



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Incentives for development of ATMPs

CAT Stakeholders Workshop
EMA - London
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An agency of the European Union





Incentives

- Incentives specific for ATMPs
 - Regulation EC No 1394/2007

- Other incentives
 - SMEs
 - Orphan medicines



Incentives: regulatory procedures

- ▶ ATMP classification: To define Borderline e.g. with medical device, transplant, cosmetics.
- ▶ ATMP Certification: Assessment of early quality and non-clinical data. Incentive only for SMEs.
- ▶ MAA: evaluation by CAT: committee with specific expertise
- ▶ Scientific advice: can be given on ANY scientific question (Quality, non-clinical and clinical). At any time point of the development. CAT contributes to all ATMP SA/PA



Financial incentives

- ▶ **Scientific Advice:** 90% fee reduction for SMEs, 65% for others
- ▶ **ATMP classification:** free, 60 days
- ▶ **ATMP Certification:** from 3810 to 5720 Euros
- ▶ 50% fee reduction for **MAA** (until 2011/2012) for hospitals and SMEs for products of particular public health interest in the Community
- ▶ **Orphan drugs:** designation free, SA free, 50%-100% reduction on MAA
- ▶ **Products legally on the market:** MAA free until 2011-2012



Incentives: dedicated expertise

- ▶ Dedicated Committee
- ▶ Dedicated EMA Secretariat
 - Use the scientific administrators at EMA
 - Teleconferences
 - Procedural advices
 - Links to other EMA sections (paediatrics, SME office, Regulatory)
- ▶ Scientific advice
 - Pre-submission meetings – recommended for ATMPs
 - Come for clarifications and follow-up advice as often as needed

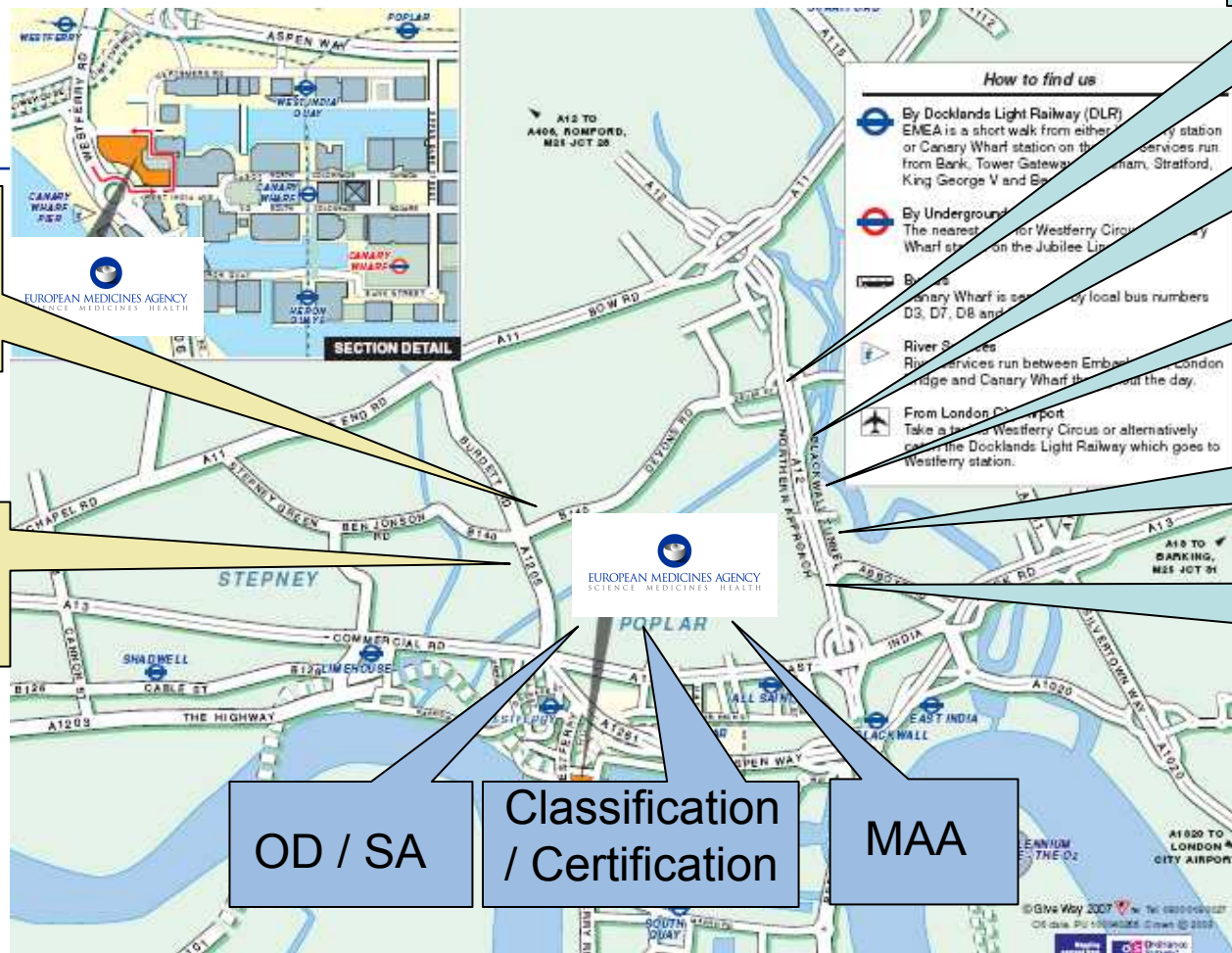


Incentives: Support to Applicants

- ▶ Innovation Task Force (ITF) Briefing Meetings [Link to ITF webpage](#)
- ▶ SME Office [Link to SME office webpages](#)
- ▶ Orphan designation [Link to ODD webpage](#)



Challenges with ATMPs: how can EMA/CAT help?



Interested Parties' mtg

Workshops, trainings

OD / SA

Classification / Certification

MAA

ITF Briefing meetings

Discussion with CAT Secretariat

SME office

SA prep. mtg

MA presubm. mtg



Thank you for your attention!

[More info? Link to ATMP webpage](#)
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