Reviewer's report

Title: Impact of price regulation on the utilization of generic cardiovascular medicines: A hospital study in Chongqing, China

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Reviewer: Brian Godman

Reviewer's report:

I have no major revisions to suggest – overall only minor revisions/suggestions to enhance the manuscript for potential readers inside and outside China.

A) General

Overall, I found the study very interesting and easy to understand. I also thought the analysis was appropriate given the limitations with data collection in China. I agree for instance with the product selection (Page 3), the data source (top of page 4), the use of actual procurement prices (Page 5), the 6 monthly time periods chosen and calculations of potential savings. In addition, the various calculations and the study limitations.

However, there are general and specific areas to consider to enhance the content of the paper. These are:

B) General (essential minor revisions)

• Better to use ‘patented’ rather than ‘branded’ to avoid any confusion as there are branded generics available in a number of countries. This can be added to the definitions use (page 4)

• Also good to expand in various sections whether dealing with generics vs. originators (ATC Level 5) or versus patented products in a class (ATC Level 4). I believe the author is mainly referring to ATC Level 5 but good to confirm this

• Regulations for the marketing authorisation of generics in China, i.e. similar to FDA regulations? This is because concerns with the quality of generics may be one reason for their generally low utilisation as seen in some European and other countries. In addition, at the top of page 10 - the author suggests that a potential future measure could be ‘further evaluation of quality consistency between generic and branded drugs should be performed’

• There are times when references could be included for the statements made – suggestions are included below

• There are also times when the English could be tightened – perhaps the journal can help with this

C) Specific (both essential and discretionary) revisions

i) Background
a) Page 1 – First paragraph – add further references to enhance the content. Possible references and information that could be added include:

- OECD have published a report showing that pharmaceutical expenditure has grown by more than 50% in real terms during the last decade - so may be worth including (page 154 - http://www.oecd.org/health/health-systems/49105858.pdf). Other potential references including country specific references on the reasons behind increasing scrutiny over pharmaceutical expenditure can be found in e.g. Godman B, Abuelkhair M et al. Payers endorse generics to enhance prescribing efficiency; impact and future implications, a case history approach. GABI 2012; 1(2): 69-83 and Godman B et al. Essential to increase the use of generics in Europe to maintain comprehensive healthcare? Farmeconomia: Health Economics and Therapeutic Pathways 2012; 13 (Suppl 3): 5-20

- Prices of originators only typically fall in European countries where there are reference prices for the molecule, i.e. patients have to fund the additional price themselves for a more expensive drug than the current reference priced molecule, which they are often reluctant to do, e.g. in Sweden with acceptance of compulsory generic substitution – references, etc., in Wettermark B et al. Recent national and regional drug reforms in Sweden – implications for pharmaceutical companies in Europe. Pharmaco economics 2008; 26: 537-550 and recently for losartan in Sweden (Godman B et al. Influence of multiple initiatives in Sweden to enhance ARB prescribing efficiency following generic losartan; findings and implications for other countries. Int J Clin Pract 2013 Apr 8. doi: 10.1111/jicp.12130. In for instance the UK, there is no obligation for the manufacturers of originators to lower their prices once generics become available. However, there are high INN prescribing rates, e.g. Bennie M et al. Multiple initiatives continue to enhance the prescribing efficiency for the proton pump inhibitors and statins in Scotland. Expert Review Pharmaco economies and Outcomes Research 2012; 12: 125-130. Consequently, suggest revising the comment made

- Prices of generics can be as low as 2% to 10% of pre-patent loss prices in Netherlands, Sweden and UK through high INN prescribing, compulsory generic substitution with the cheapest generics and transparency in the pricing of generics (References mentioned). This includes the Netherlands with its preference pricing policies (building on ref 8 - van Woerkom M et al. Ongoing measures to enhance the efficiency of prescribing of PPIs and statins in the Netherlands; influence and future implications. Journal of Comparative Effectiveness Research 2012; 1: 527-38). May be worth mentioning this in the introduction as this reflects a possible goal for the authorities in China

- There have also been increasing use of generics in Portugal with recent measures (mentioned in the Farmeconomia reference – above) – as the author has referenced a paper from Portugal in the introduction

- There are substitution targets for pharmacists in France – mentioned in e.g. Farmeconomia reference as well as Sermet C et al. Ongoing pharmaceutical reforms in France; implications for key stakeholder groups. Applied Health Economics and Health Policy 2010; 8: 7-24. May be worth including this as a
comment, e.g. pharmacists’ incentives to dispense generics

b) Page 1 – second paragraph

- Better to say ‘INN name’ rather than ‘generic’ name – Line 5 – as in line with academic publications

- Line 5/6 – why has INN prescribing not been followed up by the Chinese government (and also address this in the discussion – later)? Now see compulsory INN prescribing increasing in some countries, e.g. Lithuania - Garuoliene K et al. European countries with small populations can obtain low prices for drugs: Lithuania as a case history. Expert Rev. Pharmacoeconomics Outcomes Res 2011; 11: 343-9, with trends in INN prescribing likely to continue to help conserve costs as well as reduce potential patient confusion especially if patients are dispensed a different branded generic on each occasion with slightly different names

- Line 8 – Do you mean ‘In China, the potential separation of drug prescription ….’ as you go on to state that the proposal has attracted much discussion but not implementation as in Japan, Korea or Taiwan. In addition on Page 3 under data sources state ‘under the current situation of no SPD’

c) Top of page 2 – It would be good to have more details of the inducements for doctors to overprescribe drugs as well as prescribe those with the highest profit margin (Ref 17) to give more substance to the rest of the paper and interesting information for the readers of this paper

ii) Methods

- Top of page 4 – second line – you refer to ‘we’ – do you mean ‘I’ as only one author?

- Start of second paragraph under ‘Selection of generics’ – not sure what is meant by ‘two specifications with one product’ – I suggest this needs further explanation


iii) Discussion

- Page 8 – lines 4 and 5. Does the author mean ‘volume index of branded drugs
to generics was 1.63’ rather than ‘volume price index’. In addition, possibly ‘the volume of branded drugs was 63% higher than generics’ rather than discussing price and then volumes?

• Page 9 – Agree that a number of factors are needed for a sustainable generics market. Some of these are outlined in Dylst P et al. Generic medicines: solutions for a sustainable drug market? Appl Health Econ Health Policy 2013. DOI 10.1007/s40258-013-0043-z, which the author may wish to look at

• Page 10 - Additional supply side measures could include greater transparency in the pricing of generics (as seen in e.g. the UK – Bennie et al and paper in Farmacoeconomica). Demand-side measures could be ensuring INN prescribing is monitored/enforced (see earlier), implement strategies to limit corruption/abuse of rebates as seen recently in Korea (Yu SY, Yang BM, Kim JH. New anti-rebate legislation in South Korea. Appl Health Econ Health Policy. 2013 Aug;11(4):311-8); and potentially prescribing restrictions for patented drugs in a class vs. generics where these are seen as similar in all/nearly all patients, e.g. statins in ‘Godman B et al. Combination of prescribing restrictions and policies to engineer low prices to reduce reimbursement costs. Expert Rev. Pharmacoeconomics Outcomes Res. 2011; 11: 121–9’ and others as well as ARBs in for instance ‘Bucsics A et al. Influence of lifting prescribing restrictions for losartan on subsequent sartan utilisation patterns in Austria; implications for other countries. Expert Review Pharmacoecon Outcomes Res 2012; 12: 809-19’

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare I have found no competing interests