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HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Resource management and better regulation
Finance, budget and controls

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SANTE A3/AMS/sg(2021)6390315

PUBLIC CALL FOR EXPRESSIONS OF INTEREST

AS REPRESENTATIVES OF PATIENTS' ORGANISATIONS, DOCTORS' ORGANISATIONS AND VETERINARIANS' ORGANISATIONS TO THE MANAGEMENT BOARD OF THE EUROPEAN MEDICINES AGENCY (EMA/21/MB)

Background

This Commission Call for expressions of interest relates to the appointment of representatives of patients', doctors' and veterinarians' organisations to the Management Board of the European Medicines Agency (EMA).

Regulation (EC) No 726/2004 of the European Parliament and of the Council lays down “*Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*”¹. For ease of reference the provisions of the regulation directly relating to the Management Board are reproduced in the Annex to this document.

Article 65 (1) of Regulation (EC) No 726/2004 states that “*two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled*”. Moreover, this Article stipulates that “*the members of the Management Board shall be appointed in such a way as to guarantee the highest level of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.*”

Under Article 65 (2) of Regulation (EC) No 726/2004, the members of Management Board shall be appointed on the basis of their relevant expertise in management and, if appropriate, experience in the field of medicinal products for human or veterinary use.

The members of the Management Board are appointed for a renewable period of three years. The three-year term of the current members expires on 14 June 2022 and this Call is intended to select candidates to replace them. Current members may reapply.

¹ OJ L 136, 30.4.2004

Composition and role of the Management Board

The Management Board is composed of one representative of each Member State, two representatives of the Commission, two representatives of the European Parliament and two members representing patients' organisations, one representing doctors' organisations and one representing veterinarians' organisation.

The Management Board is the European Medicines Agency's governance body, with general responsibility for budgetary and planning matters. This includes, in particular:

- The appointment of the Executive Director;
- The adoption of annual and multi-annual work programmes of EMA and the annual report on the Agency's activities;
- The adoption of opinions on the rules of procedure of the scientific committees of EMA as well as the adoption of procedures for the performance of scientific services;
- The adoption of the internal financial provisions;
- The adoption of the budget of EMA.

Workload and allowances

Active and regular participation of the appointees is essential for the functioning of the Management Board. Appointees will be expected to attend the meetings of the Management Board that meets for one or two days four times a year² at the EMA premises or in some cases virtually. Applicants should take into account that meetings involve preparatory work. They should also be prepared to work with electronic methods for the management and exchange of documents. The working documents are in English and the meetings are also conducted in English. Therefore, a good command of English is essential.

Travel, accommodation and subsistence costs for the members of the Management Board will be met by EMA according to its reimbursement rules for delegates.³

Independence

Members of the Management Board shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of their financial interests or as soon as their interests change. Members are required to provide declarations of any specific interests at each meeting, which might be considered prejudicial to their independence in relation to the items on the agenda.

For this purpose, it is essential that applicants submit, together with their application, a duly completed declaration of interest form (as explained below). All applicants will be

² Meeting dates are published here:

<https://www.ema.europa.eu/en/about-us/who-we-are/management-board/management-board-meetings>

³ Cf. [Rules for reimbursement of expenses for delegates and experts attending meetings.](#)

subject to a pre-screening of any potential competing interests in line with the rules of EMA⁴.

Any detected direct interest could lead to the exclusion from the appointment process.

Assessment criteria

Assessment of expressions of interest will be based on:

- Whether individuals represent patients', doctors' or veterinarians' organisations at a European level. Ability and experience in representing organisations, and the characteristics of the organisations represented will be assessed*;
- Whether individuals have competencies and experience relevant to the tasks of the Management Board according to Article 65(1) and (2) and Article 66 of Regulation No (EC) 726/2004;⁵
- Based on Article 65(1) last paragraph, the Council shall take into account the expertise provided by the members already appointed to the Management Board in order to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union;⁶

*The documents adopted by the European Medicines Agency on the criteria to be fulfilled for patients' and healthcare professionals' organisations will be considered in the assessment process.⁷

Application procedure and closing date

Interested persons must comply with the requirements below, otherwise their applications will not be taken into consideration.

