Enhancing the utilisation of generic clopidogrel: a case history for future guidance?

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1. **Introduction**

2. Methodology

3. Results

4. Conclusions

Generic clopidogrel is an increasing focus in view of resources released and different salts

- The increasing focus on pharmaceuticals arising from the continual pressures has resulted in a number of initiatives among European health authorities and health insurance agencies regarding generics
- This includes clopidogrel with annual sales of the originator at $9.7bn to $9.8bn in 2009 and 2010
- However differences in the salt between originator and generic clopidogrel, as well as different indications initially, could potentially reduce savings from generic availability with the originator company keen to retain sales
- Consequently, there is a need to appraise health authority and health insurance activities to provide future direction

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Knowledge from payers and their advisers used to determine health authority activities

- Literature review of English language papers in PubMed, MEDLINE and EMBASE between 2005 and April 2011
- Combined with insight from payers and their advisers in over 20 European countries and regions to analyse and collate regional and country responses (main method as only limited number of publications)
- Findings validated with the payers and their advisers in each European country to enhance the robustness of the findings

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There was typically pragmatic approaches among countries to enhance generics

- There was considerable variation among countries on:
  - Dates when generic clopidogrel first reimbursed
  - Activities to enhance prescribing of generic clopidogrel
  - Activities by the originator company to delay/ withdraw generic clopidogrel formulations as well as successfully cast doubt on concerns with generic clopidogrel
- However, typically pragmatic approaches adopted among health authorities and health insurance agencies across Europe to enhance potential savings following EMA approval of generics

There was typically pragmatic approaches among countries to enhance generics, e.g.:

Country	Year reimbursed	Activities
Austria	2008	Authorities wrote public letters stating no difference between generic and originator in response to Cardiologists' concerns. Activities to enhance generic prescribing include no prescribing restrictions, financial incentives to physicians and regular publications
Croatia	2006	Reference pricing based on the lowest priced molecules encourages prescribing of generics vs. originator
Germany	2008	Differences in salts and indications typically dismissed by physicians aided by educational inputs such as letters and articles, rebate negotiations and budgets linked with financial incentives
Lithuania	2009	No problem with mandatory INN prescribing for clopidogrel. Community pharmacists obliged to stock cheapest generic to force down prices (already leading to a reduction in originator prices)
Scotland	2009	Pragmatic approach with area D & TCs recommending prescribing of generics aided by high INN prescribing and low prices for generics (with market forces)

However, delaying tactics in a minority brought about by current regulations

Country	Activities
Norway	Generic clopidogrel reimbursed Jan 2010. However, patent and indications challenged leading to removal October 2010. Accepted again March 2011 with extended indications
Portugal	First generic approved in April 2009 and reimbursed Dec 2009. Some generic formulations later withdrawn due to manufacturing concerns. However, others withdrawn following lawsuits by originator leading to temporary suspension (12 formulations to date)
Slovenia	Generic clopidogrel available June 2006 to June 2008. Subsequently withdrawn following successful challenge by originator company. Available and reimbursed since May 2010

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Typically a pragmatic approach to generic clopidogrel. Considerable variation in prices

- Generally a pragmatic approach among health authorities and health insurance agencies to generic clopidogrel following marketing authorisation
- Activities to enhance prescribing of generic clopidogrel mirror those for other generics alongside extensive education in some
- However, activities not possible in some countries following successful challenges by originator company to the availability of generic clopidogrel
- Considerable variation in reimbursed prices of generic clopidogrel vs. originator across Europe. Likely to see convergence in the future as resource pressures grow

Considerable variation in reimbursed prices. However, trend is downwards as more launched

Country	75mg pack of clopidogrel (DDD = 75mg)	Reimbursed prices for 75mg (April to July 2011)
Austria	30 x 75mg	Reimbursed price (KVP) €17.95 (€0.59/ DDD) – 73% below pre-patent loss prices
England	30 x 75mg	GB£2.50 (€2.88) (€0.096/ DDD) – 93% below pre-patent loss prices
Estonia	28 x 75mg	Cheapest generic- €10.64 (€0.38/DDD) - 77% below 2009 originator price. Copays vary between 10 to 50%
Finland	28 x 75mg	€11.04 (€0.39/ DDD) – 86% below pre-patent loss prices
Germany	100 x 75mg	April AVP price (cheapest generic) - €44.18 (DDD = €0.44) – 84% below 2009 originator price
Lithuania	28 x 75mg	€4.11 (€0.15/ DDD) – 52% below 2009 originator prices
Serbia		€0.41/ DDD – 33% below 2008 originator prices
Slovenia	28 x 75mg	Reimbursed price in May 2011: €17.41 (€0.62/ DDD) – 33% below January 2010 originator prices
Sweden	30 x 75mg	SEK64 (AUP) (€9.20 - €0.31/DDD) –88% below pre-patent loss prices

Thank You

Any Questions!

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