 1.

- **Table 4** ***"Expert panel members' allowed involvement in providing opinions/views in the framework of CECP/PECP".*** It applies to expert panels tasks related to the Clinical Evaluation Consultation Procedures (CECP) or Performance Evaluation Consultation Procedures (PECP) – see tasks B1 - B2 of Table 1.

In accordance with the relevant Commission Implementing Decision (EU) 2019/1396[5] the Commission may take appropriate measures in case of reasonable doubt or breach of trust with regards to experts' obligations on independence, impartiality, objectivity and confidentiality.

References

1. Regulation (EU) 2017/745 on medical devices (MDR)

2. Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)

3. Commission decision EU (2016) 3301 establishing horizontal rules on the creation and operation of Commission expert groups

4. European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts - EMA/626261/2014, Rev. 1, 6.10.2016

5. Commission implementing decision EU (2019) 1396 on laying down the rules for the application of Regulation (EU) 2017/745 as regards the designation of expert panels in the field of medical devices

Abbreviations

CDS / CIPR	Clinical Development Strategy / Clinical Investigation Proposal
CECP	Clinical Evaluation Consultation Procedure
CME	Continuing Medical Education
CPD	Continuing Professional Development
CRO	Clinical Research Organisation
CS	Common Specifications
CV	Curriculum Vitae
DOI	Declaration of Interests
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EURL	European Union Reference Laboratory
IVD	*In vitro* diagnostic (medical device)
IVDR	Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices
MDR	Regulation (EU) 2017/745 on medical devices
MFR	Manufacturer
MS	Member State
NB	Notified Body
PECP	Performance Evaluation Consultation Procedure
PMCF	Post Market Clinical Follow-up

ANNEX I

Table 1. Expert panels' tasks for the provision of *ad hoc* advice and CECP/PECP opinions/views with relevant MDR[1]/IVDR[2] articles. The last column links to the relevant tables of Annex II.

Task code	MDR art.	Task description	Relevant table (Annex II)
A1	106.10a	Provide scientific, technical and clinical assistance to the Commission and the MDCG in relation to the implementation of the MDR	2
A2	106.10b	Contribute to the development and maintenance of appropriate guidance and CS for clinical investigations, clinical evaluation & 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	2
A3	106.10c	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	2
A4	106.10d	Contribute to the development of standards at international level, ensuring that such standards reflect the state of the art	2
A5	106.10f	Contribute to identification of concerns and emerging issues on the safety and performance of medical devices	2
A6	106.11	Advise on 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	2
A7	55.3 MDR 50.3 IVDR	Provide scientific advice in relation to the safety and performance of any device in the group of certain class III / IIb medical devices and class D IVDs	2
A8	61.2	Provide views on the manufacturer's intended clinical development strategy (CDS) and proposals for clinical investigations (CIPR)	3
B1	54 / 106.9	Provide scientific opinions according to the CECP	4
B2	106.10g	Provide views in accordance with Article 48(4) of the IVDR on the performance evaluation of certain *in vitro* diagnostic medical devices (PECP)	4

ANNEX II

Table 2. Possible involvement and restrictions of expert panel members in regard to ***ad hoc*** **advisory tasks** (tasks A1 – A7 of Table 1). The table shows exclusion (X), full involvement (F) and possible restrictions (A,R,M,T) in regard to roles of experts in case of current or past interests. Where a 3-year cooling off period applies, no restrictions will apply beyond that period (not shown in the table).

