BARRIERS AND OPPORTUNITIES FOR THE UPTAKE OF BIOSIMILAR MEDICINES IN BELGIUM

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Background

- Biosimilars
  - What are they?
    - Similar but not identical copies of the reference product
  - How are they approved?
    - EMA: specific pathway based on “comparability exercise”
    - Demonstrate that the biosimilar and the reference medicinal product (originator) have similar profiles in terms of quality, safety and efficacy
  - For which products?
    - Under evaluation (02/2013): infliximab, follitropin alfa and filgrastim
Background

- Biosimilars are seen as an opportunity to reduce pharmaceutical expenditures for RIZIV – INAMI.
- But..
  - Biosimilar uptake in Belgium is close to zero
- Question introduced by Minister of Social Affairs and Public Health
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<th>Objective:</th>
<th>• Identify barriers and measures which may influence biosimilar uptake in Belgium and abroad</th>
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| Method (1): International perspective | • Price, uptake, savings and barriers and policy measures  
• Structured literature review  
• Closer look: France, The Netherlands, Germany and Sweden |
| Method (2): Belgium | • Biosimilar perception and acceptability  
• Face-to-face interviews  
  (N= 30; relevant actors )  
• Websurvey  
  (8 scientific societies N=1126 ; 11.2%) |
Lessons from abroad

Price & savings
- Less price reduction than with generics (higher production and marketing cost)
- Price reduction varies in different product classes and across countries
- Little (no) evidence on current savings

Barriers
- Make prescribers “aware” of biosimilars
- Physician prescription habits
- Hospital setting:
  “competitive price” biosimilar > “discounted price” originator

Policies for uptake
- A single successful strategy for high uptake? No
- High uptake for Sweden & no specific policies
- High uptake for epoetin in Germany (quotas, policy in dialysis centres & information)
- A possible success factor(s): general framework to stimulate generic use
Information and clinical barriers in Belgium

Knowledge

- Market approval requirements (level of similarity, extrapolation of indications, etc)
- Available information on safety and efficacy
- Interchangeability
- Pharmacovigilance requirements

Attitude (concerns) towards biosimilars

- Questions EMA procedure for market authorization
- Need for more clinical evidence on safety and efficacy, in particular concerning extrapolation of indications
- Uncertainty on real cost-savings

Lack of appropriate information dissemination

- Not enough information and contacts from biosimilar companies
- Insufficient information provided by the authorities
Financial barriers in Belgium

In hospital settings, biosimilars are not the least expensive alternative

- Discounted price for originator is lower than biosimilar price

Fringe benefits may influence prescription habits

- Research and training funds
- Larger services to patients (education) that enhance compliance
Belgium: policy measures for biosimilars

Policy measures (summer 2012):

1) Category F for epoetin,
2) Increase reimbursement for epoetin biosimilar,
3) Biosimilar in “low-cost quotas” and
4) Epoetin and growth hormone included in hospital prospective budget

Increase biosimilar use: No
INAMI-RIZIV Savings: Yes, but only one-shot savings (on-patent pharmaceuticals)
Recommendations

To the FAGG – AFMPS, the BCFI – CBIP, FARMAKA vzw, the Network of clinical pharmacists (MFC – CMP), the National Council for Quality Promotion (NRKP– CNPQ ), to the health care industry

- Information to health care professionals on the comparability exercise, safety and efficacy track record, pharmacovigilance requirements

To universities

- Idem and information on economical prescribing should be included in health care professional curriculum.
Recommendations

To the Scientific Associations of health care professionals, to the National Council for Quality Promotion (NRKP–CNPQ), and to the Colleges of Medical Doctors

- Idem and address use of biosimilars for naïve patients and substitution during treatment
- Clinical practice guidelines leading to well-targeted use of biologicals (reference product, biosimilars and second-generation products) may outpace biosimilar-related savings

To the European Medicines Agency (EMA)

- Easy access to clear information on all clinical trials and to post-marketing studies for public authorities and health care professionals
Recommendations

To the Minister of Social Affairs and Public Health

• In the short-term,
  • Discussion with all involved partners to set a quota system (applicable to naïve patients, per hospital, guidelines and financial incentives or penalties)
  • Transparency on discounts, advantages and services granted by the health care industry.

• In the medium-term, study alternative modes of financing for pharmaceuticals excluded from the hospital prospective budget
  • Reimbursement by RIZIV – INAMI should reflect prices paid and other advantages received by hospitals
  • Savings from these policy measures should in part be returned to hospitals
Colophon from KCE reports 199

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