Reviewer's report

Title: Generic Medicines: Do You Get What You Pay For? A Review Of The Differences And Similarities Between Generic Drugs And Their Proprietary Counterparts, Including Economic Benefits Associated With Usage Of Generic Medicines, Using Ireland As A Case Study.

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Reviewer: Atholl Johnston

Reviewer's report:

This is a well written description of progress a generic formulation needs to go through on order to get marketing approval. However the economic argument advanced for the possible savings that may arise from the use of generics is too simplistic focusing as it does solely on the acquisition cost of the drugs and ignoring any possible additional costs that might arise from the use of generics.

Major Compulsory Revisions

The authors also take a simplistic approach to the efficacy and safety of generic products. Rather like homeopaths they assume, without evidence, that these formulations are safe and effective and therefore don’t need to be tested for therapeutic equivalence against existing products. In a 48 page article they devote a scant page and a half and 9 references out of 107 to the question “Are generic medicines really the same as brand name medicines?”. Their breath of coverage of this topic is very narrow and deals very superficially with only three drug classes. Their mention of differences in Fosamax generics, for example, is referenced by a newspaper article rather than any of the number of peer reviewed papers on this subject.

The authors fail to discuss therapeutic areas where generic substitution is not supported by medical opinion, for example, modified release formulation, narrow therapeutic index drugs etc.

There should also be some discussion about switchability and prescribaility of generic medicines, that is can patients’ drugs be switched between generics. In addition, the authors have not discussed the attitude of patients to generic substitution or the detrimental effects on treatment persistence and adherence that can result from the widespread and random use of generics.

The authors have also ignored the topic of therapeutic substitution, a very ethically questionable practice that has arisen from generic substitution. This is the pressure that has been exerted on doctors by payers to switch patients from their existing drug therapy to another drug in the same class solely for economic, and not medical, reasons. For example from atorvastatin to simvastatin, because the latter has gone “generic” while the former remained branded.
Discretionary Revisions

Finally, like it or not, major pharma contribute, support, and pay for a great deal of medical education and patient support. This is a hidden benefit which health authorities fail to acknowledge. However, these functions need to be funded and who is going to bear that cost?

Quality of written English: Acceptable

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

Declaration of competing interests:

I have been, and am, a consultant for, and own stock in, several pharmaceutical and biotech companies. I, my family members, and friends use generic and branded drugs. I am also a tax payer and fund, at least in part, the National Health Service in the UK.