EMA
EUROPEAN MEDICINES AGENCY

Streamlining product-specific bioequivalence guidance

MWP CP-OEG

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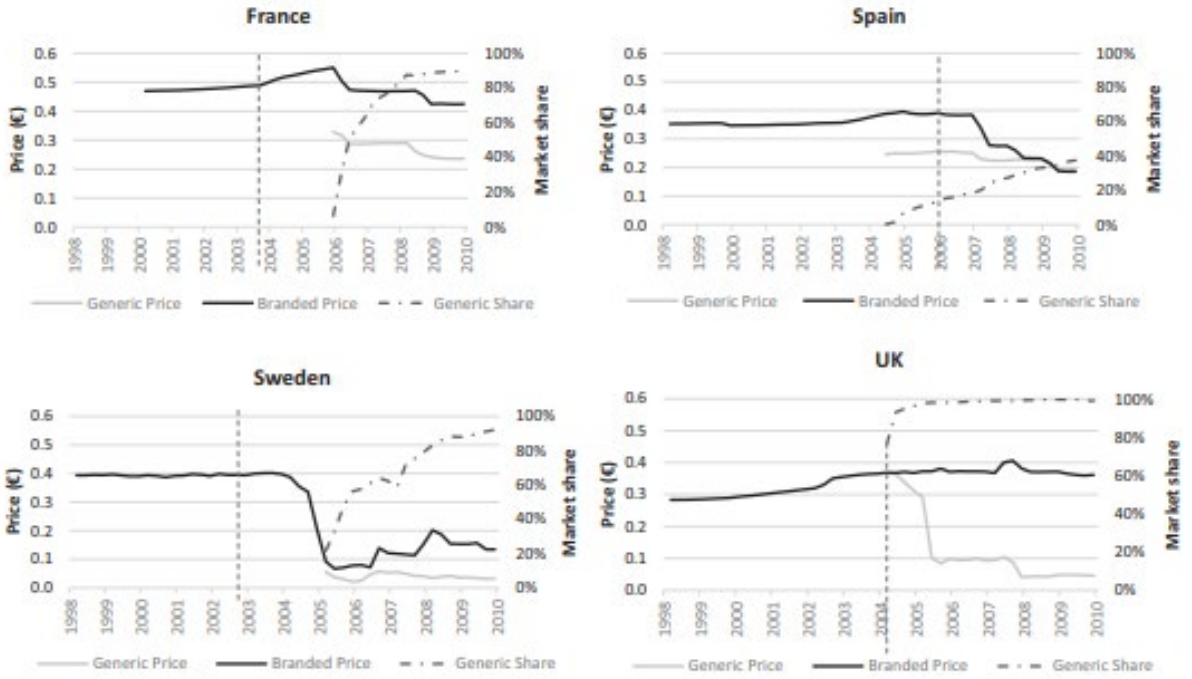
Generics

- In high-in come countries, about 20% of all money spent on health care goes to medicines prescribed.
- The use of generic drugs is an important tool to reduce healthcare spending.



Wouters et al., 2017

Product specific bioequivalence guidelines (PSBGL)

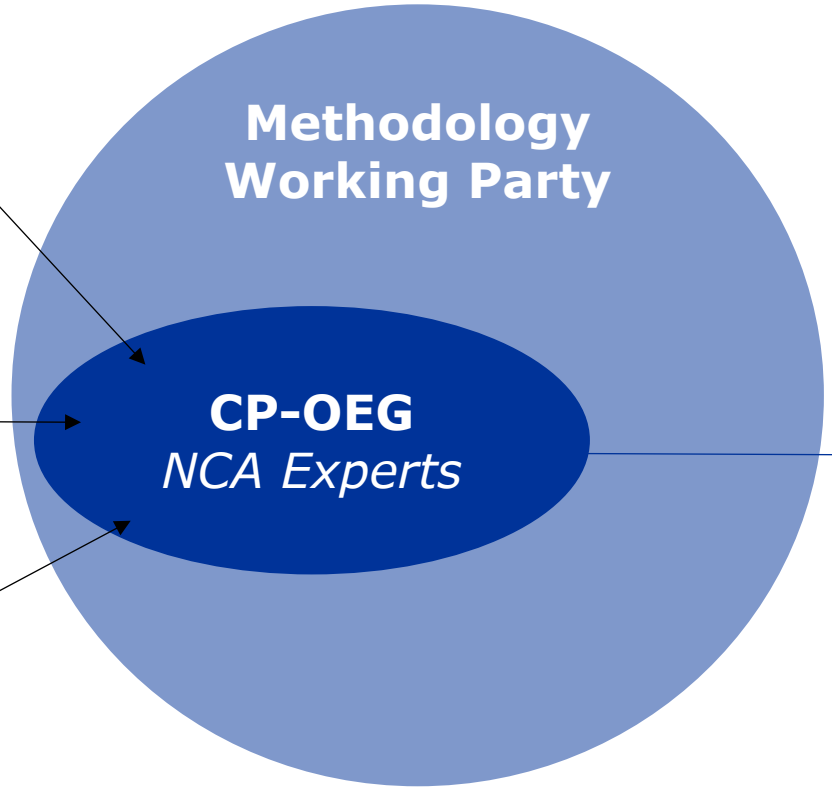
- First PSBGL in 2009 by PKWP
- Concept paper on the development of product-specific guidance on demonstration of bioequivalence 2013 (EMA/CHMP/423137/2013)
  - Guidance on design of the PK study to demonstrate bioequivalence
  - Stakeholders: generic pharmaceutical industry
    regulators in the European Union
- Currently 91 PSBGL approved + 2 under public consultation

