



HAL
open science

Mapping regulators' early interactions procedures to support innovation

Auxane Delage, Luc-Sylvain Gilbert, Hsin-Yu Kuo, Anna Couturier, Aurélie Mahalatchimy

► **To cite this version:**

Auxane Delage, Luc-Sylvain Gilbert, Hsin-Yu Kuo, Anna Couturier, Aurélie Mahalatchimy. Mapping regulators' early interactions procedures to support innovation. European Society for Gene & Cell Therapy Congress 2023, Oct 2023, Bruxelles (BEL), Belgium. halshs-04290584

HAL Id: halshs-04290584

<https://shs.hal.science/halshs-04290584>

Submitted on 16 Nov 2023

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Mapping regulators' early interactions procedures to support innovation

Auxane Delage¹, Luc-Sylvain Gilbert², Dr. Hsin-Yu Kuo³, Dr. Anna Couturier⁴, Dr. Aurélie Mahalatchimy⁵

¹EuroGCT Information Officer on Ethical, Legal & Societal issues (ELSI), Research Engineer and PhD student in law, Law Faculty, UMR 7318 International, Comparative and European laws, DICE CERIC, CNRS, Aix Marseille Univ., Toulon Univ., Aix-en-Provence, France; ²EuroGCT Information Officer on ELSI, Research Engineer in law, UMR 7318 DICE CERIC, CNRS, Aix Marseille Univ., Toulon Univ., Aix-en-Provence, France; ³EuroGCT Information Officer on ATMP Product Development Pathway, Centre for Regenerative Medicine, Institute for Regeneration and Repair, University of Edinburgh, UK; ⁴EuroGCT Project Manager, Centre for Regenerative Medicine, Institute for Regeneration and Repair, University of Edinburgh, UK; ⁵EuroGCT Deputy coordinator and WP4 leader, Permanent Researcher in law at the French National Centre for Scientific Research (CNRS, CR), Law Faculty, UMR 7318 DICE CERIC, CNRS, Aix Marseille Univ., Toulon Univ., Aix-en-Provence, France. **Acknowledgements:** This work has been supported by European Union's Horizon 2020 EuroGCT project (GA: No 965241) and by ANR-funded I-BioLex project (ANR-20-CE26-0007-01).

Introduction & Aim

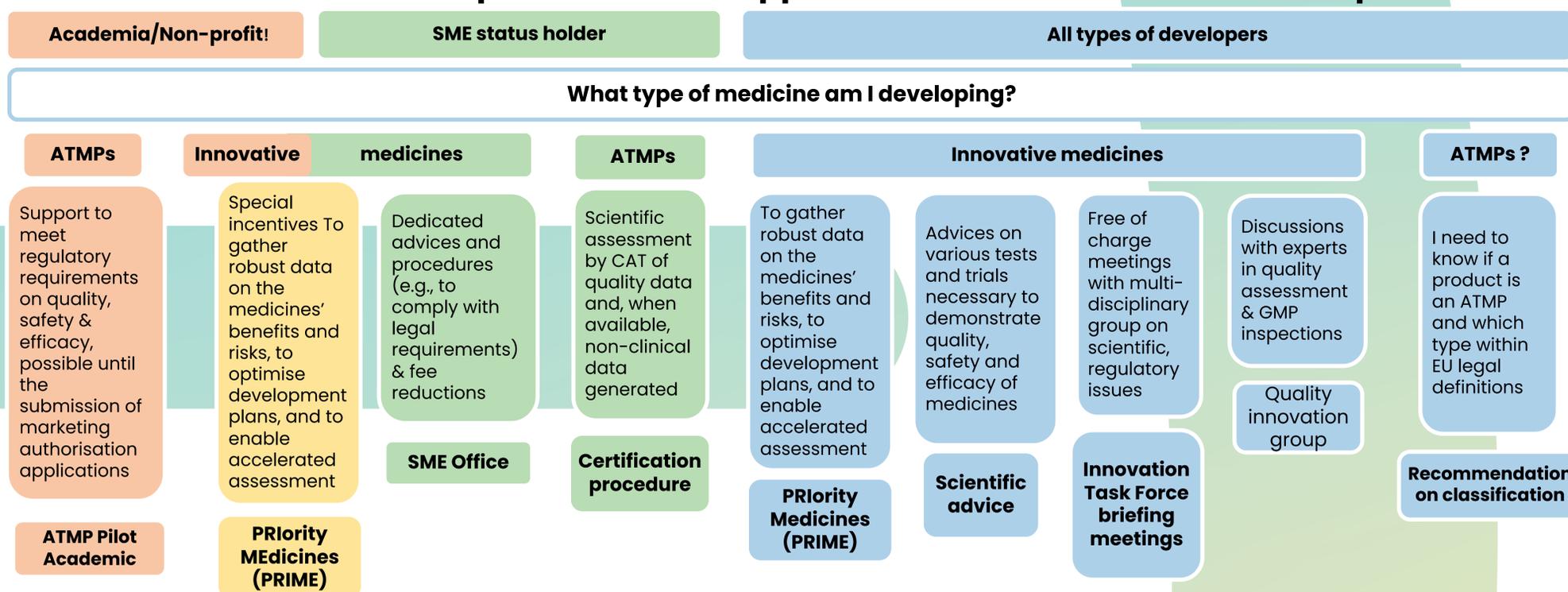
Early interactions procedures with regulators are implemented to support innovative medicines development, and the specific challenges they face.

