Biosimilar Policies in European Countries

Peter Schneider

Austrian National Public Health Institute

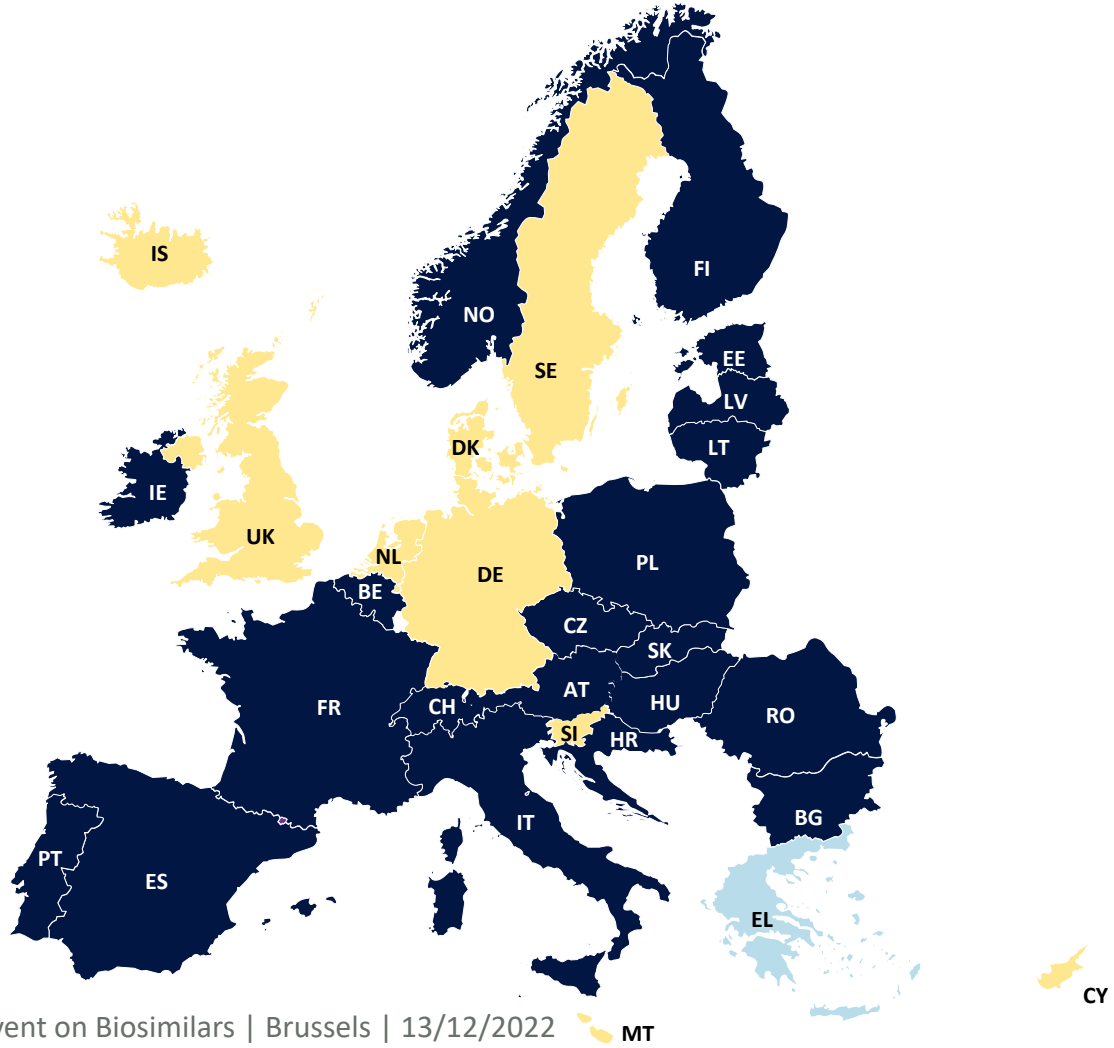
Stakeholder Event on Biosimilar Medicinal Products
Brussels, 13 December 2022

Gesundheit Österreich GmbH

Methods

- Query within the Pharmaceutical Pricing and Reimbursement Information (PPRI) Network
  - 26 EU MS (all except LU)
  - IC, NO, CH and UK
  - Brazil, Canada, Israel & Saudi-Arabia
- Prefilled survey on biosimilar policies
- Launched in May 2022
- Response rate: 24 countries
  - For those countres which did not participate in this data was obtained from previous queries/studies

