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EU Regulatory Update

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Disclaimer

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- **EMA**: “The views expressed in this presentation are my personal views and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.”

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EU Regulatory activities

2024

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- Ongoing work on Pharma Revision
  https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en
- New Regulation on substances of human origin
  ← starting materials for cell based ATMPs
  https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/new-eu-rules-substances-human-origin_en
- Ongoing activities on the interfaces of medicines with medical devices and in vitro diagnostics
  - COMBINE project (clinical trials)
    https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies_en
  - Focus group on joint scientific advice
- Updates on the implementation of the Medical device and In vitro diagnostics Regulations
  https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

CAT Workplan 2024

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15 Years of EMA Committee for Advanced Therapies

Scientific symposium on the work of the CAT and the future of ATMPs

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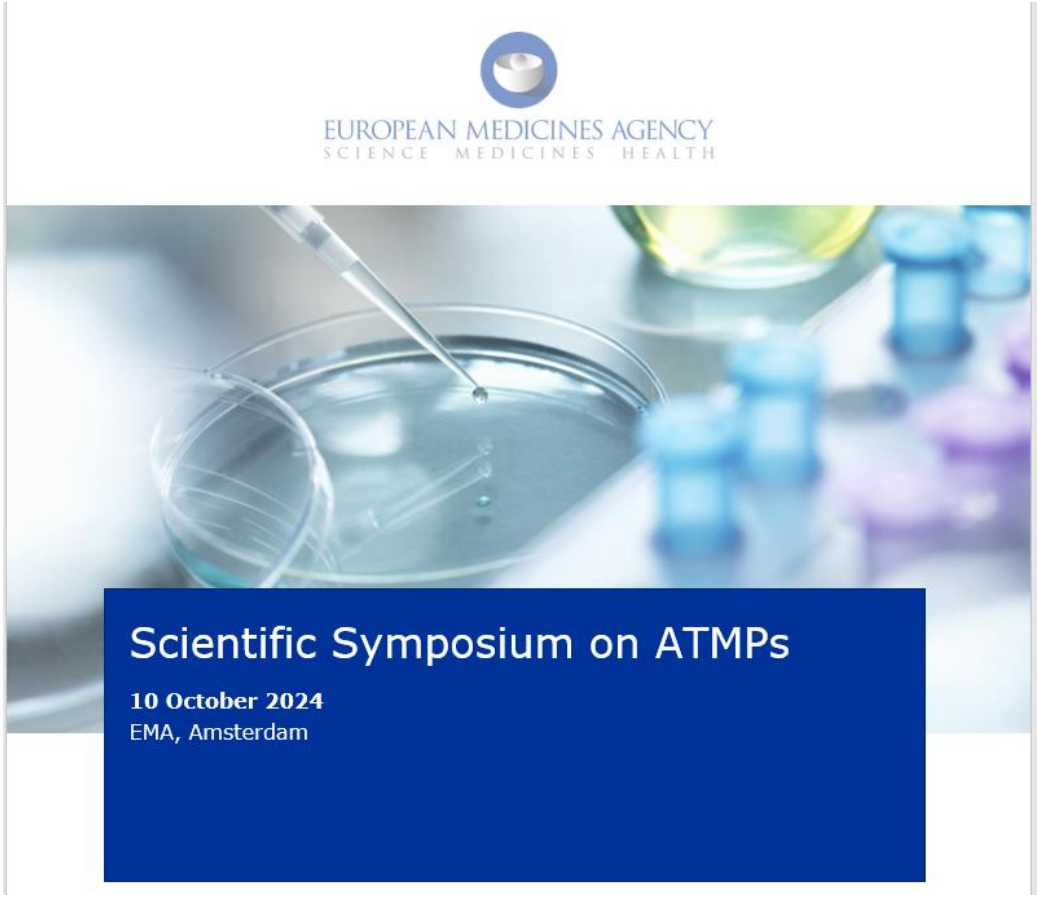

- Contributions from experts in the field
- CAT stakeholders and previous CAT chairs
- Communicate on the work and achievements of CAT
- *Contribution – Evolution - Revolution*
- Hybrid meeting

Thank you to the members of the drafting groups!!!!

Questions?