The GMO framework

Translating Innovation into access for ATMPs

3rd EU-Innovation Network multi-stakeholder meeting

Session 3 Hot topics: opportunities for improvements

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Rome, 15 November 2024

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GMO framework applied to ATMPs

Directive 2009/41/EC on the contained use of genetically modified micro-organisms

"any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment"

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

"any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment"

⇒ Not developed specifically for medicinal products

⇒ Gene therapy medicinal products (ATMPs)

Recombinant viral vectors

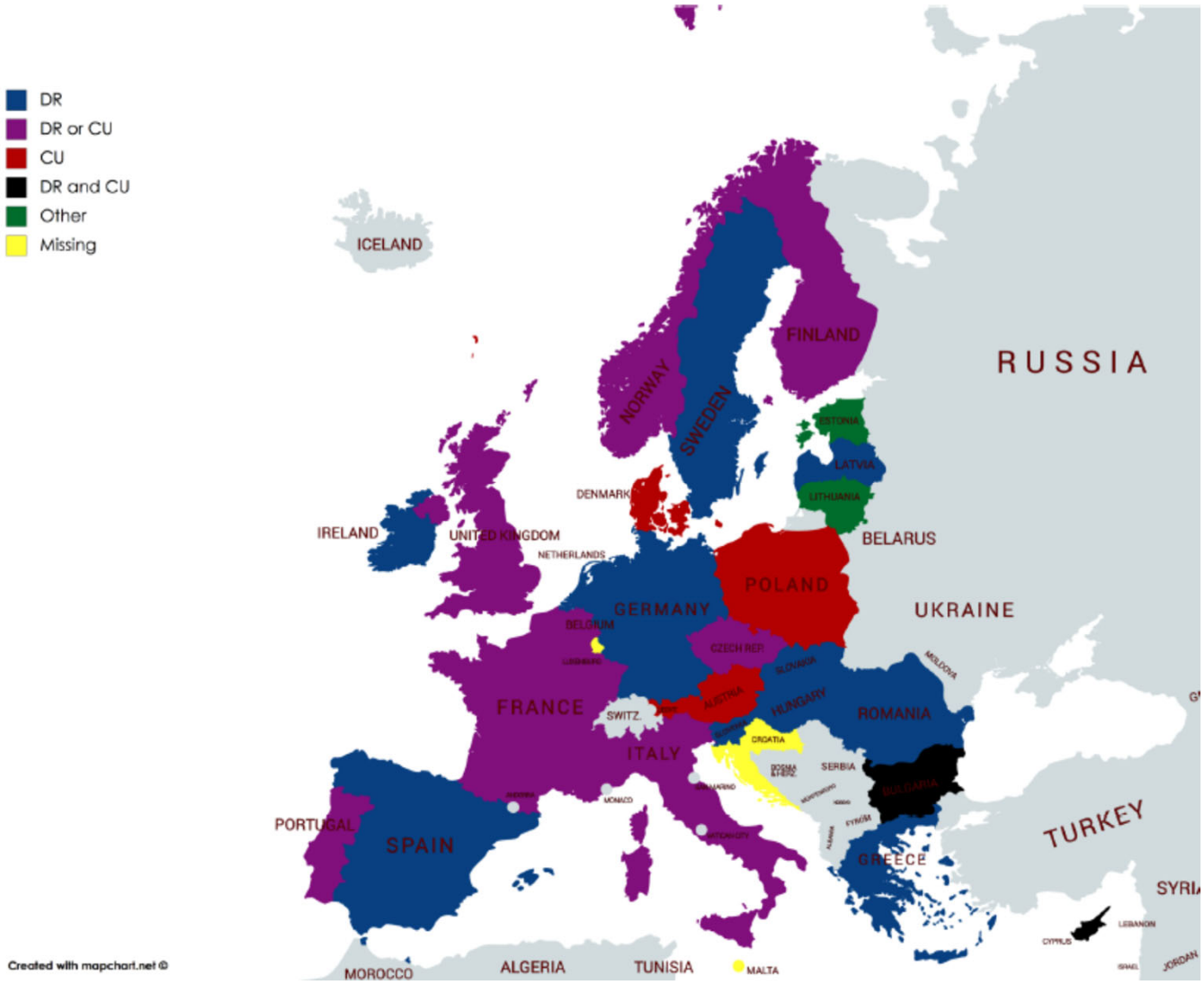
Genetically modified cell products

⇒ Compliance with GMO is a legal requirement

⇒ National laws

⇒ Risks assessed differently during development and at MAA

Deliberate release (DR) and contained use (CU) in EU



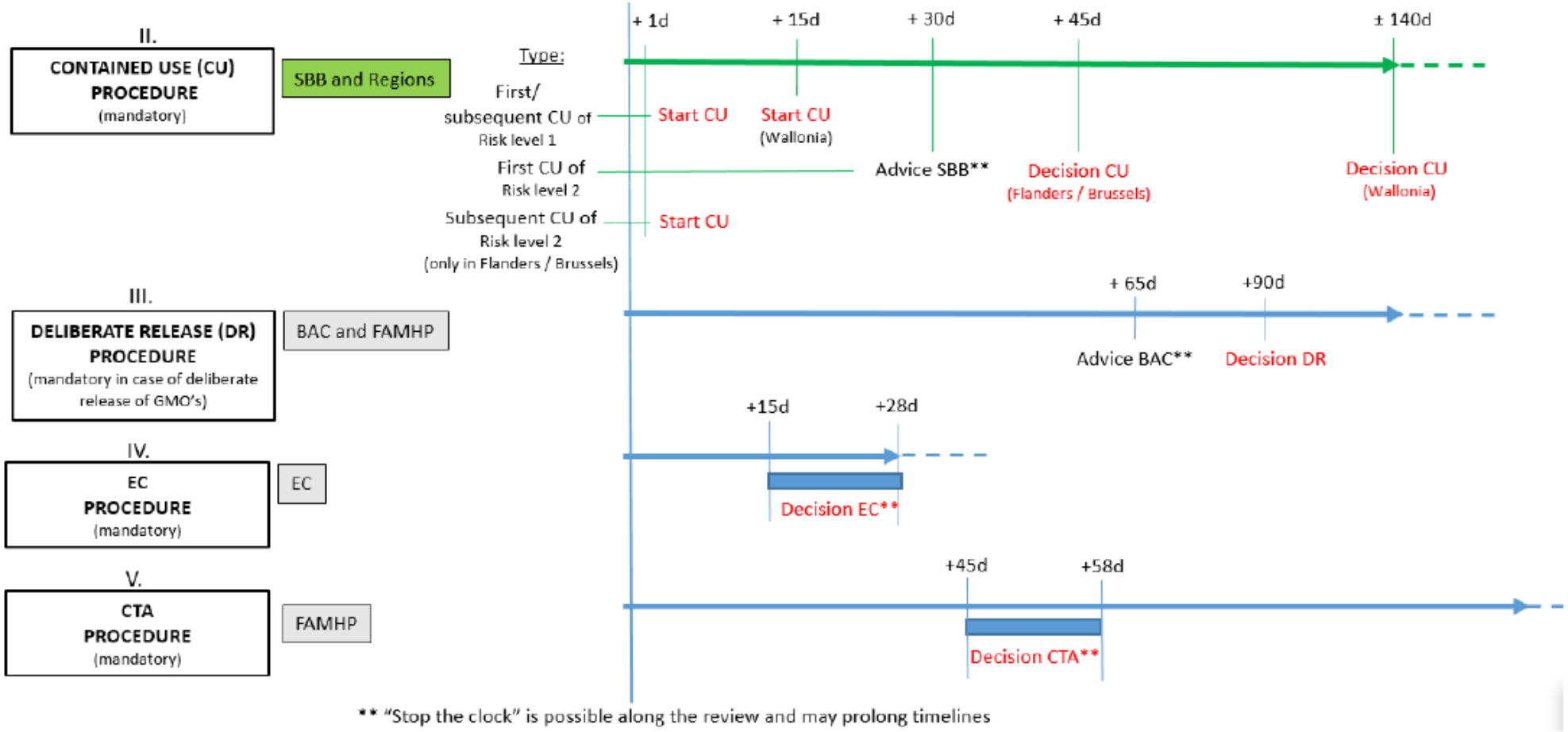
- Different competent authorities

- Different procedures

- Different requirements

- Different timelines

GMO assessment in Belgium



Interplay ATMP and GMO legislations

- Work group
- In the context of clinical trials
- Purpose of harmonisation
- Voluntary basis