(Selected) Biosimilar Policies in European Countries
Pricing of Biosimilars | Price link policies



Price link for generics and biosimilars

Price link for generics, but not biosimilars

No price link, neither for generics nor biosimilars:

No information available

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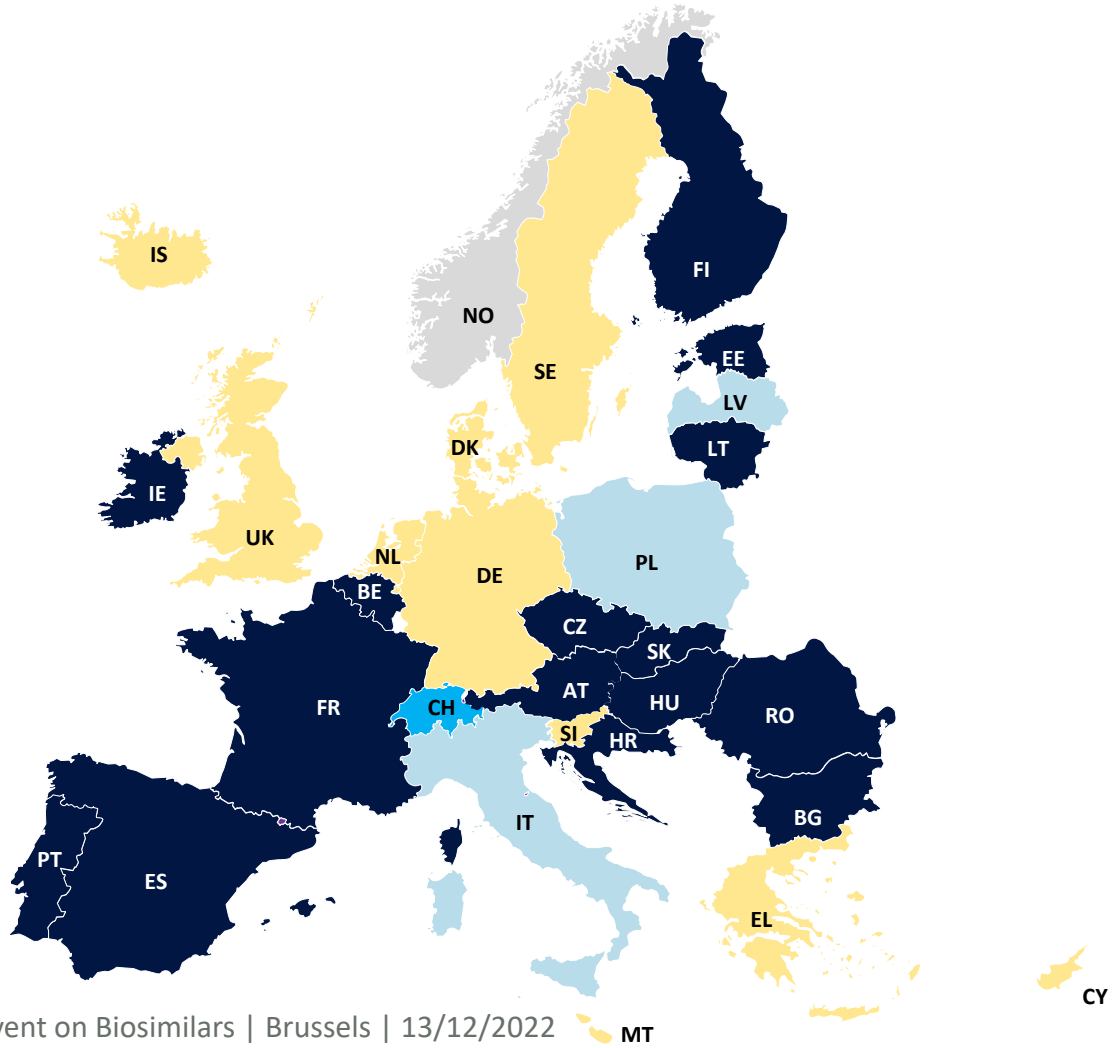
(Selected) Biosimilar Policies in European Countries
Pricing of Biosimilars | Price link policies



