

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

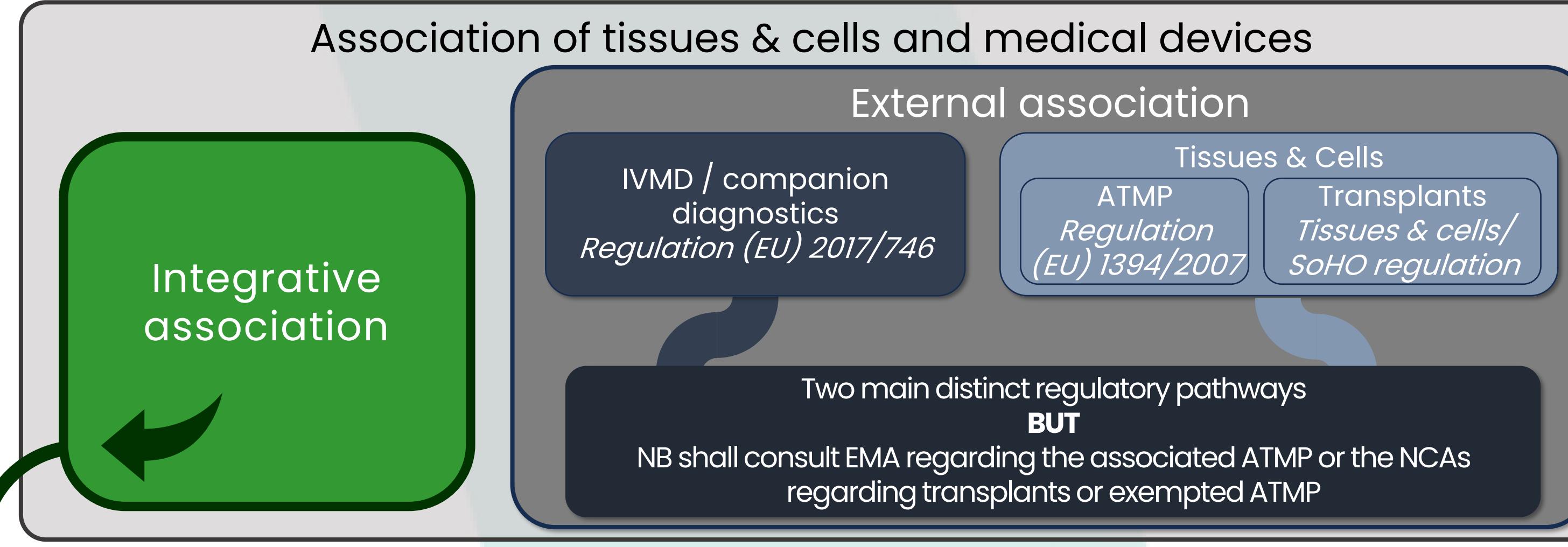
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Introduction

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.



Tissues and cells
of Animal origin

Combined Products

Tissues and cells
of Human origin

Collection

Regulation (EC)
1069/2009

Animal tissues and cells
(animal by-products derivatives)
↓
Animal by-products establishments

NCAs for animal
by-products

NCAs for blood
and
NCAs for tissues
& cells

Donors

Directive 2002/98/EC
(blood)
(tissues & cells)
Regulation (EU)
2024/1938
(SoHO)
To be replaced by

Qualification

Medical device

Non-viable
↓
Ancillary
action
↓
Viable
↓
Primary
action

Combined
ATMP

Regulatory pathways to market

Class I
Manufacturer EU Declaration Annex IV
Annex I General safety and performance requirements
Annex II & III Technical Documentation
Annex IV Declaration of conformity

Certification procedure

Class determination

Class
III

Notified body evaluation

Annex I General safety and performance requirements
Annex IX Quality Management System Evaluation + Technical documentation Evaluation
Annex XI Part A Production Quality Assurance
Annex XI Part B Production Verification

TSE
Animal origin**
Reg. (EU)
722/2012
Annex I
Risk Analysis And Risk Management
MS ancillary action***

Non-TSE
Animal origin**
Regulation (EU) 2017/745
MD NCAs
NB Consultation of NCAs for
Medicinal products
Human Tissues & cells / SoHO

ATMP: Advanced Therapy Medicinal Product
CAT: Committee for Advanced Therapies
CHMP: Committee for Human Medicinal Products
GMP: Good Manufacturing Practices
MP: Medicinal Product
NB: Notified Body
NCAs: National Competent Authorities
SoHO: Substance of Human Origin

NB Designation and Supervision

Regulation (EU) 2017/745
* "The application for a marketing authorisation for a combined advanced therapy medicinal product shall include, where available, the results of the assessment by a notified body [...] of the medical device part or active implantable medical device part."
Article 9(3) Regulation (EU) 1394/2007

** Transmissible spongiform encephalopathy (TSE) animal origin: "animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats"
Art 1 Regulation (EU) 722/2012

*** Medicinal Substance (MS): "a substance which, if used separately, may be considered to be a medicinal product"
Annex IX 5.2 Regulation (EU) 2017/745

Regulation (EU) 1394/2007
Regulation (EU) 726/2004

Manufacturing authorisation procedure

Manufacturer

MP NCAs evaluation

Compliance

EU GMP for ATMP
European Pharmacopoeia

Manufacturing
Authorisation

Centralised marketing
authorisation procedure

EMA evaluation on MP and MD
aspects

CHMP
Directive 2001/83/EC

Annex I of Regulation (EU) 2017/745
for MD aspects

Opinion

European Commission

Marketing
Authorisation

Commercialisation and post-market surveillance & vigilance

