

The potential of generics policies: more room for exploitation. PPRI Conference Report

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Introduction: This Conference Report aims to provide an overview of key results, messages and conclusions of the PPRI Conference with regard to generics.

Method: The Pharmaceutical Pricing and Reimbursement Information (PPRI) Conference, organized by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, took place in Vienna, Austria on 29 and 30 September 2011, with keynote talks, presentations of policies and research results, poster sessions and panel discussions.

Results: Several presentations and discussions addressed the topic of generics (64% of all invited contributions, 46% of the accepted abstracts). European and non-European countries use incentives to promote generics as part of their pharmaceutical policy. Budgetary pressure on policy makers has created a sense of urgency to encourage measures to increase generics uptake (i.e. achieve a higher generics market share). There are considerable differences between the prices of originators and (lowest) generic medicines. Presentations included case studies on how to enhance generics uptake.

Conclusion: Although policies on generics were not a specific programme strand of the conference, this was a recurring theme throughout. An important lesson from the Conference was that the full potential of policies on generics has yet to be fully exploited. Generics uptake could be improved by a more consistent implementation of generics policies.

Keywords: competition, conference, generics policies, generics uptake, medicines prices, pricing, reimbursement

Introduction

On 29 and 30 September 2011 the WHO Collaborating Centre (WHO CC) for Pharmaceutical Pricing and Reimbursement Policies organized the second PPRI Conference in Vienna, Austria. This was attended by 275 delegates (officials and staff of public authorities and payers, pharmaceutical companies, researchers) from 56 countries, and included 60 speakers, panelists and chairs. It addressed pharmaceutical policies from a public health perspective, from both a European and global context.

The first PPRI Conference took place in June 2007 in order to present preliminary results of the research project 'Pharmaceutical Pricing and Reimbursement Information' (PPRI) co-funded by the European

Commission, Directorate General Public Health and Consumers (DG SANCO) which ran from September 2005 until the beginning of 2008 [1-3]. The first PPRI Conference focused on European pricing and reimbursement policies [4], but generics policies were not a key topic at the conference. Just one presentation, by Professor Richard Laing from WHO, about availability, affordability and price components of medicines in developing and transitional countries [5], highlighting price differences between originators and generic medicines assessed according to WHO/HAI (Health Action International) methodology [6, 7], addressed the generics policy.

The second PPRI Conference was organized in response to requests from participants at the previous conference for a

follow-up, and was an activity under the terms of reference of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (established in June 2011). The conference objective was to provide information about the activities and the results of the PPRI and Pharmaceutical Health Information System (PHIS) projects. The PPRI initiative has continued as a voluntary networking and information sharing initiative of competent authorities for pricing and reimbursement after the PPRI project officially ended in 2008. The PHIS project (September 2008 to April 2011) [8] was based on the lessons learned and looked particularly at medicines management in the inpatient sector, for which scant literature existed. As a result, the PHIS project called for an urgent improvement in cooperation at the interface between outpatient and hospital sectors [9].

The second PPRI Conference therefore had a focus on 'hospital pharma and interface management' and contained three parallel strands: (1) pricing and reimbursement, (2) rational use of medicines and (3) hospital pharma and interface management. The majority of the participants (more than 50 per cent) attended the strand on 'pricing and reimbursement'. The topics of generics and generics policies appeared in all three strands.

Panelists and speakers in the plenary sessions

Generics were mentioned in 48 (64%) of the total of 75 contributions (presentations, posters, panel discussions), and in 22 of 48 accepted abstracts (46%). During the first high-level panel discussion Mr Kees de Joncheere, then Regional Adviser for Health Technology and Pharmaceuticals for WHO Europe (now Head of the Essential Medicines Department in WHO Headquarters), stressed the great potential of generics policies and the need to apply these more frequently. Mr Richard Bergstrom, President of the European Federation of Pharmaceutical Industries and Associations (EFPIA), stated that 'once patents expire, prices should fall to a low, but sustainable, level'. In this panel discussion but also throughout the conference there appeared to be a common understanding that generics competition works

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well. Dr Andreas Seiter (World Bank) [10], expressed concern about having a pricing regulation policy that fixes a difference between the originator and the generic(s) (so-called 'generic price link', [11]) because this could impede further benefits and savings that could be achieved through full generics competition.