- Higher price reduction for generics than for biosimilars
- Same extent of price reduction
- Higher price reduction for biosimilars than for generics
- No price link for generics or biosimilars
- No information on price reduction for generics and/or biosimilars

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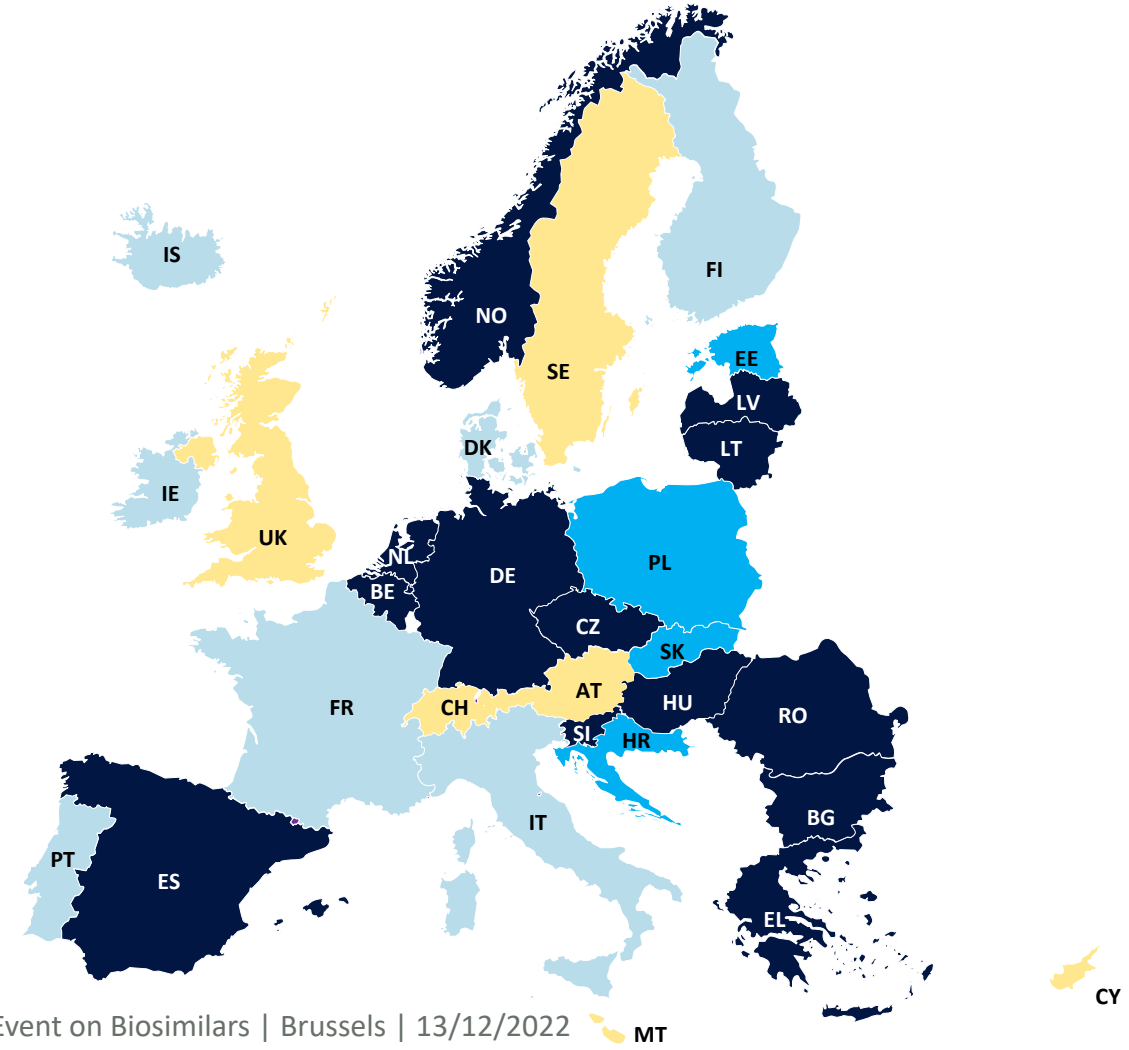
(Selected) Biosimilar Policies in European Countries Reimbursement | Reference Price System (RPS)



- RPS with generics and biosimilars included
- RPS, but biosimilars excluded
- RPS, but no information whether or not biosimilars are included
- No RPS in place
- No information available