⇒ Advanced Therapies / GMO requirements for investigational products
https://health.ec.europa.eu/medicinal-products/advanced-therapies_en

Repository of national requirements

https://health.ec.europa.eu/medicinal-products/advanced-therapies/genetically-modified-organism-gmo-aspects-investigational-medicinal-products_en

Austria	Italy
Belgium	Latvia
Bulgaria	Lithuania
Croatia	Luxembourg
Cyprus	Malta
Czechia	Netherlands
Denmark	Poland
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	Sweden
Ireland	

EEA countries

Norway

Other countries

United Kingdom

Achievements

- Question & answers document

- In vivo gene therapy:
  - Good practice document
  - Common application forms for AAVs and for viral vectors

- Genetically modified human cells:
  - Good practice document
  - Common application form

- Oncolytic viruses: considerations for the evaluation of shedding

⇒ List of countries that have endorsed each document

Evolution of pharmaceutical legislation

- Transfer of GMO assessment from the GMO framework to the pharma framework

- Transfer of ERA assessment competence to EMA (opinion by CHMP)

  ⇒ Submission under CTIS
  ⇒ Opinion by CHMP under 45 days
  ⇒ Guidelines

Contact

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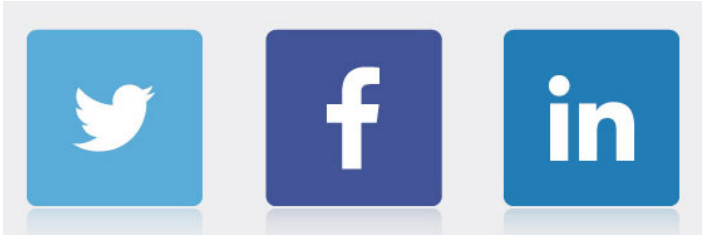

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