UPDATE REGULATORY FRAMEWORK SoHO

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NEW EU REGULATION

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REGULATION (EU) 2024/1938 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 June 2024

on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

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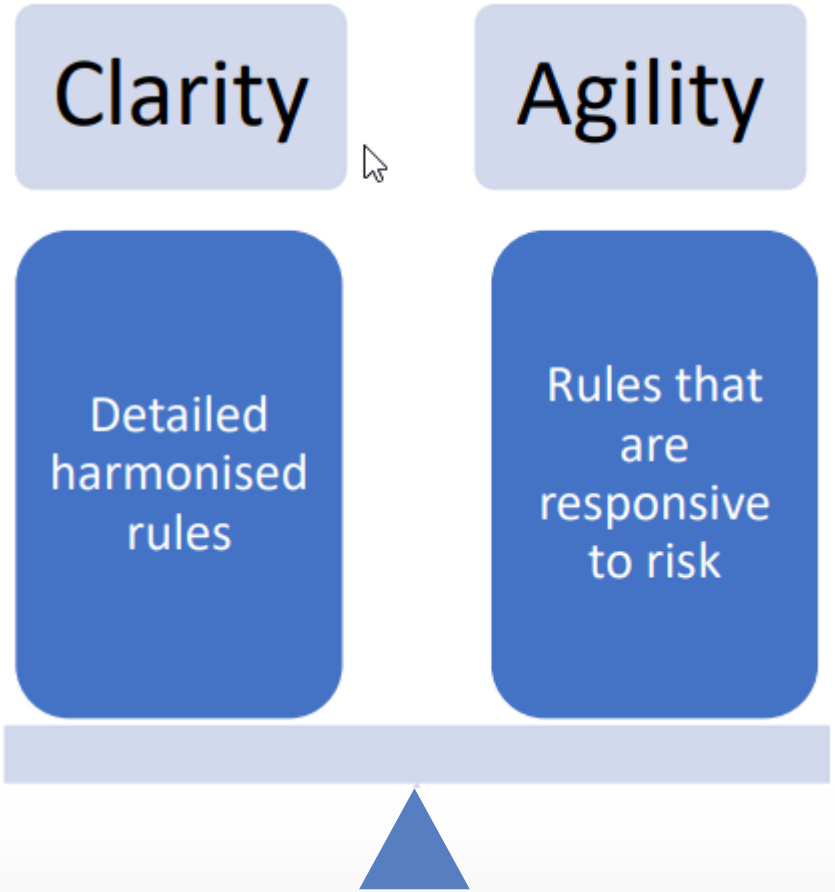
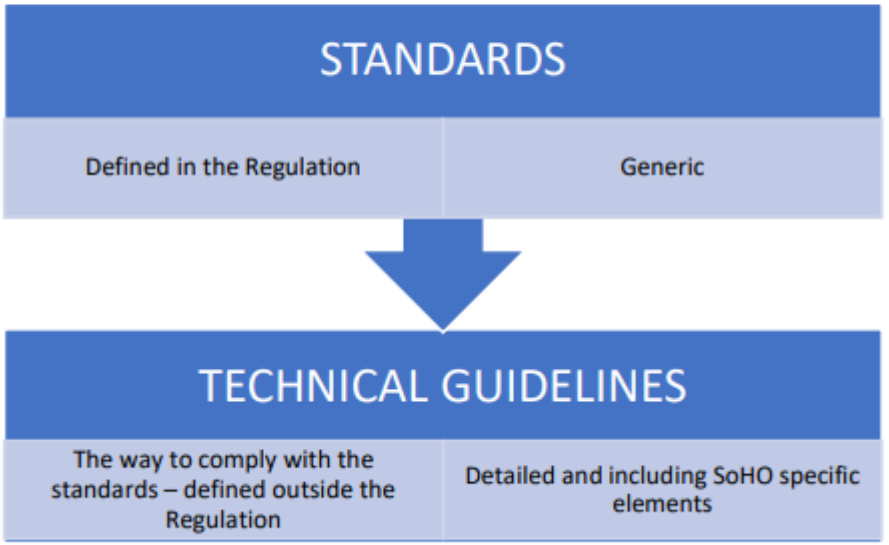
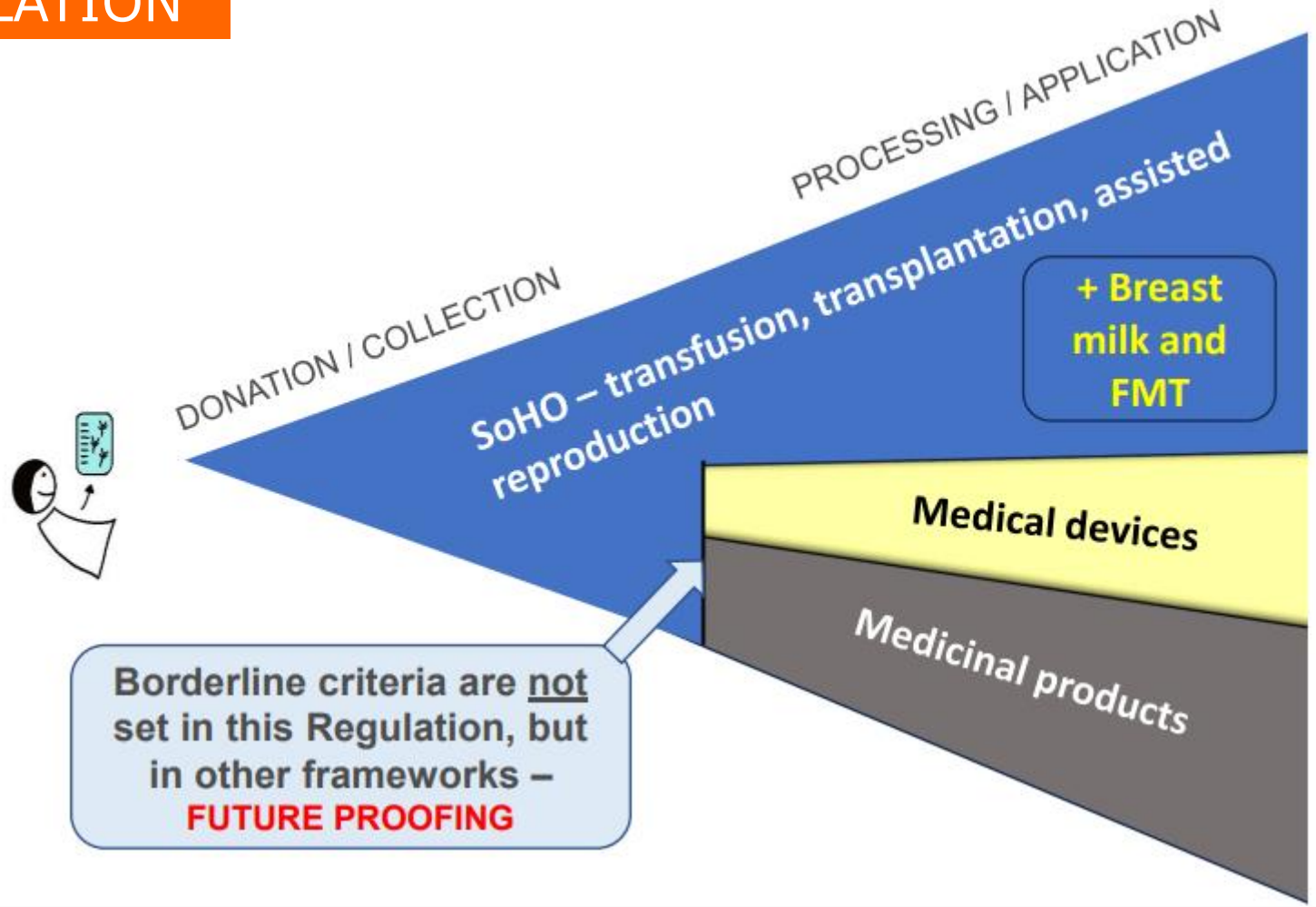
Revision of the law of 2008

