V

(Announcements)

ADMINISTRATIVE PROCEDURES

EUROPEAN COMMISSION

Call for expression of interest for expert panels on medical devices and *in vitro* diagnostic medical devices

804/PP/GRO/CODEL/20/

(2019/C 323/05)

1. Background

The new EU regulations on medical devices (Regulation (EU) 2017/745, hereinafter the 'MDR') and *in vitro* diagnostic devices (Regulation (EU) 2017/746, hereinafter the 'IVDR') came into force in 2017. Both regulations, and in particular the MDR draw on the expertise of advisors appointed to so-called 'expert panels'. Expert panels have been designated by the Commission following consultation with the MDCG ([1]) in relevant medical fields and other areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice (see Commission Implementing Decision (EU) 2019/1396).

Expert panels have a broad spectrum of tasks: in the context of conformity assessments of devices, expert panels respond to mandatory consultation procedures by notified bodies in regard to the clinical evaluation assessment of certain high-risk medical devices ([2]) and the performance evaluation for certain *in vitro* diagnostic medical devices ([3]) ([4]).

In addition and depending on need, expert panels:

— provide scientific, technical and clinical assistance to the Commission, the MDCG, manufacturers and notified bodies in relation to the implementation of the MDR (Article 106(10) of the MDR);

— respond to voluntary consultations by manufacturers concerning their intended clinical development strategy (Article 61(2) of the MDR);

— provide advice to Member States, notified bodies and manufacturers, for instance on appropriate data sets for conformity assessment of devices and in particular with regard to clinical data required for clinical evaluation (Article 106(11) of the MDR);

— contribute to the development of relevant documents (Article 106(10) of the MDR) such as Common Specifications (Article 9 of the MDR) as well as international standards and relevant guidance documents;

— provide advice to the MDCG and Commission on the safety of medical devices (Article 55(3) of the MDR) and *in vitro* diagnostic devices (Article 50(3) of the IVDR).

The Commission hereby is calling for expressions of interest to draw up a list of candidates that are eligible and apt in regard to their expertise in relevant clinical or other scientific technical areas. From the list of suitable candidates, expert panel members will be appointed in the following areas:

— Orthopaedics, traumatology, rehabilitation, rheumatology

([1]) MDCG: Medical Device Coordination Group (MDR Article 103).

([2]) Class IIb medical devices for administering or removing medicinal products and class III implantable medical devices, which fulfil the criteria stipulated in Annex IX Section 5.1.

([3]) For class D *in vitro* diagnostic devices, where no Common Specifications are available.

([4]) Applicants are referred to the different implementation timelines for the MDR and IVDR, which apply from 26 May 2020 and 26 May 2022, respectively. Expert panels might therefore commence work at different times.

— Circulatory system

— Neurology ([5])

— Respiratory, anaesthesiology, intensive care

— Endocrinology and diabetes

— General and plastic surgery, dentistry

— Obstetrics and gynaecology, including reproductive medicine

— Gastroenterology and hepatology

— Nephrology and urology

— Ophthalmology

— *In vitro* diagnostics (IVD)

An additional expert panel is designated to be in charge of the decision referred to in point (c) of Section 5.1 of Annex IX to Regulation (EU) 2017/745 (hereinafter the 'Screening Panel'). For consultation procedures on the clinical evaluation assessment of certain high-risk medical devices, these experts will decide against predefined criteria whether a scientific opinion will be produced on a given dossier by one of the above expert panels.

Candidates are informed that the expert panels' workload is unequally distributed between different medical fields, which is also reflected in the size of panels. Due to the nature of the tasks, a higher number of experts with clinical expertise and strong link to medical devices will be needed for the composition of the panels (with exception of the IVD panel), as opposed to experts with other (non-medical) or scientific expertise.

In the application form candidates will have the possibility to indicate which expert panel would best fit their expertise (a text version of the online application form is provided in Annex I). This preference will be used to group applications during the evaluation phase and must not be understood as an application specifically for the chosen panel.

Applicants who have been included in the list of eligible and apt candidates, but who have not been appointed to an expert panel, may be included on a central list of available experts ([6]).

