Regulations of the Tissue and Cell Therapies in Slovenia

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Cell and Tissue Therapies Public Impact

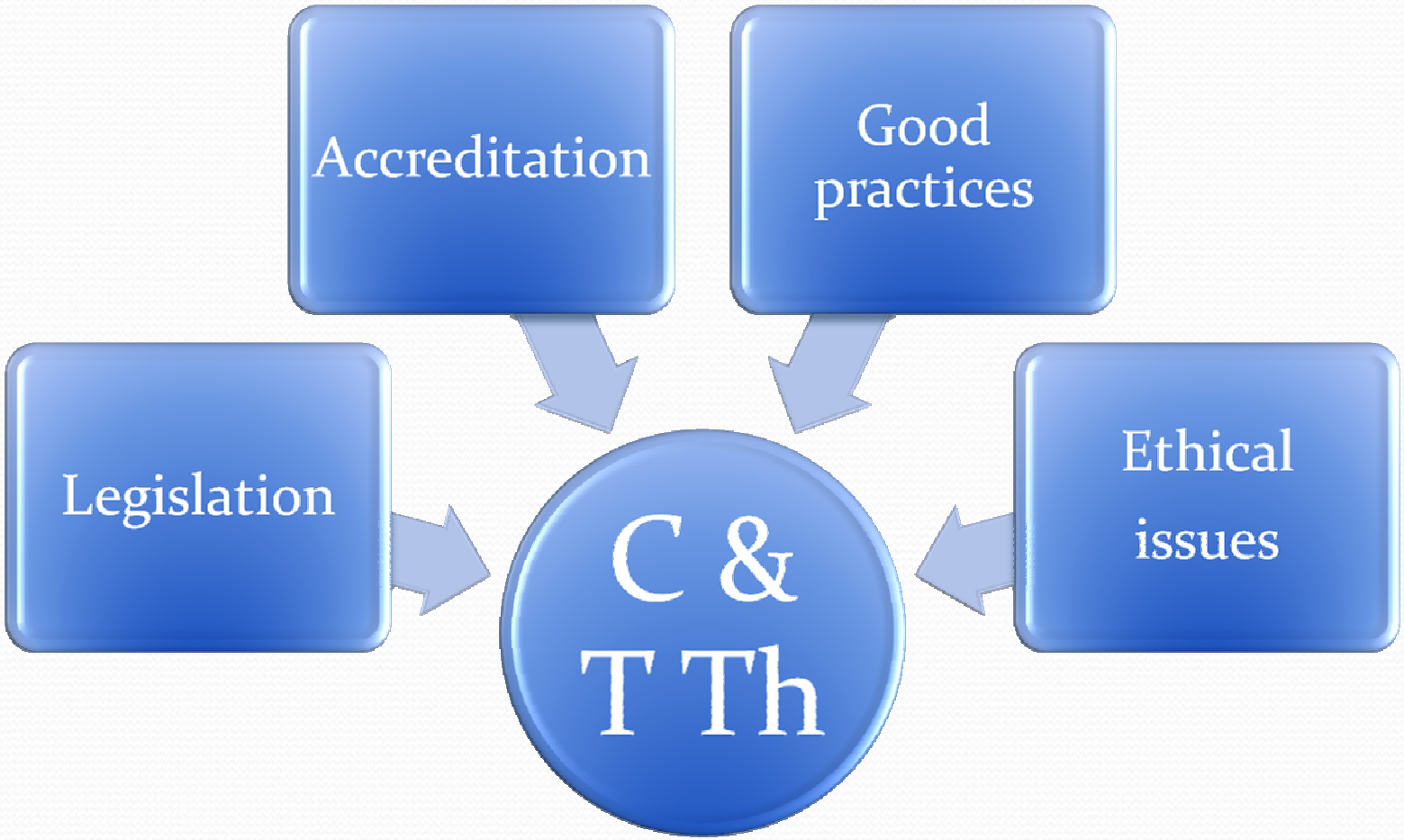
C&TTh - Potentiality

- Scientific – expansion of knowledge base
- Therapeutic -
- Economical
- Life sciences and biotechnology are widely recognised to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies.(**Life sciences and biotechnology —A strategy for Europe** Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions COM(2002) 27 European Commission)

