Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

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?**
    - **Approved : growth hormone (2006), epoetins (2007) and filgrastim (2008)**
    - **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**

Objective:	• **Identify barriers and measures which may influence biosimilar uptake in Belgium and abroad**
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	INAMI-RIZIV Savings
No	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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