EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2012
EMA/MB/740454/2012 Endorsed

European Directorate for the Quality of Medicines and Healthcare (EDQM) participation at the Committee for Advanced Therapies (CAT)

Management Board meeting 13 December 2012

Background note

In April this year, Dr Keitel, Director of EDQM orally raised the issue of possible observership for the European Directorate for the Quality of Medicines and Healthcare (EDQM) at meetings of the Committee on Advanced Therapies. This was followed up with an official letter to the chair of the CAT, Dr Christian Schneider on 11th of May 2012. The Committee for Advanced Therapies (CAT) welcomes this observership. The relevant correspondence is attached to this note.

The Management Board is reminded that, as part of its activities in the context of the European Pharmacopoeial standards, coordination of the Official Medicines Control Laboratories (OMCL) network and the biological standardisation program, the EDQM is closely involved in international harmonisation activities concerning cell and gene therapies. There is therefore a potential for synergies and avoidance of duplication, particularly in the context of guideline and standard development.

Article 77 of Regulation (EC) No 726/2004, provides the possibility for the European Commission to invite representatives of international organisations to participate as observers in the work of the Agency, in agreement with the Management Board and the relevant committee.

EDQM already participates as an observer in the Herbal Medicinal Products Committee following a consultation process with the European Commission and the Management Board.

Matters for consideration

The Management Board is invited to agree to the participation of the European Directorate for the Quality of Medicines as an observer to the work of the Committee for Advanced Therapies.

The European Commission has indicated that it agrees to this participation provided that the rules applying to observers of the Committees of the European Medicines Agency are respected, in particular, as regards the information related to specific medicinal products applications and provided that the Board is in agreement.

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