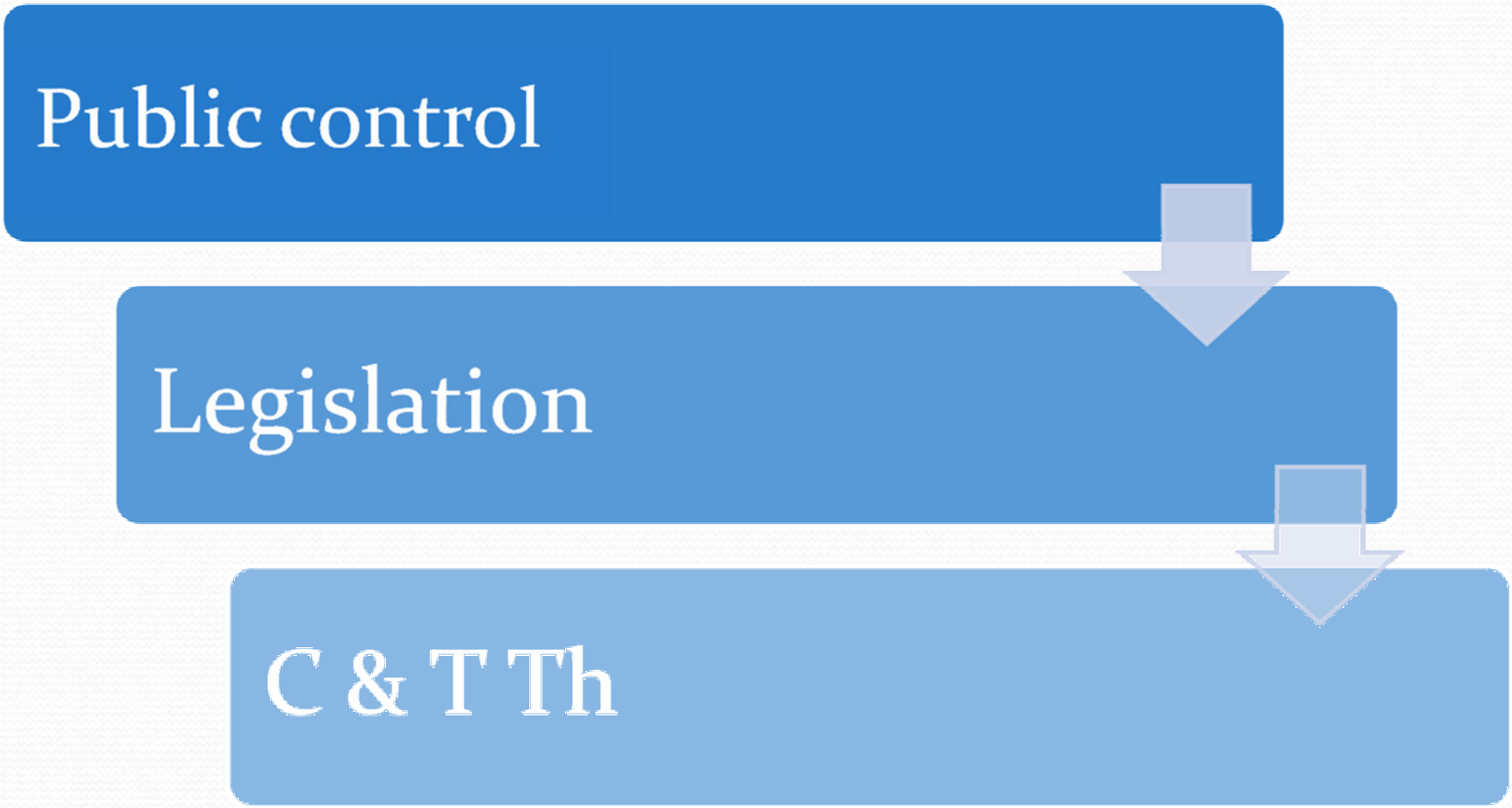
C&TTh - Risks

- Risks characteristics
  - Globality - informatisation
  - Complexity -
  - Ambivalency
  - Objectivity
  - Subjectivity

