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WHAT REGULATORY PATHWAYS FOR HEALTH TECHNOLOGIES USING BOTH MEDICAL DEVICES AND TISSUES AND CELLS IN THE EUROPEAN UNION?

AND TISSUES AND CELLS IN THE EUROPEAN UNION?

Valentin Roby¹, Auxane Delage², Luc-Sylvain Gilbert³, Adrien Bottacci⁴, Aurélie Mahalatchimy⁵

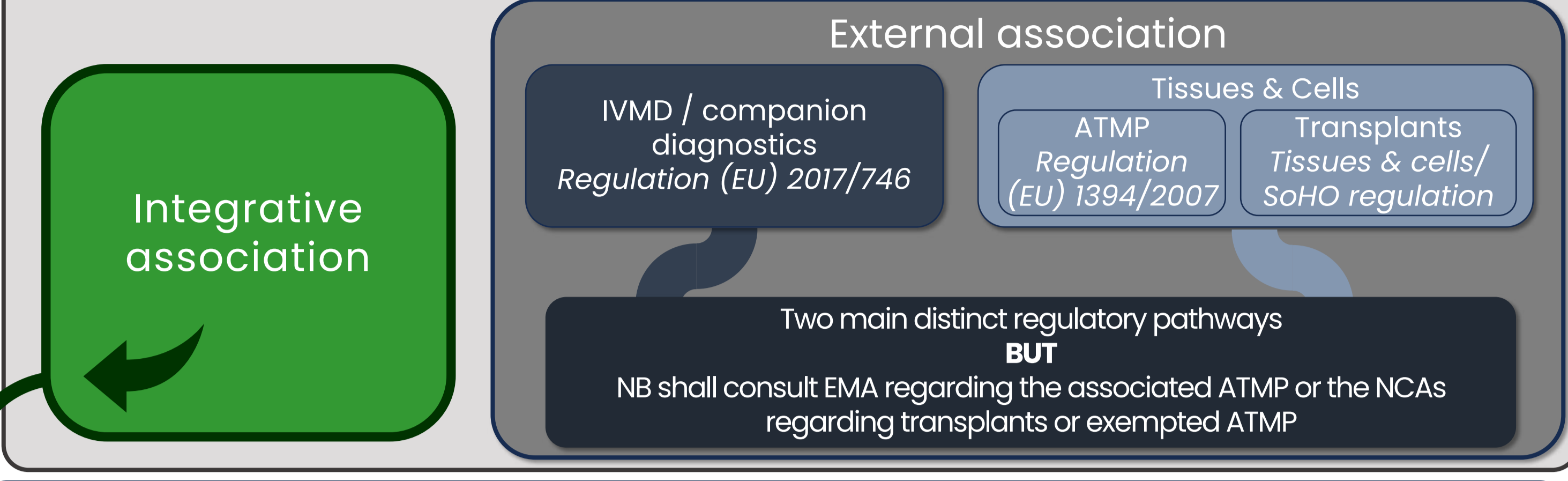
¹ Research Engineer in law, EuroGCT and I-BioLex research projects, Law Faculty, Aix Marseille Univ, CNRS, DICE, CERIC, Aix-en-Provence, France; ² EuroGCT Information Officer on Ethical, Legal & Societal issues, Research Engineer and PhD student in law, Law Faculty, Aix Marseille Univ, CNRS, DICE, CERIC, Aix-en-Provence, France; ³ EuroGCT Information Officer on Ethical, Legal & Societal issues, Research Engineer in law, Law Faculty, Aix Marseille Univ, CNRS, DICE, CERIC, Aix-en-Provence, France; ⁴ PhD student in law, CNRS, DICE, ADES CERIC, Aix-en-Provence, France; ⁵ Permanent Researcher in law at the French National Centre for Scientific Research (CNRS, chargée de recherche), Law Faculty, Aix Marseille Univ, CNRS, DICE, CERIC, Aix-en-Provence, France; EuroGCT Deputy coordinator and WP4 leader.

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Introduction

Medical applications of tissues & cells, whether from human or animal origin, can be various. The legal classification of health technologies based on the association between Medical Devices (MD) or In Vitro Medical Devices (IVMD) and tissues & cells is poorly explored and known. Yet, from their collection to the patient administration, they must go through the appropriate regulatory pathways according to their legal classification. Knowing the applicable regulatory pathways is crucial for complying with legal and regulatory requirements and adapting development strategies. This poster clarifies and discusses the regulatory pathways applicable to the associations between MD and tissues & cells, be they of human or animal origin, from the collection of the biological starting materials to the commercialisation of the final health technologies.

