European Commission

Enterprise and Industry
Directorate-General

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The Regulation on Advanced Therapies

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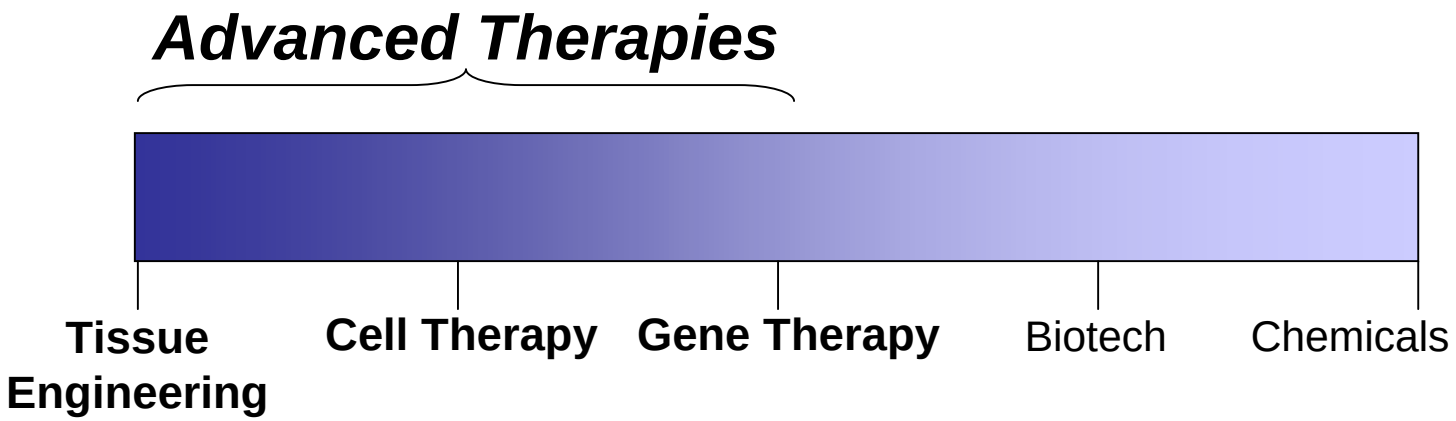
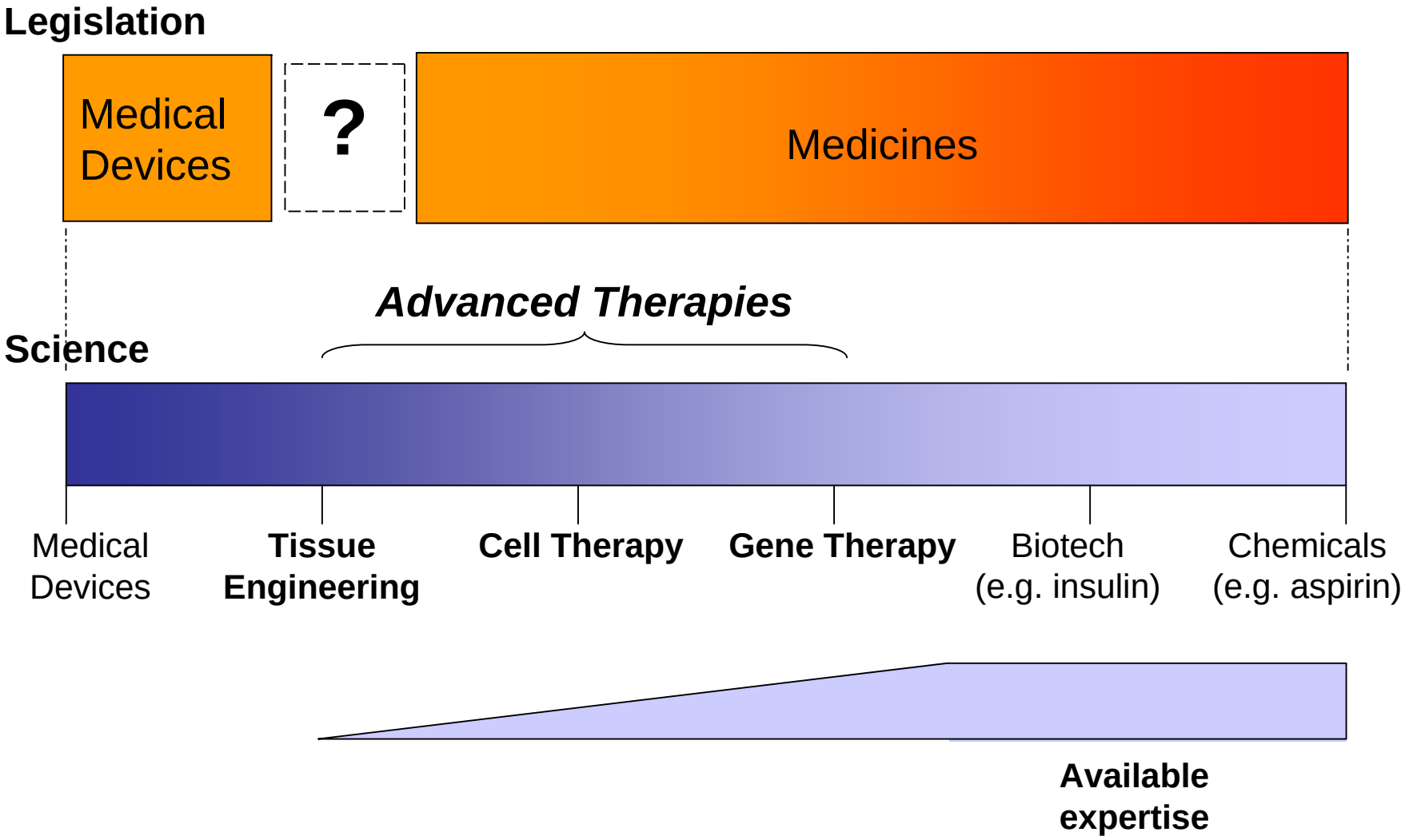
Advanced Therapies – What do we mean?

