Enterprise and Industry
Directorate-General

European Commission

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Tissue-Engineering & Advanced Therapies

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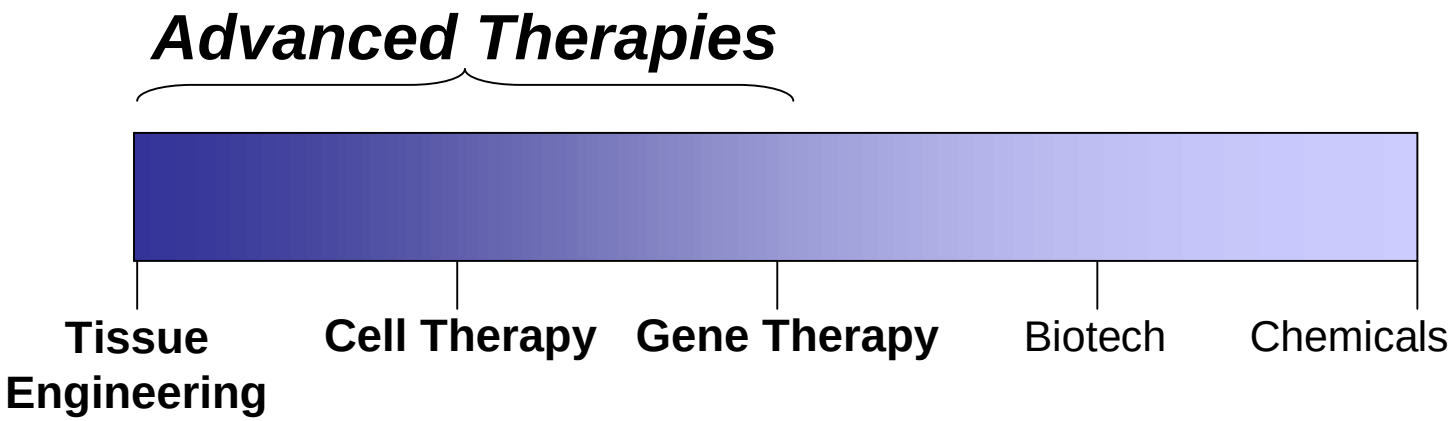
Advanced Therapies – What do we mean?

Medicinal products based on

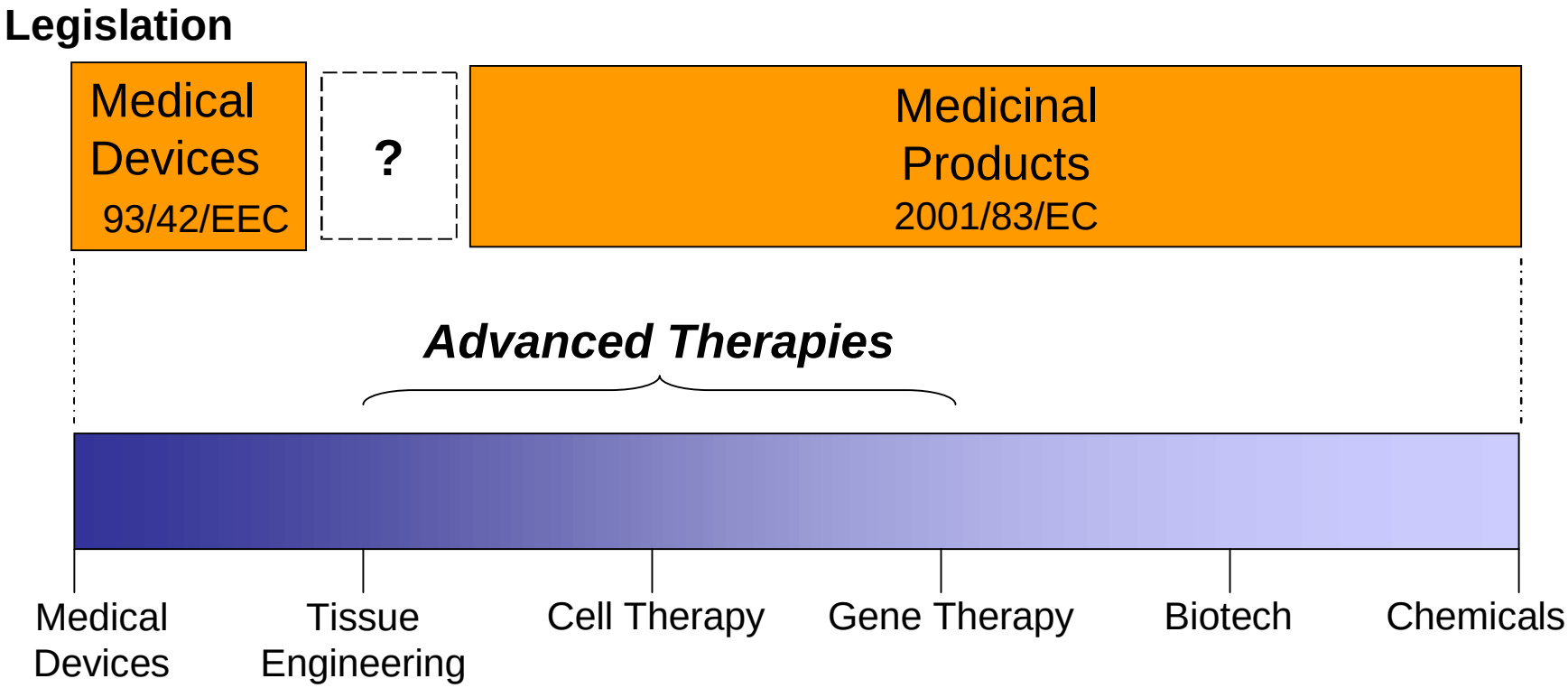
- Genes : gene therapy
- Cells: cell therapy
- Tissues : tissue engineering