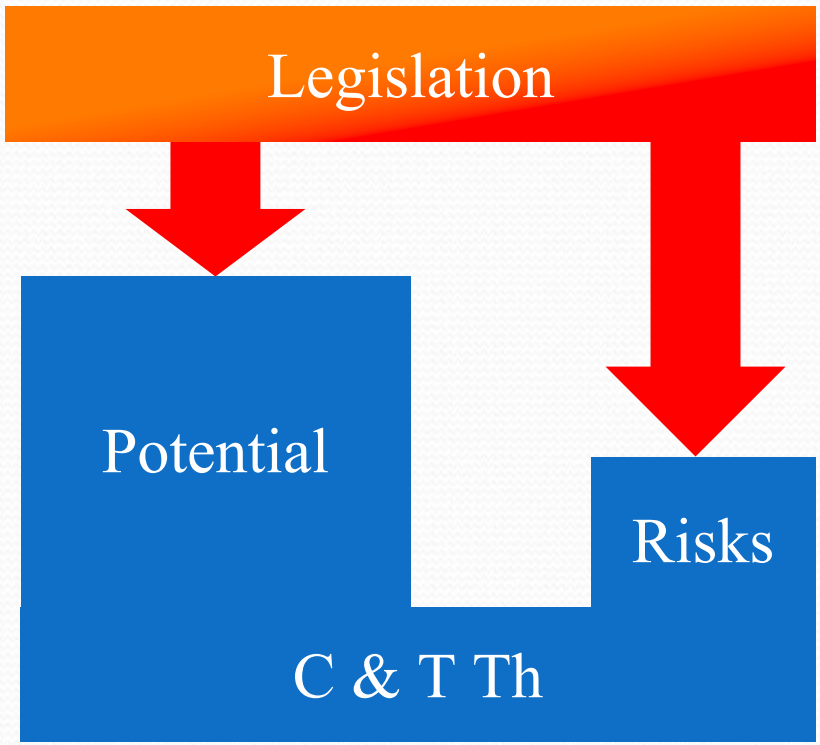
Regulatory mechanisms



C & TTh - Legislation



Legislation goals



EU directives on Tissues and cells

- **Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells**
- **Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells Text with EEA relevance**
- **Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells Text with EEA relevance**

Legislation in Slovenia

- Directive transposition:
- Act on quality and safety of human tissues and cells, for the purposes for medical treatment
- Zakon o kakovosti in varnosti človeških tkiv in celic, namenjenih za zdravljenje (ZKVČTC) Ur.l. RS, št. 61/2007 = **Datum sprejema:** 22.06.2007 **Datum objave:** 10.07.2007 **Datum začetka veljavnosti:** 09.08.2007 **Datum začetka uporabe:** 06.11.2007

Coments to the Act on quality and safety of human tissues and cells

- Discrimination between private and public establishments in possibility to do all tissue and cells activities (protection of public interess and transparency assurance)
- Donor's centers – bodies without defined scope of acitivities
- Central role of Slovenia-transplant
  - poorly defined duties and responsibilities
  - not defined relationship with competent authority
- Unnecessary complexity

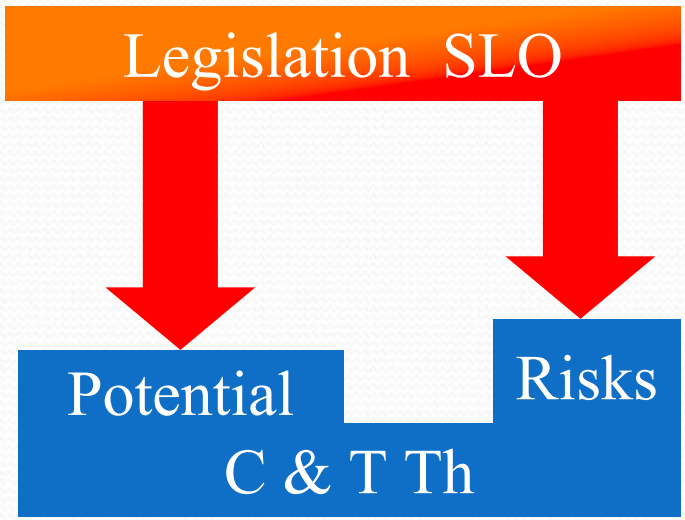
Regulations in preparation

1. On autologous tissues and cells
2. On donation, procurement, testing, processing, preservation, storage, distribution and disposition of human tissues and cells
3. On conditions for accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes and supervision of tissues establishments
4. On histovigilance,
5. On traceability of tissuse and cells and products and materials in contact with tissues and cells
6. On import/export of tissue and cells and of manufactured products derived from human tissues and cells
7. On donation and collection of tissues and cells
8. On documentation in clinical use of tissues and cells
9. On recipient selection

Comments to the regulations

- Gaps resulting from the Act
  - Define and agree missing data
- Overlapping between the particular regulations
  - Merging of regulation
- Unnecessary complex administrative obligations
  - Simplification of administrative work

Instead of conclusion – personal opinion



Legislation in Slovenia does not encourage development of tissue and cell establishments and consequently is breaking inner potential of cell and tissue therapies.