Interested persons must complete, print, sign and date the application and the declaration of interests forms, which are available on the Health and Food Safety Directorate-General's website:

https://ec.europa.eu/health/documents/public_call/call_index_en

The application must include:

- (a) the completed application form (signed),
- (b) the completed declaration of interests form (signed),
- (c) a CV,

⁴ More information on handling of competing interests is available [here](#).

⁵ See in Annex below.

⁶ See in Annex below.

⁷ [Criteria to be fulfilled by patients' and consumers' organisations or by healthcare professionals' organisations involved in European Medicines Agency \(EMA\) activities.](#)

And: [Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria.](#)

(d) a recommendation letter from the organisation that the applicant wishes to represent.

The Commission reserves the right to ask for further supporting documents at a later stage, if deemed necessary.

Applications, including the necessary documentation, must be submitted in one of the official languages of the European Union. It would, however, be appreciated, without it being a requirement, if at least a summary of experience and other pertinent information could also be provided in English in order to facilitate the selection procedure.

The appointment is nominal for individual natural persons. However, these individuals are appointed with the purpose of representing interested parties via organisations at the European level. Therefore, applications to this Call need to be submitted in agreement with the organisation that the applicant intends to represent. This agreement should be demonstrated in the recommendation letter – as an attachment (e) for the application.

Organisations can put forward (i.e. support by a recommendation letter) more than one candidate.

In submitting an application, applicants accept the procedures and conditions as described in this Call and in the documents to which it refers. In compiling their application, applicants may under no circumstances refer to any documents submitted in prior applications (example: photocopies of previous applications will not be accepted). Any misrepresentation in the supplied information may lead to exclusion from the present Call.

The **deadline** for submission of applications is **20 October 2021**.

The complete application must be sent:

by electronic means not later than 20 October 2021, 11:59 p.m, **Brussels time**, to the following address:

SANTE-CALL-AGENCIES@ec.europa.eu

The subject of the email should contain the reference number of the Call for expressions of interest: EMA/21/MB.

For any further information on this Call, please contact SANTE-CALL-AGENCIES@ec.europa.eu by referring in the subject of the email to the reference number of the Call: EMA/21/MB.

Appointment process

All candidates applying to this Call for expressions of interest will be informed of the outcome of the selection process. Candidates who are not appointed may be invited to constitute a reserve list to be used in the event of the need to replace experts who are unable to complete their mandate.

Based on the assessment criteria listed above, the European Commission shall draw up a list of candidates. The European Parliament will be consulted on this shortlist prior to appointment by the Council to the Management Board.

Protection of personal data

The Commission will ensure that candidates' personal data are processed as required by Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39). This applies in particular to the confidentiality and security of such data. For more detailed information on the scope, purposes and means of the processing of their personal data in the context of this Call, candidates are invited to consult the specific privacy statement published on the Call webpage at the following address: https://ec.europa.eu/health/documents/public_call/call_index_en.

ANNEX

Provisions directly relating to the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Article 56

1. The Agency shall comprise:
 - a) the Committee for Medicinal Products for Human Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for human use;
 - aa) the Pharmacovigilance Risk Assessment Committee, which shall be responsible for providing recommendations to the Committee for Medicinal Products for Human Use and the coordination group on any question relating to pharmacovigilance activities in respect of medicinal products for human use and on risk management systems and it shall be responsible for monitoring the effectiveness of those risk management systems;
 - b) the Committee for Medicinal Products for Veterinary Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for veterinary use;
 - c) the Committee on Orphan Medicinal Products;
 - d) the Committee on Herbal Medicinal Products;
 - da) the Committee for Advanced Therapies;
 - e) the Paediatric Committee;
 - f) a Secretariat, which shall provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them;
 - g) an Executive Director, who shall exercise the responsibilities set out in Article 64;
 - h) A Management Board, which shall exercise the responsibilities set out in Articles 65, 66 and 67.