NEW EU REGULATION

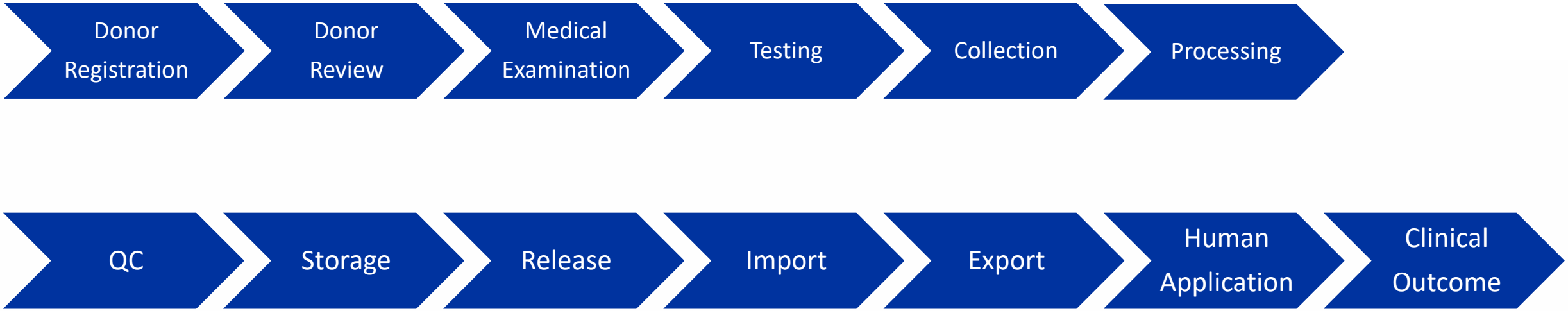




SCOPE REGULATION



ENTITY AND ESTABLISHMENT



TECHNICAL GUIDELINES

Commission Implementing Legislation → "where the Commission deems necessary"

EC

If none:

Technical Guidance on the EU SoHO Platform → Published & updated by ECDC/EDQM

edqm

Inspectors shall deem the standards to be met

OR:

"Equivalent" Guidance → Demonstrated by MS to achieve the standards in the Regulation

NCA

MS shall demonstrate compliance with standards – **may do so** by demonstrating equivalence to ECDC and EDQM

OR:

Other guidelines or methods based on international standards or scientific evidence

Entities shall demonstrate equivalence to inspectors – **may do so** by demonstrating equivalence to ECDC and EDQM

EDQM GUIDE

Position of good practice guidelines

Standards

Tissue and cell (TC) entities must establish, maintain and update a quality management system, appropriate to their activities, achieving a high level of quality of tissues and cells. (Article 37.1)

GPGs

2.1.2 Each TC entity and tissue establishment (TE) should develop, document and maintain a QMS which facilitates meeting all the relevant standards and good practice guidelines of this Guide and with the requirements of national and, for EU Member States, EU legislation.