2. **Features of the Group**

2.1. *Composition*

In accordance with the MDR Article 106(3), the Commission determined the number of members of each panel in accordance with requisite needs. The following maximum numbers of experts will be appointed for each panel:

Panel name	Number of advisors
Screening panel	86
Cardiovascular/lymphatic system	30
Orthopaedics, traumatology, rehabilitation, rheumatology	35
Neurology	15
Respiratory, anesthesiology, intensive care	5

([5]) Including devices to restore hearing (e.g. cochlear implants) and vision (e.g. retinal implants).
([6]) The central list of available experts shall not exceed 1 000 experts.

Panel name	Number of advisors
Endocrinology and diabetes including insulin delivery systems	5
General and plastic surgery, Dentistry	20
Obstetrics and gynaecology including reproductive medicine	5
Gastroenterology and hepatology	5
Nephrology and urology	5
Ophthalmology	5
In vitro Diagnostics	30

As outlined in the eligibility and selection criteria (see sections 4 and 5 of this call), the selection procedure will take into account the educational background, professional experience, experience with high risk medical devices and *in vitro* diagnostic devices, additional non-clinical, technical/scientific and regulatory expertise, language and other skills.

Experts must not have any financial or other interest in the medical device industry that could affect their impartiality. Applicants must therefore submit a duly completed DOI form (Annex II), indicating any interest that may compromise or reasonably be perceived to compromise their independence, including any relevant circumstances relating to their close family members. Procedural guidance to compile the DOI is annexed to this call (Annex III).

Experts shall act in their own personal capacity and shall not delegate their responsibilities to any other person. In performing their functions, they shall respect the principles of independence, impartiality and confidentiality and act in the public interest. Their advice shall be based on scientific, technical and/or clinical considerations only.

If appointed to an expert panel, candidates will be asked to sign a declaration of confidentiality and commitment (Annex IV), as well as annual written updates of their declarations of interest and written and/or oral updates of their declarations of interest before meetings. These declarations will be made public ([7]).

2.2. *Appointment*

Members shall be appointed as advisors to expert panels by the Commission and in consultation with the MDCG from applicants complying with the requirements referred to in chapter 4 (eligibility criteria) and 5 (selection criteria) of this call.

Members shall be appointed for three years and their term of office may be renewed ([8]) as long as members continue to satisfy the eligibility and selection criteria (sections 4 and 5 of this call). They shall remain in office until replaced or their appointments are renewed.

In order to ensure continuity and the smooth functioning of the expert panels, persons on the list of eligible and apt candidates who are not appointed to an expert panel may be included in a central list of available experts. The list may be used to appoint replacements, to provide advice or to support the work of expert panels as needed. The list resulting from the call is valid for five years from the date of its establishment. It may be updated by the Commission at any time based on applications received during the 5-year period and requisite needs. Upon expiry of the list, a new call for expression of interest might be organised.

([7]) DOI shall be made public according to MDR, Art. 106(3).
([8]) In agreement with MDR, Art. 106(5).

Members who are no longer capable of contributing effectively to the group's deliberations, who do not comply with, or have acted in breach of, the conditions set out in the Commission Implementing Decision (EU) 2019/1396 or in Article 339 of the Treaty on the Functioning of the European Union or who resign, shall no longer be invited to participate in any meetings or deliberations of the panel and may be replaced for the remainder of their term of office.

2.3. *Operation of the Expert Panels*

The work of the expert panels shall comply with principles of high levels of expertise, independence, impartiality and objectivity, commitment, transparency and confidentiality.

Independence will be ensured by means of regular Declarations of Interests (DOI) and a conflict of interest management policy.

Expert panel members shall actively contribute to the work of the panel. They shall sign a declaration on commitment to this effect (Annex IV).

Depending on demand and subject to fluctuations, experts are expected to be available for panel-related tasks (from remote) and to attend meetings by video-/teleconferencing in average not exceeding 2 to 3 days/month. In addition, experts may be required to occasionally attend physical meetings.

On a proposal by and in agreement with the Commission, common rules of procedure (ROP) shall be adopted by simple majority of the Coordination Committee ([9]). Expert panels shall elect a Chair and a Vice-Chair from among its members at the beginning of each term. The Chair's and Vice-Chair's responsibilities include close interaction with the Commission secretariat, coordination of timely delivery of advice and other roles as outlined in the ROP. For specific tasks, the Chair will on a rotating basis and based on their expertise appoint rapporteurs or co-rapporteurs amongst panel members.