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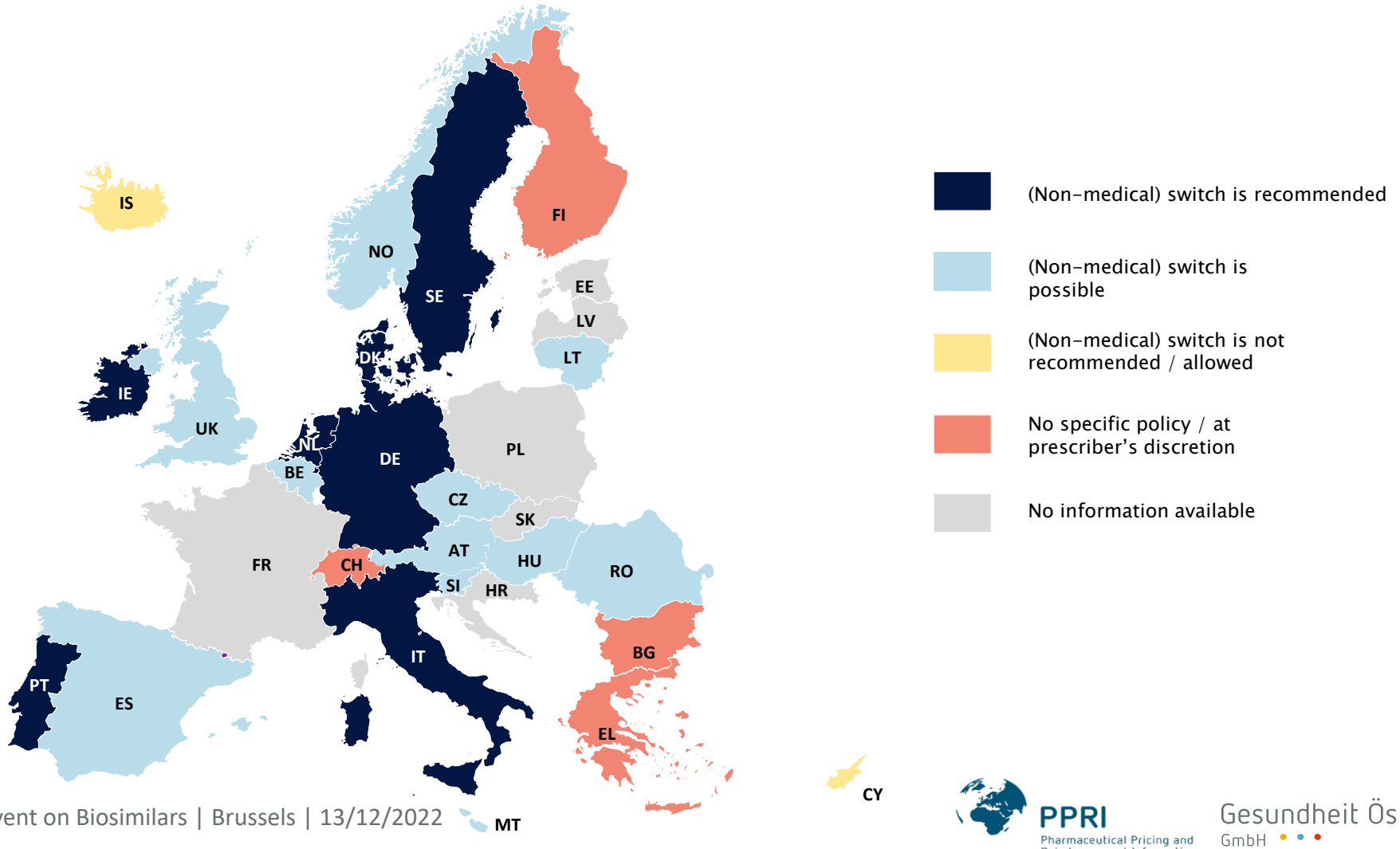
(Selected) Biosimilar Policies in European Countries
Switching to / between biosimilars (2022)