Recommendations

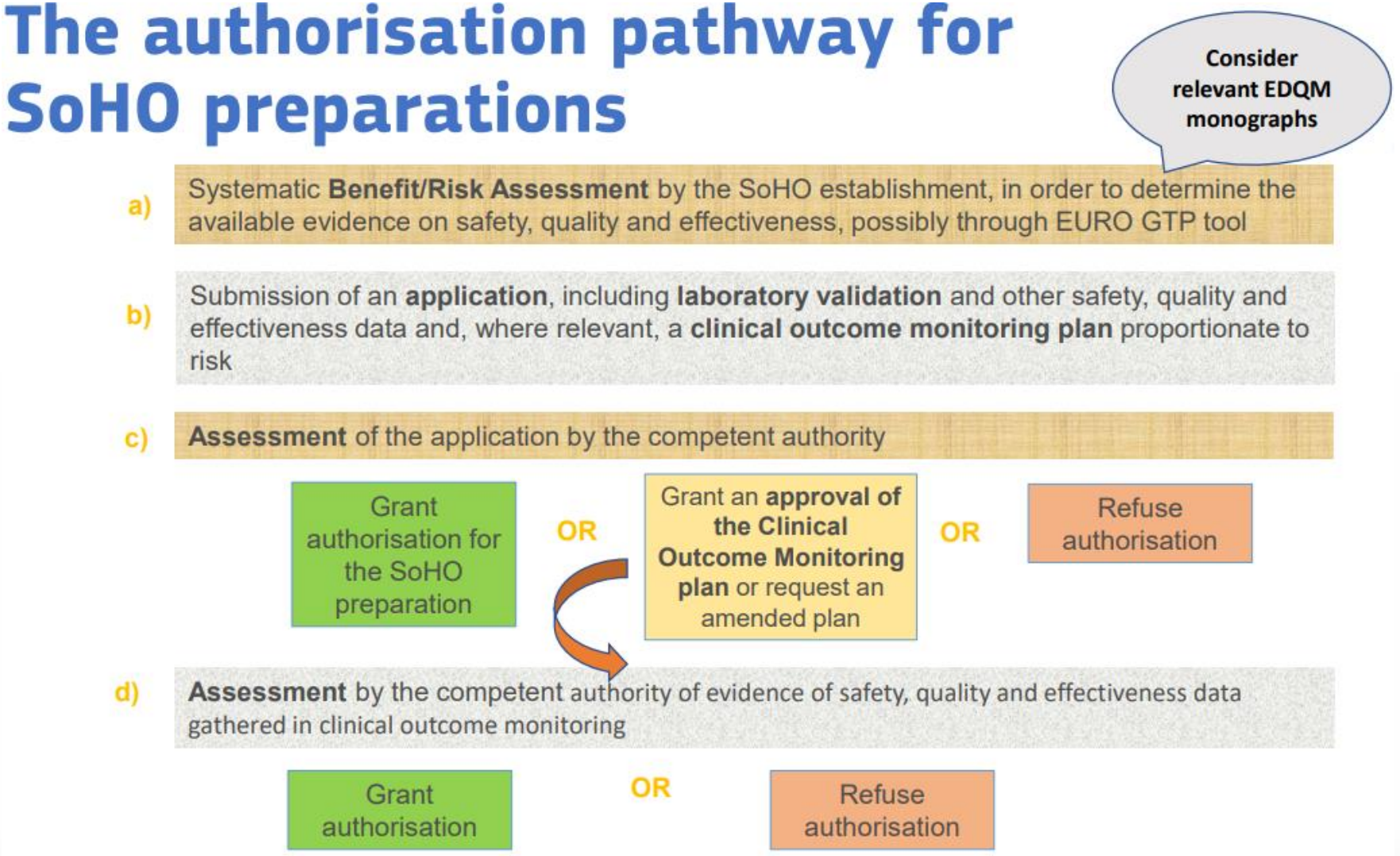
The basic concepts of quality management, good practice and quality risk management are interrelated and interconnected. They are described here in order to emphasise their relationships and their fundamental importance to all activities.