Expert panel consultations on clinical evaluation assessments and performance evaluations (decisions, scientific opinions, scientific views, as well as any other output) ([10]) will typically be prepared and adopted by remote work of its members. Teleconferences may be scheduled as needed.

Expert panel members involved in providing other types of advice will also work remotely, such as for contributions to the development of Common Specifications (CS), contribution to international standards development, reviewing manufacturer's intended clinical development strategy/clinical investigation proposals and other tasks, but they may also attend physical meetings as required (typically not exceeding two meetings per year).

Members are expected to actively contribute to discussions of the expert panels, examine and provide comments on documents under preparation respecting due deadlines. Members must have a sufficient level of IT literacy to be able work remotely, including electronic methods for the management and exchange of documents. Working documents will be made available and drafted in English. Meetings will be also held in English.

Expert panel's opinions on clinical evaluation assessments, performance evaluations and on manufacturer's intended clinical development strategies/clinical investigation proposals shall be adopted by consensus ([11]). 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.

Applicants for expert panel membership are informed that the ultimate responsibility for conformity assessment of high-risk devices remains with the notified body. Expert panels will not be held liable for the non-binding advice provided to notified bodies as part of their work.

2.4. *Remuneration for expert panel members*

Experts shall be remunerated at a fixed price of 450 euros/day worked.

([9]) In agreement with Commission Implementing Decision (EU) 2019/1396, Art. 7.

([10]) As defined in Article 54(1), Article 106(9), (10), (11), (12), Article 55(3), Article 61(2), and Section 5.1 of Annex IX of the MDR and in Article 48(4), (6), 50 (3), Annex IX, Section 4.9 and Annex X, Section 3 (j) of the IVDR, respectively.

([11]) MDR Art. 106 (12) 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.'

Provisions for remuneration are outlined in the Annex of Commission Implementing Decision (EU) 2019/1396. Members of expert panels or experts assigned in support of the expert panels' work shall be entitled to remuneration for their preparatory work and participation, in person or from a distance by electronic means, in meetings of the expert panels. If applicable, travel and subsistence expenses for participation in physical expert panel meetings organised by the Commission shall be reimbursed. Reimbursement shall be made in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources.

Candidates are informed that in accordance with Article 237 of the Financial Regulation [12] and for the purpose of transparency a list of experts who signed contracts with the institution is published annually. The list includes the specific task, the names of individuals, their regional localisation and their remuneration if it exceeds 15 000 EUR per signed contract.

2.5. *Transparency*

The activities of the expert panels shall be carried by observing principles of transparency. The Commission shall publish all relevant documents on a dedicated website. In particular, it shall make available to the public, without undue delay:

— the names of the members of expert panels;

— the names included in the central list of available experts;

— the members' *Curriculum Vitae*, declarations of interests [13], confidentiality and commitment;

— the expert panels' common rules of procedure;

— certain opinions adopted by panels (in accordance with MDR Article 106(12)).

Exceptions to publication shall be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001 and the Article 109 of the MDR on confidentiality.

2.6. *Confidentiality*

The members of the expert panels as well as assigned experts are subject to the obligation of professional secrecy, which by virtue of the Treaties and the rules implementing them applies to all members of the institutions and their staff. In line with Commission Implementing Decision (EU) 2019/1396, expert panel members shall not divulge information, including commercially sensitive or personal data, acquired as a result of the panel's work, even after they have ceased to be members. They shall sign a declaration on confidentiality to this effect (Annex IV). In line with Commission Implementing Decision (EU) 2019/1396, panel members shall comply with the Commission's security rules on the protection of EU classified and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443 and 2015/444. Should panel members fail to respect these obligations, the Commission may take appropriate measures.

3. **Application procedure**

Interested individuals are invited to submit their application to the European Commission by following the instructions on the following website: https://ec.europa.eu/growth/sectors/medical-devices_en

As the working language of the expert panels is English, all applications must be completed in English.

An application will be deemed admissible only if it is sent by the deadline and includes the documents referred to below. An application will only be considered if it has been submitted via the above link.

Inclusion on the central list of available experts entails no obligation on the part of the Commission concerning the appointment as panel member.

