EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2012
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Terms of Reference of the Management Board Telematics Committee

Management Board meeting 13 December 2012

Background note

The Terms of Reference of the Management Board Telematics Committee (MBTC) were last revised and adopted at the meeting of the Management Board in December 2011. A change to the composition of the Committee is now proposed.

Matters for consideration

Following the EMA Management Board (MB) meeting on 4 October 2012, the MB Chair suggested to expand the Patients' representative membership – referred to in the MBTC terms of reference – to all civil society representatives. This would give the opportunity to select from a wider range of candidates (i.e. rather than selecting from currently two possible candidates, the selection would also include the *Doctors' organisations* representative and the *Veterinarians' organisations* representative). Considering that the initial proposal for the Patients' representative on the MBTC came from the European Commission, the MB Secretariat have sought the opinion of DG SANCO on this matter and they were in agreement.

On this basis, the proposal for revised terms of reference was presented to the MBTC at their meeting on 12 November 2012. Having also accepted the proposal, the revised MBTC Terms of Reference are submitted to the EMA MB in the attached document with changes clearly highlighted.

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Management Board Telematics Committee

Terms of reference

The European Medicines Agency's (the Agency's) Management Board Telematics Committee (The Committee, MBTC) is a committee of the Agency's Management Board (Management Board, Board) and replaces and builds on the work of the former "Telematics Steering Committee" as the decision-level body governing the EU Telematics Programme. The Committee reports to the Management Board.

1. Composition

   1.1 The Committee consists of:

   - four members of the Management Board, one of which is a representative 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, one of which is a representative of the business area
   - one representative from the European Commission

   1.2 The Committee is chaired by a member of the Management Board, who is appointed by the Board.

   1.3 The Committee members are appointed for a three year period (renewable), or until such time as they are no longer represented on 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.

2. The role of the Committee includes:

   2.1 Setting the strategic goals for EU Telematics in line with the legal bases and European Commission policy.

   2.2 Reviewing the multi annual and annual budgets for the Agency delivered as part of the EU Telematics projects and recommending the budgets to the Management Board (in conjunction with the Management Board budget topic coordinators).

   2.3 Reviewing and approving prioritisation of EU Telematics projects.

   2.4 Ensuring that the appropriate framework is in place to support the implementation of the Telematics programme and the delivery of the strategic goals identified in the EU Telematics Programme

   2.5 Providing a liaison role between the Agency and the National Competent Authorities (NCAs) and Heads of Medicines Agencies in matters relating to the European Telematics Programme

   2.6 Recommending significant changes to the plan including new telematics initiatives or working groups for approval by the Board

2.7 Approving Chairperson(s) for each of the working groups

2.8 Monitoring the following through various review mechanisms including regular reports from the Telematics Management Committee and from the Agency's ICT unit:

- high-level progress of programme and project implementation,
- budget-related matters, within the scope of the EU Telematics Master Plan; and
- the risks affecting the programme.

2.9 Monitoring the results of programme and project audits through summary audit reports, and through access to the full audit reports and presentations by the various TIG Chairmen (as requested).

2.10 Providing feedback via the Management Board to the Agency, European Commission, NCAs and Heads of Medicines Agencies on issues relating to EU Telematics.

2.11 Playing a leading role for all aspects of telematics relevant to the European Medicines regulatory network, including:

- raising awareness and engagement on telematics at the level of the Management Board, NCAs and Heads of Medicines Agencies;
- promoting interoperability between the Agency and the NCA systems;
- promoting the use of teleconferencing and videoconferencing facilities throughout the European Medicines regulatory network;
- identifying the potential impact of EU telematics programme on the Agency and NCAs.

3. Meetings

3.1 The Committee meets a minimum of twice per year face-to-face. Any additional meetings will normally be held as teleconferences.

3.2 Each member of the Committee may be accompanied to meetings by a nominated IT expert for technical support.

3.3 Each member of the Committee and his/her IT expert will be reimbursed for travel and per-diem by the Agency in accordance with the Agency's reimbursement rules.

3.4 Meetings are convened by the Committee Chairperson or at the request of at least 5 members.

3.5 All documentation relating to the meeting will normally be circulated a minimum of 3-5 working days in advance of the meeting date

3.6 Any ad-hoc documentation provided at the meeting, for example presentations, will normally be circulated to all members of the Committee within 3 working days of the meeting date

3.7 Minutes of the meeting will be taken by the Agency's secretariat and will normally be circulated to all members of the Committee for comment within 2 weeks of the meeting date. Minutes may be approved by written procedure.

3.8 The quorum for Committee meetings is 50% plus one (i.e. six if the full membership is in place).