Current approach of selection of PSBGL products

CHMP
Centralised generics

CMDh
Decentralised generics

SAWP
Advice on generics



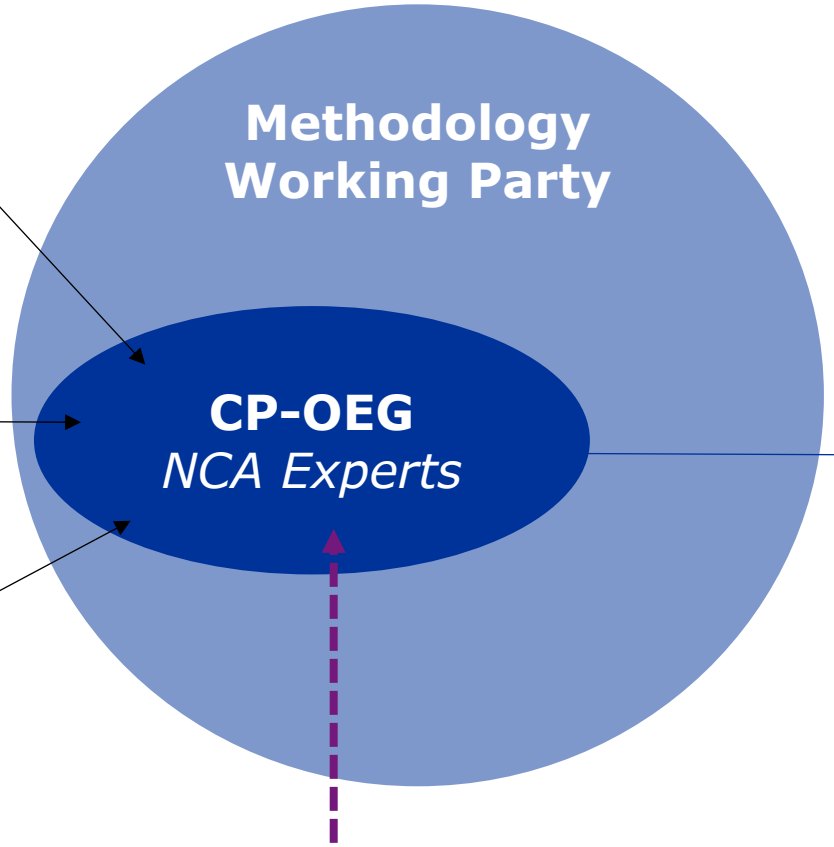
Output
Advice (internal)
PSBGL (published at EMA site)
Q&A (published at EMA site)

Proposed approach of choosing PSBGL products

CHMP
Centralised generics

CMDh
Decentralised generics

SAWP
Advice on generics



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(Generic) Pharma Stakeholders?

Points for discussion

- The way of proposing products for PSBGL
  - CP-OEG selection based on product characteristics
  - CHMP/CMDh/SAWP requests
  - Generic Pharma Industry
    - Yearly EU survey, collection via MWP stakeholder meeting
    - Yearly open call for a month for generic pharma industry to propose top 5 candidates for PSBGL
      - 5 candidates can be proposed per stakeholder with argumentation
- Number of proposed PSBGL candidates by Pharma
  - The most frequent proposed candidates will be selected with a maximum of 5 candidates
  - Selected candidates will be announced on the designated EMA website: Product-specific bioequivalence guidance | European Medicines Agency (EMA)
    - Number of PSBGL candidates cannot exceed the number of respondents
    - Yearly review of the number of candidates

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Thank you

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