Volume 10 • Number 6 • 2007
VALUE IN HEALTH

International Price Comparisons for Novel and Follow-on Drugs: A Response

Elizabeth Ellen Roughead, PhD,[1] Ruth Lopert, Bmed, MMedSc,[2] Lloyd Norman Sansom, AO, PhC, BsC, PhD[1]

[1]Sansom Institute, University of South Australia, Adelaide, SA, Australia; [2]George Washington University, Washington DC, USA

Ridley [1] acknowledges that two recent studies have shown that when innovative medicines that provide a substantive health gain are considered, prices in developed countries are comparable with those in the United States [2,3]. He goes on to suggest that price differentials for follow-on or "me-too" drugs require further study as these prices are also important for global pharmaceutical research and development (R&D), international trade policy, and US government procurement of pharmaceuticals. We believe there are a number of assumptions in the debate about prices of follow-on drugs that deserve challenge.

Both Ridley [1] and Calfee et al. [2] characterize mechanisms for establishing which pharmaceuticals will be funded in other countries as "price controls." This assertion is not necessarily correct from other country perspectives. The Australian system is considered to be about valuing pharmaceuticals and implicit in that valuation is a judgment about the type of R&D that is valued. Lower prices for follow-on or me-too products should be considered a signal to the pharmaceutical industry that research in these areas is not valued as highly. What is perceived as price control may equally be perceived as the impact of market forces. The differential which is not acknowledged in the global debate is the extent to which differences in prices reflect differences between US values and those of other countries, particularly when the value applies to follow-on or me-too medicines where the output may be valued very differently. It is difficult to uphold the argument that other countries should pay for R&D that the United States values but other countries may not.

Ridley also highlights the argument that other countries' pharmaceutical reimbursement systems are "slowing the process of drug development worldwide" [4]. Pharmaceutical R&D expenditure has risen from approximately $18 billion in 1990 to $37 billion in 2002, proportional to increased sales [5]. In most developed countries, pharmaceutical expenditure has risen at a faster rate than overall health expenditure [5]. Thus, pharmaceutical R&D funding is likely to have grown proportional to health R&D. This contention is supported by data which show that pharmaceutical R&D was 37% of all health R&D in 1988 in the United States, Canada, France, Germany, and Japan. By 1997 this had risen to 46% [6]. Given the further increase in pharmaceutical expenditure since 1997 as a proportion of all health expenditure, it is likely to be even higher today. By comparison, pharmaceutical sales only represent 12–20% of health expenditure [7]. Given these data it does not seem unreasonable to question whether we are currently overinvesting in pharmaceutical R&D, which is not targeting unmet clinical needs.

Finally, the lack of transparency of US prices is often neglected in these debates. All international pricing studies that suggest the US prices are higher should be viewed with caution until US pharmaceutical prices achieve full transparency. Calfee et al. did not include rebates in their analysis of US prices and yet, added rebates to the German prices [2]. Published data from 2006 show that for 29 of the 43 products in Calfee et al.'s study [2], Veterans Affairs—Federal Supply Schedule prices and Big 4 prices were lower than the Federal Supply Schedule prices. Our study also found that the US government obtains substantial discounts even on innovative medicines [3]. Until prices are transparent, we have no reason to believe that significant discounts are not also available to pharmacy benefit managers and other large institutional purchasers.

Countries have adopted mechanisms for making decisions about purchasing and valuing pharmaceuticals not solely in response to future R&D needs, but also taking into account current population needs. The Australian reimbursement system, which operates within the context of the National Medicines Policy [8], specifically identifies this objective of balancing the needs of access for both individuals and communities with the needs of a viable and responsible pharmaceutical industry. Achieving a balance between health gains that could be made for the community now and health gains possible in the future is imperative, but not well understood and clearly valued differently in different countries. Very often when the debate focuses on prices and their putative impact on future R&D, the effect of high prices on health gains foregone because of the lack of access is ignored. Health, pharmaceutical, and trade policies should aim to balance these needs.

Address correspondence to: Elizabeth E. Roughead, Sansom Institute, University of South Australia, Adelaide, SA 5000, Australia. E-mail: libby.roughead@unisa.edu.au

10.1111/j.1524-4733.2007.00248.x

1098-3015/07/512 512–513

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