			Role in the expert panel			
			Appointed panel members			Temporarily assigned experts
Interest code	Declared interest	Time since declared interest (years)	Chair*	Rapporteur Co-Rapporteur	Reviewing member	
E1	Employment (executive role)	CURRENT interest	X	X	X	X
E1-past		ANYWHEN in the past	X	X	X	X
E2	Employment (lead role in development of medical device)	CURRENT interest or 0 - 5	X	X	X	X
E2-past		>5	X	X	X	X
E3	Employment (cross company role other than executive role)	CURRENT interest	X	X	X	X
E3-past		0 - 3	X	X	X	X
E4	Employment (medical device involvement other than lead role in development of medical device)	CURRENT interest	X	X	X	X
E4-past		0 - 3	X	X	X	X
C1	Consultancy to company (cross medical devices / general)	CURRENT interest	X	X	X	X
C1-past		0 - 3	A2	F2 - R2	F2 - M2	F2 - T2
C2	Consultancy to company (individual medical device)	CURRENT interest	X	X	X	X
C2-past		0 - 3	A2	F2 - R2	F2 - M2	F2 - T2
S1	Strategic advisory role for company (cross medical devices /general)	CURRENT interest	X	X	X	X
S1-past		0 - 3	A2	F2 - R2	F2 - M2	F2 - T2
S2	Strategic advisory role for company (individual medical device)	CURRENT interest	X	X	X	X
S2-past		0 - 3	A2	F2 - R2	F2 - M2	F2 - T2
FI	Financial interests	CURRENT interest	X	X	X	X
FI-past		0 - 3	F	F	F	F
PI	Principal investigator	CURRENT interest	A2	F2 - R2	F2 - M2	F2 - T2
PI-past		0 - 3	A2	F	F	F
I	Investigator	CURRENT interest	A2	F2 - R2	F2 - M2	F2 - T2
I-past		0 - 3	A2	F	F	F
G	Grant/other funding to organisation/institution	CURRENT interest	A2	X	X	X
G-past		0 - 3	F	F	F	F
CFM	Close family member's interest	CURRENT interest	A2	X	X	X
CFM-past		0 - 3	F	F	F	F

Table 2 legend. Assessment outcomes for declared interests of medical device experts

Code	Possible restrictions to be applied
F	Full involvement in activity allowed
F2	Full involvement in activity allowed for tasks A1 – A4
X	No involvement in activity allowed
A2	Restrictions in regard to Chair role: Cannot act as Chair for tasks A5 – A7 in relation to any medical device from the declared company
R2	Restrictions in regard to rapporteur and co-rapporteur roles: Cannot act as rapporteur or co-rapporteur for tasks A5 – A7 in relation to any medical device from the declared company
M2	Restrictions in regard to reviewing member role (for appointed panel members): Cannot act as reviewing member for tasks A5 – A7 in relation to any medical device from the declared company
T2	Restrictions in regard to reviewing member role (for temporarily assigned experts): Cannot act as a reviewing member for tasks A5 – A7 in relation to any medical device from the declared company

** When the Vice-Chair is not replacing the Chair he/she will act either as Rapporteur/Co-rapporteur or as reviewing member and the corresponding restrictions shall apply.*

Table 3. Expert panel members' allowed involvement in ***ad hoc*** **advice on clinical development strategies / clinical investigation proposals (CDS/CIPR)** (task A8 of Table 1). The table shows exclusion (X), full involvement (F) and possible restrictions (A,R,M,T) in regard to roles of experts in case of current or past interests. Where a 3-year cooling off period applies, no restrictions will apply beyond that period (not shown in the table).

			Role in the expert panel			
			Appointed panel members			Temporarily assigned experts
Interest code	Declared interest	Time since declared interest (years)	Chair*	Rapporteur Co-Rapporteur	Reviewing member	
E1	Employment (executive role)	CURRENT interest	X	X	X	X
E1-past		ANYWHEN in the past	X	X	X	X
E2	Employment (lead role in development of medical device)	CURRENT interest or 0 - 5	X	X	X	X
E2-past		>5	X	X	X	X
E3	Employment (cross company role other than executive role)	CURRENT interest	X	X	X	X
E3-past		0 - 3	X	X	M2	T2
E4	Employment (medical device involvement other than lead role in development of medical device)	CURRENT interest	X	X	X	X
E4-past		0 - 3	A2	X	M2	T2
C1	Consultancy to company (cross medical devices / general)	CURRENT interest	X	X	X	X
C1-past		0 - 3	A2	R2	M2	T2
C2	Consultancy to company (individual medical device)	CURRENT interest	X	X	X	X
C2-past		0 - 3	A2	R2	M2	T2
S1	Strategic advisory role for company (cross medical devices /general)	CURRENT interest	X	X	X	X
S1-past		0 - 3	A2	R2	M2	T2
S2	Strategic advisory role for company (individual medical device)	CURRENT interest	X	X	X	X
S2-past		0 - 3	A2	R2	M2	T2
FI	Financial interests	CURRENT interest	X	X	X	X
FI-past		0 - 3	F	F	F	F
PI	Principal investigator	CURRENT interest	X	X	X	X
PI-past		0 - 3	A2	R2	M2	T2
I	Investigator	CURRENT interest	X	X	X	X
I-past		0 - 3	A2	R2	M2	T2
G	Grant/other funding to organisation/institution	CURRENT interest	A2	R2	M2	T2
G-past		0 - 3	F	F	F	F
CFM	Close family member's interest	CURRENT interest	A2	R2	M2	T2
CFM-past		0 - 3	F	F	F	F