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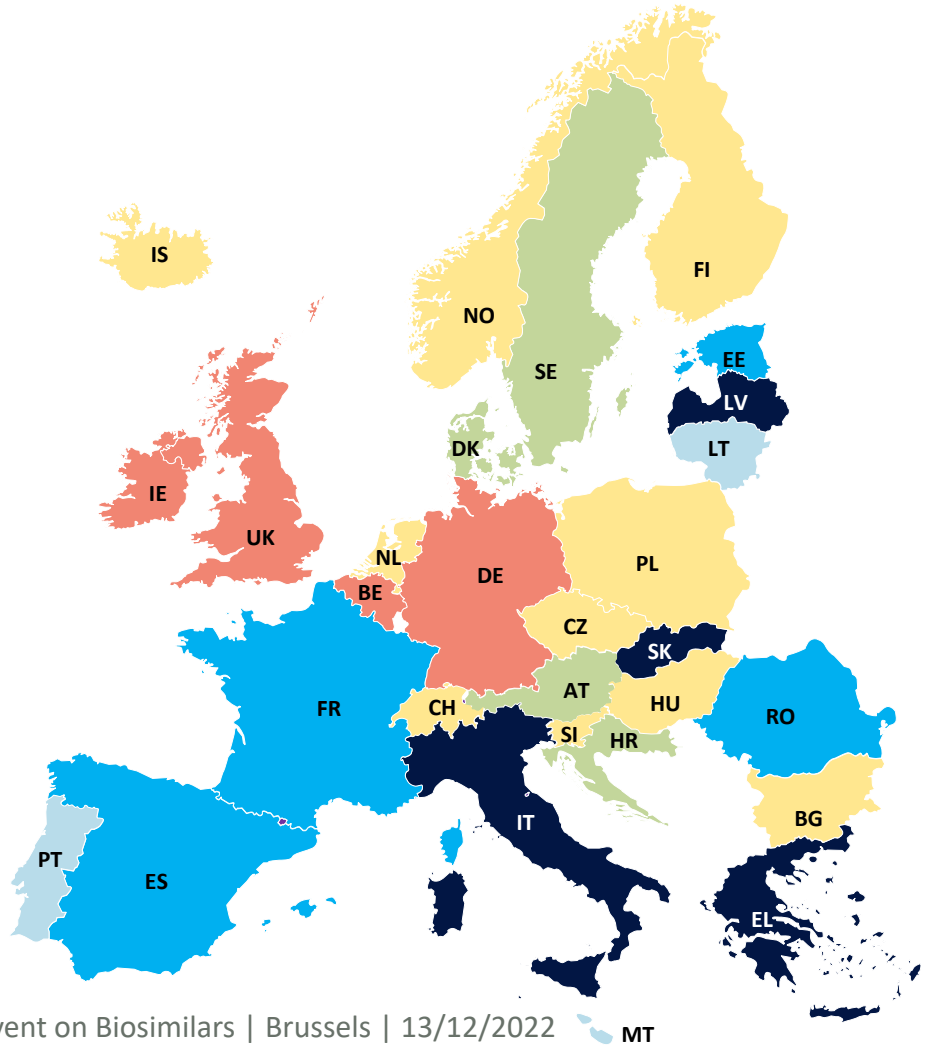
(Selected) Biosimilar Policies in European Countries Prescribing by INN



- INN prescribing is mandatory, including for biosimilars
- INN prescribing is mandatory, but not allowed for biosimilars
- INN prescribing is mandatory, but indicative for biosimilars
- INN prescribing is indicative, including for biosimilars
- INN prescribing is indicative, but not allowed for biosimilars
- INN prescribing not allowed
- No information available

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Discussion

- Classification of policies
  - Policies on medicines are embedded within the respective national pharmaceutical system
  - Interpretation against the backdrop of this regulatory framework
- Supply side measures vs. Demand side measures
  - Supply side measures are easier to implement, but full potential seems to be untapped (differences in scope of the measures)
  - Demand side measures are more heterogenous even more difficult to assess/classify
- Point of administration pose a challenge on regulations
  - Several biosimilars are administered at the interface between in-patient and outpatient sector;
  - Existing regulatory framework do have difficulties to capture them

Thank you for your attention

Peter Schneider
Researcher
WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies
Pharmacoeconomics Department

Gesundheit Österreich GmbH | Austrian National Public Health Institute
Stubenring 6
1010 Wien
T: +43 1 515 61 – 116
M: +43 676 848 191 – 169
peter.schneider@goeg.at
www.goeg.at

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