Supporting documents

Each application shall include the following documents:

— A completed electronic application form;

[12] Regulation (EU, Euratom) 2018/1046 on the financial rules applicable to the general budget of the Union, repealing Regulation (EU, Euratom) No 966/2012.

[13] Applicants are informed that according to MDR, Art. 106 (3) DOIs will be made public.

— A curriculum vitae (CV) in electronic format (preferably.pdf), not exceeding four pages. Europass format may be used;

— A copy of your national ID or passport as proof of citizenship;

— A declaration of interests (DOI) using the standard DOI form annexed to this call. Candidates must disclose therein any circumstances that could give rise to a conflict of interest. Submission of a duly completed DOI form is necessary in order to be eligible to be appointed in a personal capacity. Additional supporting documents may be requested at a later stage.

Deadline for application

Candidates who wish to be considered for appointment as advisors to expert panels in the first cycle of appointments must submit a duly completed application by 10 November 2019.

Candidates may submit an expression of interest at any time prior to the last three months of validity of the list of available experts (5 years from the date of its establishment). The date of validity of the central list of available experts will be published on the Commission webpage: https://ec.europa.eu/growth/sectors/medical-devices_en

Protection of personal data

The Commission ensures that applicants' personal data are processed as required by Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies. For more detailed information on the scope, purposes and means of the processing of their personal data in the context of this call, applicants are invited to consult the specific privacy statement, which is attached to this call (Annex V) and available on the website for submission.

4. **Eligibility**

Applicants must have:

— Full rights as a citizen of a Member State of the EU, EFTA or Turkey;

— A university degree in a relevant medical or scientific area at graduate level;

— At least 10 years of relevant professional experience in areas related to the subject of the call (medical, non-medical, scientific and technical or regulatory);

— Good knowledge of the English language allowing active participation in deliberations and writing reports in English ([14]);

— No financial interest or other interest in the medical device industry or in a notified body or any other organisation or sector, which could affect their independence, impartiality and objectivity ([15]).

Applicants who do not meet these criteria will be excluded from the selection procedure.

5. **Selection criteria**

Applications that meet the eligibility requirements will be evaluated based on the provided evidence, against the following criteria relating to technical and professional capacity:

— Educational background

— Professional experience in medical, scientific or technical areas relevant to the call

— Direct experience with the use of medical devices and IVDs, clinical investigation with medical devices, experience with quality assurance/standardisation of IVDs research & development, reports or analysis of medical device problems or failures

([14]) As a guide, 'Ability to work in English' corresponds to level B2 or above, as set out in the Council of Europe reference document for the European Language Portfolio ('Common European Framework of Reference: Learning, Teaching, and Assessment'). For more information please refer to: http://europass.cedefop.europa.eu/en/resources/european-language-levels-cefr

([15]) Applicants are referred to MDR Art. 106 (3), 107, Commission Implementing Decision (EU) 2019/1396, Art. 12 and the Declaration of Interest (DOI) form.

— Scientific impact of relevance to high risk medical devices (e.g. 20 most relevant publications, number and impact factor of publications)

— Experience in providing scientific advice and with analysing complex information

— Experience in working in committees/organisation committees/expert groups

— Experience in a multi-disciplinary/international environment

— Experience as chairperson or coordinator (management of groups to deliver quality outputs and keeping deadlines)

— Experience in regulatory affairs of medical devices or *in vitro* diagnostic devices

— Experience in regulatory affairs of medicinal and/or combination products.

6. **Selection procedure**

The selection procedure shall consist of an assessment of the applications performed by a Selection Committee against the selection criteria listed in chapter 5 of this call, followed by the establishment of a list of eligible and apt candidates, and concluded by the appointment of the members to the appropriate expert panel or the central list of available experts, respectively.

When defining the composition of the expert panels, the Commission shall aim at ensuring a high level and balanced representation of relevant expertise (clinical, technical, scientific and regulatory expertise), while taking into account the specific tasks of the group, the type of expertise required and the expected workload. The Commission shall seek a geographical and a gender balance.

For any further information please contact JRC-MEDICAL-DEVICES@ec.europa.eu

ANNEXES (see https://ec.europa.eu/growth/sectors/medical-devices_en):

I — Application form

II — Declaration of interest (DOI) form

III — Procedural guidance on declaration of interests

IV — Declarations on confidentiality and commitment

V — Privacy statement