2. The committees referred to in paragraph 1(a) to (da) may each establish standing and temporary working parties. The committees referred to in paragraph 1(a) and (b) may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the committee concerned may delegate certain tasks associated with drawing up the scientific opinions referred to in Articles 5 and 30.

When establishing working parties and scientific advisory groups, the committees shall in their rules of procedures referred to in Article 61(8) provide for:

 - a) the appointment of members of these working parties and scientific advisory groups on the basis of the lists of experts referred to in the second subparagraph of Article 62(2); and
 - b) Consultation of these working parties and scientific advisory groups.

3. The Executive Director, in close consultation with the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use, shall set up the administrative structures and procedures

allowing the development of advice for undertakings, as referred to in Article 57(1) (n), particularly regarding the development of new therapies.

Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

4. The Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use may, if they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 65

1. The Management Board shall consist of one representative of each Member State, two representatives of the Commission and two representatives of the European Parliament.

In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint the Management Board.

The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.

2. The members of the Management Board shall be appointed on the basis of their relevant expertise in management and, if appropriate, experience in the field of medicinal products for human or veterinary use.
3. Each Member State and the Commission shall appoint their members of the Management Board as well as an alternate who will replace the member in his absence and vote on his behalf.
4. The term of office of the representatives shall be three years. The term of office may be renewed.
5. The Management Board shall elect its Chairman from among its members.
The term of office of the Chairman shall be three years and shall expire when he ceases to be a member of the Management Board. The term of office may be renewed once.
6. Decisions of the Management Board shall be adopted by a majority of two-thirds of its members.
7. The Management Board shall adopt its rules of procedure.
8. The Management Board may invite the chairmen of the scientific committees to attend its meetings, but they shall not have the right to vote.
9. The Management Board shall approve the annual work programme of the Agency programme and forward it to the European Parliament, the Council, the Commission and the Member States.
10. The Management Board shall adopt the annual report on the Agency's activities and forward it by 15 June at the latest to the European Parliament, the Council, the Commission, the European Economic and Social Committee, the Court of Auditors and the Member States.

Article 66

The Management Board shall:

- a) adopt an opinion on the rules of procedures of the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use (Article 61);
- b) adopt procedures for the performance of scientific services (Article 62);
- c) appoint the Executive Director (Article 64);
- d) adopt the annual work programme and forward it to the European Parliament, the Council, the Commission and the Member States (Article 65);
- e) approve the annual report on the Agency's activities and forward it by 15 June at the latest to the European Parliament, the Council, the Commission, the European Economic and Social Committee, the Court of Auditors and the Member States (Article 65);
- f) adopt the budget of the Agency (Article 67);
- g) adopt the internal financial provisions (Article 67);
- h) adopt provisions implementing the Staff Regulations (Article 75);
- i) develop contacts with stakeholders and stipulate the conditions applicable (Article 78);
- j) adopt provisions for providing assistance to pharmaceutical companies (Article 79);
- k) adopt rules to ensure the availability to the public of information concerning the authorisation or supervision of medicinal products (Article 80).

Chapter 2

Financial Provisions

Article 67

1. Estimates of all the revenue and expenditure of the Agency shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Agency.
2. The revenue and expenditure shown in the budget shall be in balance.
3. The Agency's revenue shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency. The European Parliament and the Council (hereinafter referred to as 'the budgetary authority') shall re-examine, when necessary, the level of the Community contribution on the basis of an evaluation of needs and taking account of the level of fees.
4. Activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive adequate public funding commensurate with the tasks conferred.
5. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure costs, and operating expenses as well as expenses resulting from contracts entered into with third parties.
6. Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.
7. The estimate shall be forwarded by the Commission to the budgetary authority together with the preliminary draft general budget of the European Union.

8. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.
9. The budgetary authority shall authorise the appropriations for the subsidy to the Agency. The budgetary authority shall adopt the establishment plan for the Agency.
10. The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.
11. Any modification of the establishment plan and of the budget shall be the subject of an amending budget, which is forwarded for the purposes of information to the budgetary authority.
12. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof. Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.