Country case studies

Presentations and posters described the pharmaceutical situation in 37 different countries, including generics policies and their outcomes. In Croatia, for instance, a generic price link and reference price system, together with policy measures targeting new medicines, have contributed significant savings to the Croatian Social Insurance in 2009 and 2010. Expenditure by Croatian Social Insurance on medicines in the outpatient sector corresponded to Euros 393 million in 2010, 2.9% lower than in the previous year. And in the first months of 2010, public pharmaceutical expenditure in the outpatient sector was 13% lower than that of the first half year of 2009, resulting in a 22% reduction in the health insurance deficit. The savings enabled 47 new innovative medicines to be added to the positive list (i.e. the list of medicines that may be prescribed at the expense of a public payer, [12]) and 13 medicines to the list of expensive hospital products from July 2009 to July 2010 [13].

Generics policies were highlighted as a policy option for countries (e.g. Ireland, Portugal, and Spain) that needed to implement a bundle of measures in order to respond to the global financial crisis. The crisis created, as one participant [14] commented, 'a sense of urgency' to implementing measures. Dr Miguel Gomes from the Portuguese Medicines Agency [15] reported that following the 'Memorandum of Understanding' with the 'Troika' (International Monetary Fund, European Central Bank, European Commission), savings measures were swiftly implemented. Previously, Portugal's pricing system for generics set a reference price (i.e. reimbursement amount within a cluster of medicines of identical active ingredient, dosage and pharmaceutical form [12]) defined by the highest priced generics in the cluster [11, 16]. This situation had been criticized as a lost opportunity for savings [17, 18]. Portugal was the only country of the EU to have higher generics market shares in value than in

volume [1], which is an indicator of a high price level of generic medicines. A change in methodology in 2010 led to the reference price being redefined as the average of the five cheapest generics [19]. Dr Gomes presented data on how the generics market had developed well, from a starting point of 3.5% in volume in 2003 to a break-even point in 2010 at which generics shares became lower in value than in volume, see Figure 1. Additional data on the development of the average generic prices confirmed a reduction in prices of generic medicines from the first months of 2010 onwards [15]. Generics policies therefore need to be designed for maximum potential benefit.

Case studies of enhancing generics uptake

Some European countries reported about differences in price between original products and generic medicines, for example, regarding generic omeprazole and simvastatin ([20], see also the article [21]) generic ACE (angiotensin-converting-enzyme) inhibitors and SSRI's (selective serotonin re-uptake inhibitors).

Dr Kristina Garuoliene, from the Lithuanian National Health Insurance Fund demonstrated how her country, with its small population, was able to achieve considerable price reductions for generic versus originator medicines, see Table 1 [22]. Dr Kristina Garuoliene also presented a case study of clopidogrel and described how public authorities and payers were concerned about how differences in the salt composi-

tion, and indications, between originator and generic clopidogrel could potentially reduce savings from generics availability. Responding to efforts by the originator company to retain sales, authorities adopted 'pragmatic approaches' to enhance generics prescribing, e.g. mandatory generic substitution, educational activities, see Table 2 [23, 24]. Still, the differences in the reimbursed prices of generic clopidogrel versus the originator were high across Europe, especially briefly after launch, but decreasing over time.

In Abu Dhabi, a new policy for generic medicines, including compulsory International Non-proprietary Name prescribing, was introduced in 2009. However, the expected savings did not fully materialize

Figure 1: Development of generics market share in Portugal, 2003–2011 [15]

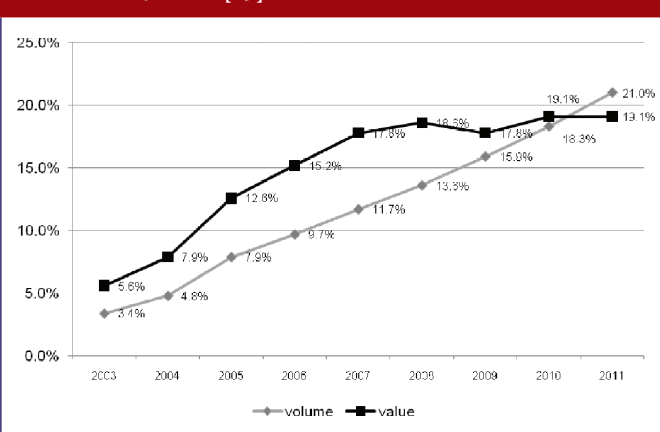


Table 1: Lithuania. Reduction (in percentage) in reimbursed expenditure/DDD for selected generic ACEI in 2009, and selected SSRI in 2007, compared to originator prices in 2001 [22]