Table 3 legend. Assessment outcomes for declared interests of medical device experts

Code	Possible restrictions to be applied
F	Full involvement in activity allowed
X	No involvement in activity allowed
A2	Restrictions in regard to Chair role: Cannot act as Chair in relation to any medical device from the declared company
R2	Restrictions in regard to rapporteur and co-rapporteur roles: Cannot act as rapporteur or co-rapporteur in relation to any medical device from the declared company
M2	Restrictions in regard to reviewing member role (for appointed panel members): Cannot act as reviewing member in relation to any medical device from the declared company
T2	Restrictions in regard to reviewing member role (for temporarily assigned experts): Cannot act as reviewing member in relation to any medical device from the declared company

** When the Vice-Chair is not replacing the Chair he/she will act either as Rapporteur/Co-rapporteur or as reviewing member and the corresponding restrictions shall apply.*

Table 4. Expert panel members' allowed involvement in providing opinions/views in the framework of **CECP/PECP** (tasks B1 - B2 of Table 1). The table shows exclusion (X), full involvement (F) and possible restrictions (A,R,M,T) in regard to roles of experts in case of current or past interests.

			Role in the expert panel			
			Appointed panel members			Temporarily assigned experts
Interest code	Declared interest	Time since declared interest (years)	Chair*	Rapporteur Co-Rapporteur	Reviewing member	
E1	Employment (executive role)	CURRENT interest	X	X	X	X
E1-past		ANYWHEN in the past	X	X	X	X
E2	Employment (lead role in development of medical device)	CURRENT interest or 0 - 5	X	X	X	X
E2-past		> 5	A2	R2	M2	T2
E3	Employment (cross company role other than executive role)	CURRENT interest	X	X	X	X
E3-past		0 - 3	A2	R2	M2	T2
E4	Employment (medical device involvement other than lead role in development of medical device)	CURRENT interest	X	X	X	X
E4-past		0 - 3	A2	R1	M1	T1
C1	Consultancy to company (cross medical devices / general)	CURRENT interest	A2	R2	M2	T2
C1-past		0 - 3	A2	R2	M2	T2
C2	Consultancy to company (individual medical device)	CURRENT interest	A2	R2	M2	T2
C2-past		0 - 3	A2	R1	M1	T1
S1	Strategic advisory role for company (cross medical devices / general)	CURRENT interest	A2	R2	M2	T2
S1-past		0 - 3	A2	R2	M2	T2
S2	Strategic advisory role for company (individual medical device)	CURRENT interest	A2	R2	M2	T2
S2-past		0 - 3	A2	R1	M1	T1
FI	Financial interests	CURRENT interest	X	X	X	X
FI-past		0 - 3	F	F	F	F
PI	Principal investigator	CURRENT interest	A2	R1	M1	T1
PI-past		0 - 3	A2	R1	M1	T1
I	Investigator	CURRENT interest	A2	R1	M1	T1
I-past		0 - 3	A2	R1	M1	T1
G	Grant/other funding to organisation/institution	CURRENT interest	A2	R2	M2	T2
G-past		0 - 3	F	F	F	F
CFM	Close family member's interest	CURRENT interest	A2	R2	M2	T2
CFM-past		0 - 3	F	F	F	F

Table 4 legend. Assessment outcomes for declared interests of medical device experts

Code	Possible restrictions to be applied
F	Full involvement in activity allowed
X	No involvement in activity allowed
A2	Restrictions in regard to Chair role: Cannot act as Chair in relation to any medical device from the declared company
R1	Restrictions in regard to rapporteur and co-rapporteur roles: Cannot act as rapporteur or co-rapporteur in relation to the declared medical device
R2	Restrictions in regard to rapporteur and co-rapporteur roles: Cannot act as rapporteur or co-rapporteur in relation to any medical device from the declared company
M1	Restrictions in regard to reviewing member role (for appointed panel members): Cannot act as reviewing member in relation to the declared medical device
M2	Restrictions in regard to reviewing member role (for appointed panel members): Cannot act as reviewing member in relation to any medical device from the declared company
T1	Restrictions in regard to reviewing member role (for temporarily assigned experts): Cannot act as reviewing member in relation to the declared medical device
T2	Restrictions in regard to reviewing member role (for temporarily assigned experts): Cannot act as reviewing member in relation to any medical device from the declared company

** When the Vice-Chair is not replacing the Chair he/she will act either as Rapporteur/Co-rapporteur or as reviewing member and the corresponding restrictions shall apply.*