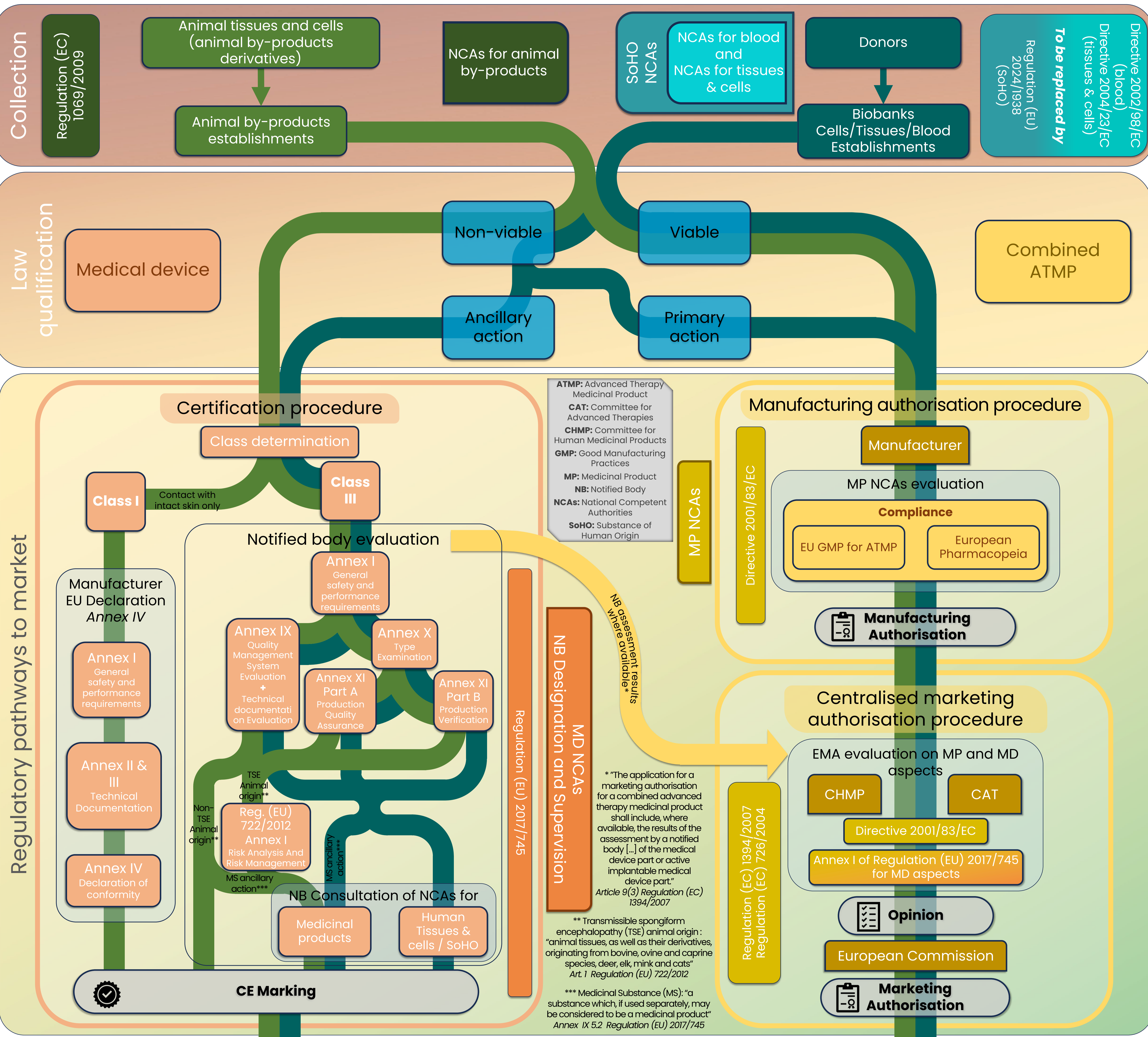
Association of tissues & cells and medical devices



Tissues and cells of Animal origin

Combined Products

Tissues and cells of Human origin



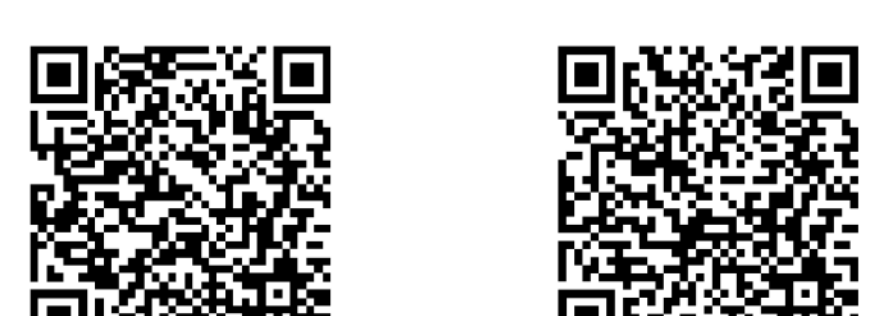
Commercialisation and post-market surveillance & vigilance

Conclusion

Significantly different from one another, the regulatory pathways to commercialisation of health products combining medical devices and tissues & cells also appear to be complex, involving several cross-references between distinct regulations and cross-linked interventions of their respective actors. If such complexity reflects the EU objective to guarantee health safety for patients to access (new) biomedical technologies, it is also challenging for appropriate regulatory compliance in their development. Nevertheless, three tools have been developed to address this challenge:

- **Dialog and support mechanisms** for developers to interact with regulators at each phase of product development: e.g., possibility to seek advice from NCAs, NBS and/or the EMA.
- **Strengthened Coordination** between Member States' and the European Commission: e.g., Medical Device Coordination Group and SoHO Coordination Board.
- **Guidance documents** are regularly issued and updated on technical, scientific and regulatory aspects: e.g., EMA, Q&A for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746), EMA/37991/2019 Rev. 5, 30 January 2025 and EMA, Guideline on quality documentation for medicinal products when used with a medical device, EMA/CHMP/QWP/BWP/259165/2019, 22 July 2021.

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- Selected Research Pathways resources:**
- Standard Marketing Authorisation Pathway;
 - Centralised Procedure for ATMPs
 - Conditional Marketing Authorisation of ATMPs
 - Manufacturing Authorisation of ATMPs
 - Good Manufacturing Practice for ATMPs