A good QMS may addresses quality management under the following headings:

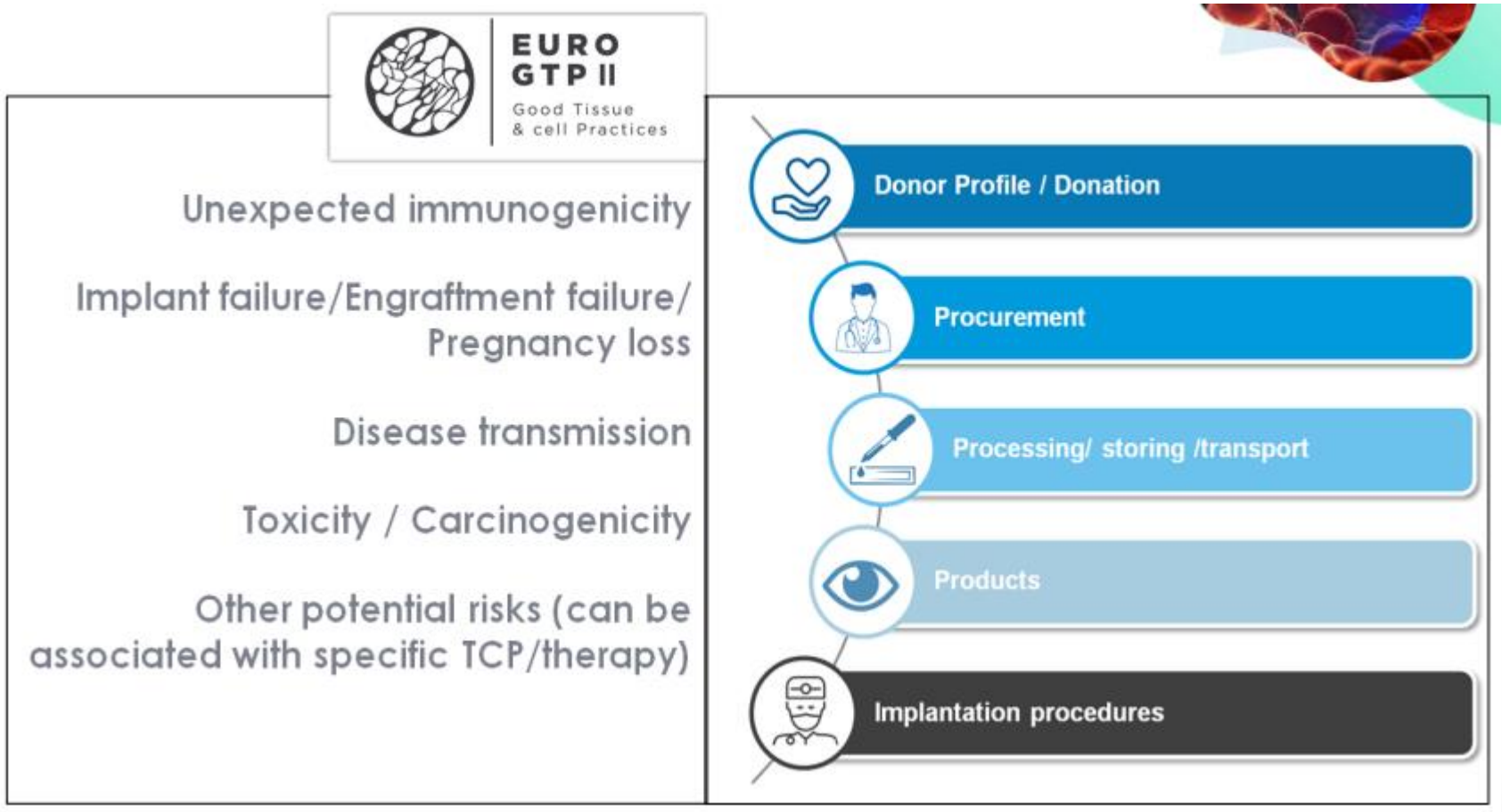
EURO GTP-2 AND MiRCA

CHANGE MANAGEMENT

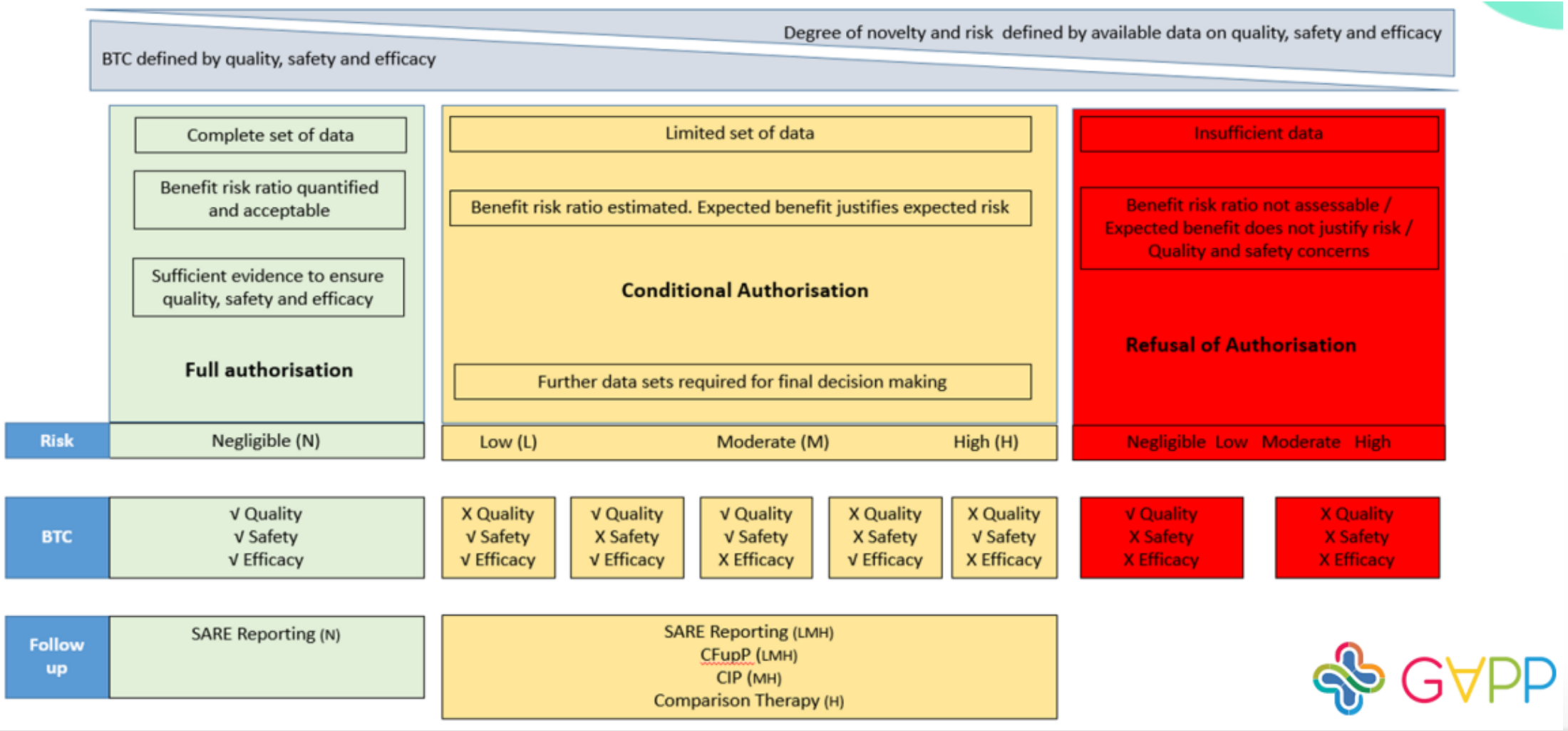
The authorisation pathway for SoHO preparations



CHANGE MANAGEMENT



RISK/BENEFIT BALANCE



SOHO PREPARATONS

Safety

- GPG
- ECDC guidelines

Quality

- GPG
- Monographs

Effectiveness

- Validation
- Follow-up

FAMHP AND SUPERIOR HEALTH COUNCIL

SAER

Superior Health Council – 3 advices

Federal agency – 8 new forms

DANK U

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