The support comes in the form of services and regulatory procedures allowing medicines' developers to interact with regulators through existing mechanisms during the development of a medicinal product.

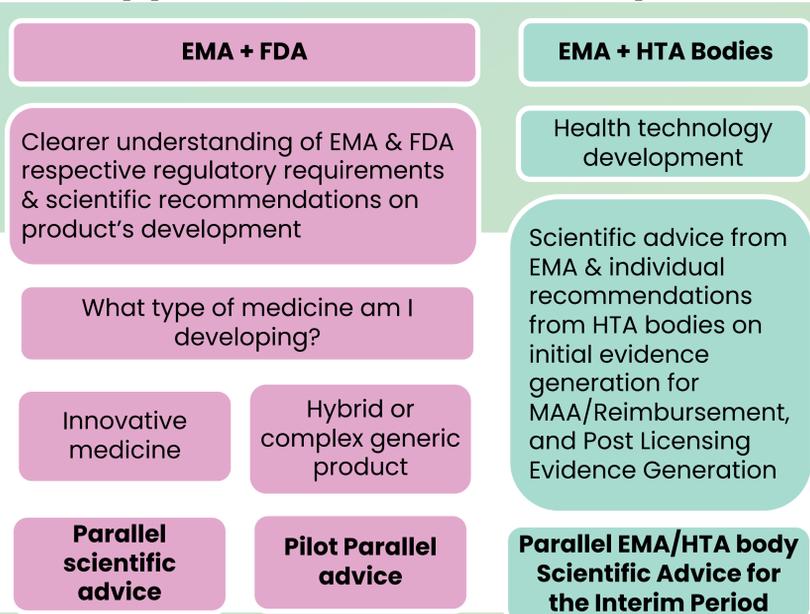
The procedures are generally dependent on the type of product developed, and on the status of the stakeholder trying to contact the regulator early. This entails a case-by-case approach to support innovation. The regulators have designed relevant tools to support different types of actors with specific challenges (SMEs, academia, industry). In addition to dedicated services and procedures, guidance developed by regulators as well as regulators' participation in various meetings also aim to support medicines' development, even though these aspects will not be considered here.

Despite limited human resources (EU and national level), Regulators have established new ways to facilitate dialogue between the institutions and the stakeholders where gaps and needs have been identified. The poster showcases the principal mechanisms in place in the European Union (EU) and in the Member States of the EEA regarding both innovative medicines and Advanced Therapy Medicinal Products (ATMPs) specifically. Communicating on the existing support at both levels bridges the knowledge gap on the existing opportunities for early interactions with regulators.

EMA's services and procedures to support innovation medicines' development



Interactions with multiple regulators to support medicines' development



FDA: Food and Drug administration, HTA: Health Technology Assessment bodies, EMA: European Medicines Agency, MAA: Marketing Authorisation Applications, GMP: Good Manufacturing Practices

Any contribution is warmly welcome!

Please join the EuroGCT ELSI Network of Expertise: provide draft content of entries, lay summaries of your research papers, to translate existing entries, to review draft entries, to provide useful updated resources.

To get involved in this collaborative work please contact the EuroGCT Information officers on ELSI:

Auxane Delage: auxane.delage@univ-amu.fr

Luc-Sylvain Gilbert: luc.gilbert@univ-amu.fr

All contributions will be credited on the EuroGCT website



Interactions with national competent authorities

Medicine developers can contact national competent authorities to interact with one or multiple regulator(s) at national level. List of national competent authorities in the EEA available on EMA's website.

Available Procedures → scientific advice, Simultaneous National Scientific Advice (ex.)

Available Services → Innovation offices (ex.)

Some EEA countries have national competent agencies but no innovation offices and do not offer SNSA.

No innovation office ≠ No interaction for exemple Iceland no innovation office but offers scientific advice.

Innovation offices and participation in Simultaneous National Scientific Advice (SNSA) in EEA countries and the UK

- Countries with innovation offices
- Countries without innovation offices
- ▨ Innovation office and leading or participating in SNSA
- ▩ Innovation office and observer role in SNSA
- ⊞ 2 Innovation offices: 1 leading or participating role and 1 observer role in SNSA

