

15 February 2018
EMA/88659/2018
EU Telematics Management Board

EU Telematics Management Board (EU TMB)

Terms of reference

The European Union Telematics Management Board (the Board) is the strategic governance body that operates on behalf of the European Medicines Regulatory Network. In this context, the Network comprises the European Medicines Agency (EMA), the network of EU national competent authorities as represented by the Heads of Medicines Agencies (HMA), and the European Commission, as represented by DG SANTE.

The Board provides the vision for, and strategic oversight of, the EU Telematics Programme and the Roadmap for its implementation.

The Board reports to the Management Board of the EMA and the Heads of Medicines Agencies (HMA), and acts as the formal point of contact with the European Commission on matters relating to the EU telematics Programme.

1. Composition

1.1 The Board consists of:

- three members of the EMA Management Board, one of which is a representative of the European Commission and one of the civil society (i.e. patients' organisation or doctors' organisation or veterinarians' organisation);
- three representatives from the Heads of Medicines Agencies group;
- three representatives from the Agency;
- the six members of the IT Directors Executive Group for Telematics;
- the EMA IT Liaison Officer.

1.2 The Board has a Chair, Vice-Chair and could have a Co-Chair all elected from amongst its members. The Chair and Co-Chair of EU TMB should be representatives of EMA MB. The Vice-Chair should be a representative of EMA.

The Chair, Co-Chair and Vice-Chair shall be elected for a period of three years, renewable once. The term of office expires when they cease to be members of this Board. Nominations for Chair, Co-Chair and Vice-Chair shall be submitted in writing to the Telematics Secretariat no later than the start of the EU TMB meeting at which the election is to take place. The election shall be by simple majority vote.



The Vice-Chair shall deputise for the Chair and Co-Chair when neither of these are able to chair either all or part of a meeting. In the absence of the Vice-Chair, the longest serving member shall deputise for the Co-Chairs.

In the event of resignation of the Chair, the Co-Chair and the Vice-Chair shall take the chair until a new election takes place.

- 1.3 The Board members are appointed for a three year period (renewable), or until such time as they are no longer representatives of the Management Board, the European Commission, the Agency or the Heads of Medicines Agencies group, or are replaced as the nominated representative by any of the aforementioned groups/bodies. Should a member be unable to attend meetings for a continuous period of 12 months, their membership shall terminate.
- 1.4 No substitution for members unable to attend the meeting will be accepted. In exceptional cases and with the permission of the Chair an observer may attend the meeting on behalf of a member who is not able to be present.
- 1.5 The Board will be supported by the Telematics Programme Management Office and the Telematics Secretariat.

2. The role of the Board includes:

- 2.1 Playing a leading role for all aspects of Telematics relevant to the European Medicines regulatory network, including:
 - developing, fostering and actively promoting the vision for telematics within the EU medicines regulatory network;
 - raising awareness and engagement on telematics at the level of the Management Board, the European Commission, NCAs and Heads of Medicines Agencies;
 - promoting interoperability and cooperation between the Agency, European Commission and the NCA ICT systems;
 - promoting the use of ICT systems throughout the European Medicines regulatory network, including, but not limited to, computerised systems for information exchange and remote meeting facilities such as teleconferencing and videoconferencing.
- 2.2 Identifying the sources of funding to achieve the strategic goals identified and working with all relevant stakeholders and partners to secure the necessary funds. As part of this activity, the Board will review the multi annual and annual work plan and budget for the EU Telematics Programme. The Co-Chairs, Vice-chair and Commission Representative will recommend the adopted work plans and budgets to the strategic management group(s) within their respective organisations (e.g. EMA Management Board; HMA; European Commission).
- 2.3 Reviewing and approving the prioritised list of projects proposed for inclusion within the EU Telematics Programme.
- 2.4 Providing strategic direction at project concept stage and ensuring that the appropriate programme and project management framework is in place and operating effectively to support the implementation of the Roadmap for delivery of the EU Telematics Programme.
- 2.5 Providing the forum for reaching agreement between the Agency, the National Competent Authorities, as represented by HMA, and the European Commission, as represented by DG SANTE, on all strategic matters relating to the EU Telematics Programme. Such matters shall

usually be considered following referral from one of the operational bodies that form part of the EU Telematics Programme structure.

- 2.6 Delegating tactical management of EU Telematics to the IT Directors Executive Group for Telematics.
- 2.7 Taking note of all relevant IT programmes and projects taking place within the network and formally agreeing the list of those which fall within EU Telematics governance and those which remain the responsibility of the originating institution. As part of this activity the Board will foster the development and subsequent integration of systems that have the potential for adoption by the wider network.
- 2.8 Providing feedback to the Agency, European Commission, NCAs and Heads of Medicines Agencies.
- 2.9 Commission, review and approve on a regular basis the Strategic Vision, Multiannual and Annual work plans, and the implementation Roadmap for the Programme.
- 2.10 Foster the adoption of international standards, as appropriate to the needs of the network, and act as the forum for reaching strategic decisions in relation to the position of the EU in the field of telematics.

3. Meetings

- 3.1 The Board meets a minimum of twice per year face-to-face. Any additional meetings will normally be held as teleconferences.
- 3.2 Expert advice in the IT domain is provided to the Board by the members of the IT Directors Executive Committee for Telematics. Where necessary, the Board may request that in duly justified exceptional cases, experts on other specific topics (e.g. legal, scientific or regulatory) attend all or part of a meeting. In such instances, the costs of attendance of the expert(s) may be reimbursed if necessary.
- 3.3 Members of the Board and where applicable, observers, will be reimbursed for travel and per-diem by the EMA in accordance with the Agency's reimbursement rules.
- 3.4 Meetings are convened by the Board Chair or at the request of at least 5 members.
- 3.5 All documentation relating to the meeting will normally be circulated a minimum of 5 working days in advance of the meeting date.
- 3.6 Minutes of the meeting will be taken by the Secretariat and will normally be circulated to all members of the Board for comment within 2 weeks of the meeting date. Minutes shall be approved by written procedure.
- 3.7 The quorum for Board meetings is at least 66% of members.
- 3.8 Agreement shall be reached by consensus wherever possible. Where this is not possible, decisions shall be taken by simple majority vote. Proxy votes are accepted.