Medicinal products based on

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



The current picture



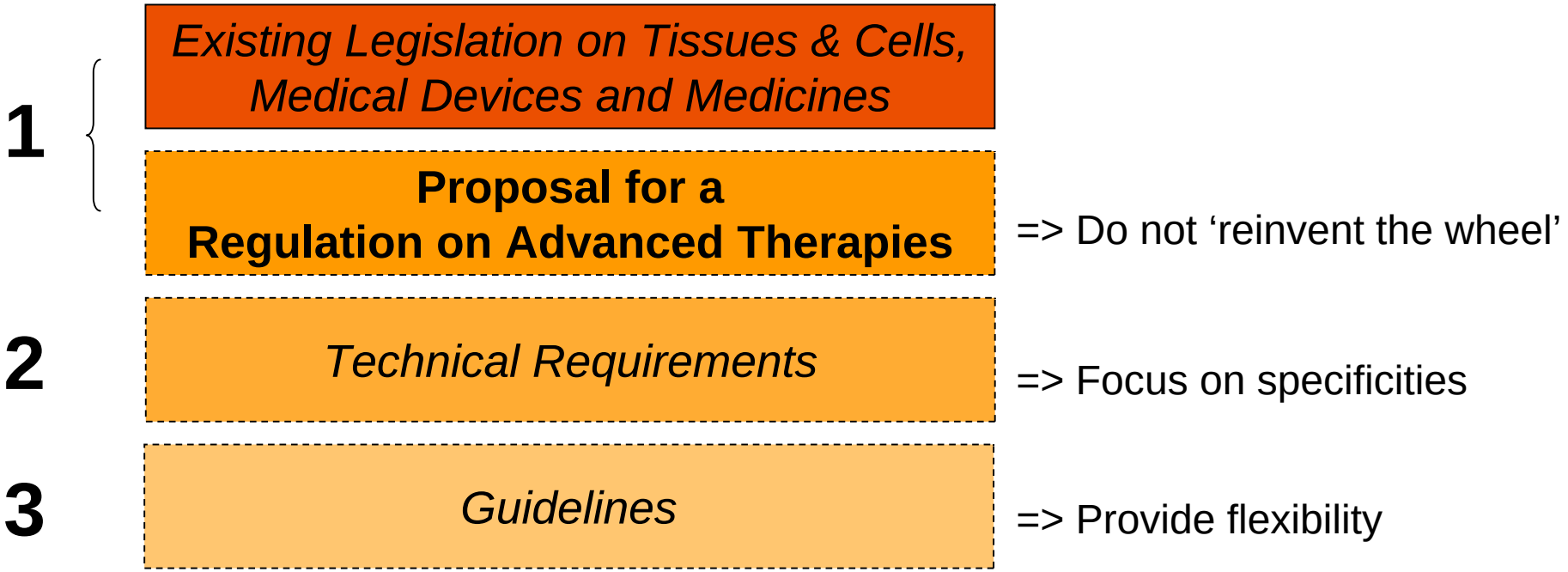
Today's regulatory patchwork

	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

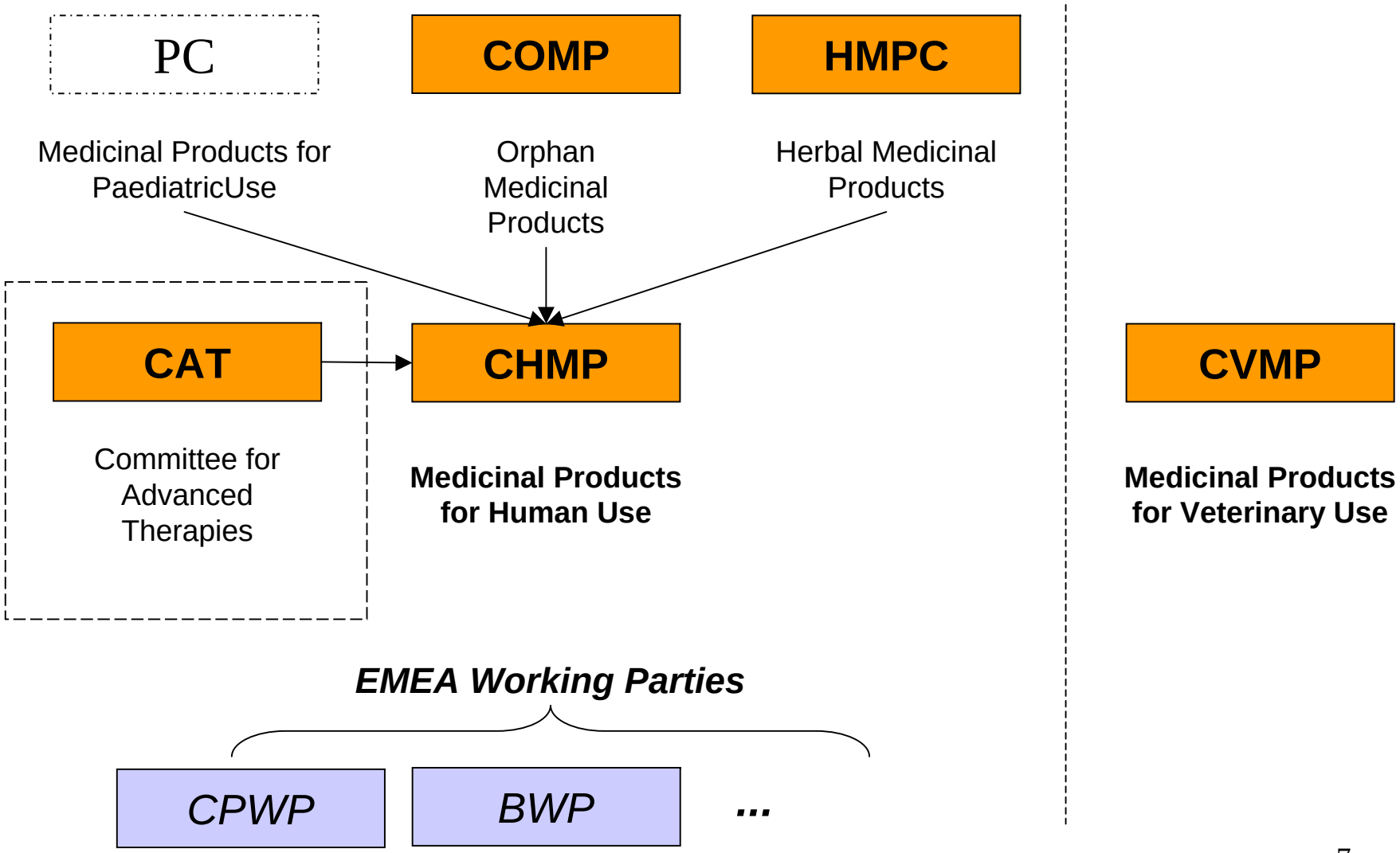
The proposed approach: 3 levels



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

EMEA Committees



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

SME specific incentives

- 90% on scientific advice fee
- 50% on MAA fee if particular public health interest, during period of transition:
  - 30/12/2011 for GT/sCT
  - 30/12/2012 for TEP
- Certification of quality/non-clinical data

Co-decision procedure

- Commission proposal: 16.11.2005
- EP ENVI 1st report: Sept. 06 (rejected)
- EP ENVI 2nd report: 30 Jan. 07 (adopted)
- EP plenary vote: 23-24 April 07
- Council: 31 May 07 -> 1st reading agreement
- Linguistic translations…
- Formal adoption 13 Nov. 07
- OJ Publication 10 Dec. 07
- Application 30 Dec. 08

Implementation (what is legally required)

EC:

- Amend Annex I to 2001/83 (Art. 7 and beyond)
- Implementing measure on certification of quality/non-clinical data (Art. 19)
- CAT patients/clinicians representatives (Art. 21)
- GCP guidelines (Art. 4)
- GMP guidelines (Art. 5)
- Traceability guidelines (Art. 16)

EMEA:

- CAT/CHMP work (Art. 20-21)
- Procedure for CAT/CHMP eval. procedure (Art. 9)
- Guidelines on Post-author. follow up /Risk management (Art. 15)

More information :

http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/index.htm

Thank you