Generic ACEI	Year generics first available	% reduction versus originator 2001 prices
Generic enalapril	1997	52%
Generic ramipril	2004	65%
Generic quinapril	2006	50%
Generic fosinopril	2006	42%
Generic SSRI	Generics available 2001	% reduction versus originator 2001 prices
Fluoxetine	Yes	92%
Citalopram	No	88%
Sertraline	No	85%

ACEI: angiotensin-converting-enzyme inhibitors; DDD: Defined Daily Dose; SSRI: selective serotonin re-uptake inhibitors.

Table 2: Strategies to enhance generic clopidogrel use and reactions from the pharmaceutical industry [23]

Country	Year reimbursed	Activities
Activities by authorities		
Austria	2008	Authorities wrote public letters stating no difference between generic and originator drug, in response to cardiologists' concerns. Activities to enhance generics prescribing include no prescribing restrictions, financial incentives to physicians and regular publications.
Croatia	2006	Reference pricing based on the lowest priced molecules encourage prescribing of generics versus originator.
Germany	2008	Differences in salts and indications were dismissed by physicians, aided by educational inputs such as letters and articles. Other generic clopidogrel-enhancing activities include rebate negotiations and financial incentives.
Lithuania	2009	Acceptance of mandatory INN prescribing for clopidogrel. Community pharmacists obliged to stock cheapest generics to force down prices (already leading to a reduction in originator prices).
Scotland	2009	A pragmatic approach with area Drugs and Therapeutics Committees recommending prescribing of generics aided by high INN prescribing and low prices for generics (with market forces).
Delaying tactics		
Norway	2010	Generic clopidogrel reimbursed in January 2010. However, patent and indications were challenged leading to removal in October 2010. Accepted again in March 2011 with extended indications.
Portugal	2009	First generics approved in April 2009 and reimbursed in December 2009. Some generics formulations later withdrawn due to manufacturing concerns. However, others withdrawn following lawsuits by originator leading to temporary suspension (12 formulations to date).
Slovenia	2010	Generic clopidogrel available June 2006 to June 2008. Subsequently withdrawn following successful challenge by originator company. Available and reimbursed since May 2010.
INN: International Non-proprietary Name.		

since there were no accompanying measures to support an increased generics uptake. Abu Dhadi is now exploring a policy of introducing demand-side measures, including educational activities and the introduction of a reference price system for medicines grouped together if they had the same active ingredients [25].

GaBI (Generics and Biosimilars Initiative) at the 'Meet the Editors' session

The relevance of generics was highlighted at the fringe 'Meet the Editors' session where Dr Brian Godman presented the *Generics and Biosimilars Initiative Journal*, of which he is a member of the International Editorial Advisory Board.

Conclusion

In the final panel discussion, experts from the Norwegian Directorate of Health, OECD, the Southern African Development Community, the WHO Collaborating Centre at Harvard University and WHO Europe stressed the importance of generics policies. The following consensus statement was issued in a conclusion document: 'Generic[s] policies appear not to be fully exploited yet. At the PPRI Conference, generics were identified as one area where competition works. There is common understanding that savings from generics might be invested for funding innovation. However, as evidence on generics penetration across the countries

demonstrated, generics uptake could be improved by more consistent generic[s] policies' [26]. The PPRI Conference confirmed that in order to achieve the best possible benefits from generics policies, they have to be carefully designed and implemented in a consistent way.

This is an original report from the PPRI Conference. Conference presentations, abstracts and posters are publicly accessible online at [//whocc.goeg.at/Conference2011/Programme](http://whocc.goeg.at/Conference2011/Programme)

For patients

The PPRI Conference offered several good practice examples as well as a few less successful stories about the implementation of generics policies. Such sharing of information is crucial for policy-makers to know the impact of generics policies. Well-informed policy-makers can contribute more effectively towards improving the accessibility of medicines, e.g. by applying generics policies in a consistent way and thus creating opportunities for innovation.

A further conclusion from the conference was that the perspectives of consumers and patients should be taken into account. Participants were reminded that pharmaceutical policies should benefit all citizens, especially vulnerable groups, and that their perspectives should be actively considered.

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