Medical and economic importance

- Promising new treatment opportunities, e.g.
  - Skin replacement in burn victims
  - Reconstruction of blood vessels
  - Cancer
  - Alzheimer
  - Parkinson
- Today a limited market, but with huge potential

The regulatory gap



Today's regulatory patchwork

	Country	Austria	Belgium	Bulgaria	Cyprus	Finland	France	Germany	Ireland	Netherlands	Poland	Slovakia	Spain	Sweden	UK
framework	not at all			●●	●●				●●	●●	●●	●			
	as medicinal product (MP)	●●	●●			●●		●●							
	as medical device (MD)														
	as MP or MD, decided on case-by-case basis												●●	●●	●●
	specific national guidance						●●								●●
	other regulations	●●										●			
authorisation	by product authorisation (PA)		●					●							
	by manufacturing authorisation (MA)	●●	●					●●							
	by accreditation... of the tissue establishment		●●									●			
	by PA and MA						●●	●					●●		
import	from EU MS mandatory through accredited... tissue establishment in your country		●●				●●					●	●●		
	from non-EU country mandatory through accredited... tissue establishment in your country		●●				●●					●	●●		

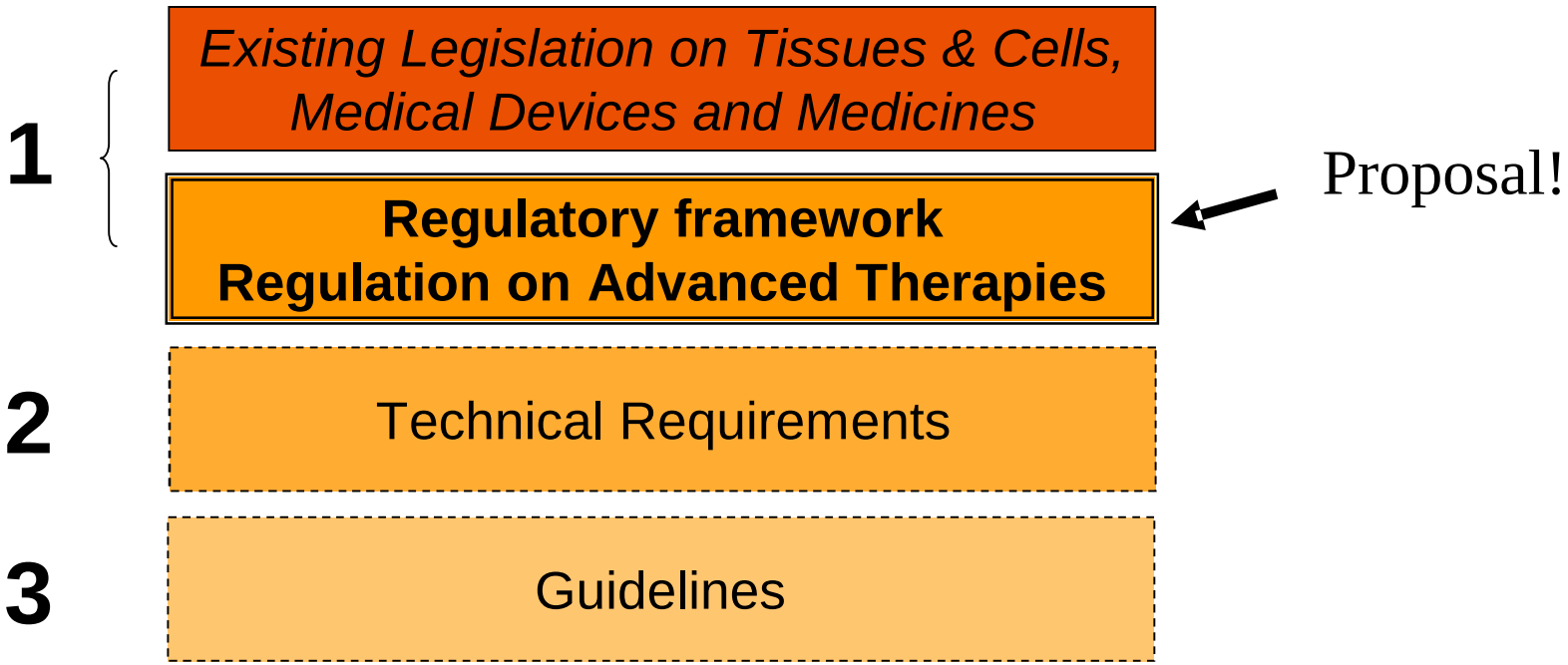
● **autologous products** ● **allogeneic products**

Ref. : Joint Research Centre, European Commission, 2004

Overall objectives

- Guarantee a high level of **health protection**
- Harmonise and facilitate **market access**
- Foster **competitiveness**
- Provide overall **legal certainty**

Regulatory levels of the overall approach



Regulation on Advanced Therapies: Key elements

- No marketing without prior approval
- Demonstration of Quality, Safety & Efficacy against tailored technical requirements
- Scientific assessment by European Medicines Agency (new scientific Committee)
- Risk management & Long-term traceability

Competitiveness Aspects

The approach provides e.g. for

- Direct access to the Community market
- Harmonised data protection of 10 years
- Accelerated assessment
- Scientific advice at reduced fee
- Special incentives for SMEs

Timing & Procedure

- **Regulation** to be adopted by Council/European Parliament
- **Technical requirements** should be ready shortly after adoption of the Regulation
- More information
  http://pharmacos.eudra.org/F2/advtherapies/index.htm