Letter to the Editors

Generic substitution: authors' response

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We thank Professor Peterson for clarifying the standards by which regulatory authorities consider the bioequivalence of generic products. We did not intend to perpetuate a myth that downplays the quality assurance for equivalence of generic drugs and, if this was the result, we apologise.

Since our publication went to press, the Department of Health (DoH) in England (speaking for the whole of the UK) decided against plans detailed within the 2009 Pharmaceutical Price Regulation Scheme (PPRS) for pharmacist-led generic substitution of medicines in primary care [1]. Following a consultation process, the DoH was swayed in its decision by the 'strong perception (by consultees) that generic substitution poses a threat to patient safety'. However, looking at the responses it seems that many others were in favour of these plans. The DoH was also unconvinced of the cost-effectiveness of generic substitution, recommending instead that other mechanisms should be utilized to support the use of generic medicines.

As noted in our article [2], only in a minority of cases is generic substitution inappropriate, and the proposals permitted the dispensing of a branded medicine when indicated explicitly by the prescriber. Nevertheless, concerns about the minority have seemingly influenced a decision that would have saved the NHS millions of pounds annually.

Moreover, in anticipation of the efficiencies achieved from generic substitution which the drug companies involved had agreed to, the PPRS made provisions for a 0.5% compensatory increase in the price of branded medicines, which account for around 80% of the NHS drugs bill, over the next 3 years. Thus while the proposal for generic substitution has been shelved, the costs of branded medicines to the NHS in the UK are allowed to rise. This decision seems perverse at a time of financial austerity.

Competing Interests

There are no competing interests to declare.

REFERENCES

- 1 Department of Health. The proposals to implement 'Generic Substitution' in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009. Response to the Consultation. 2010. Available at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_120431 (last accessed 21 December 2010).
- 2 Duerden MG, Hughes DA. Generic and therapeutic substitutions in the UK: are they a good thing? *Br J Clin Pharmacol* 2010; 70: 335–41.

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