To the Editors:

The drug regulatory authority

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I refer to the letter in the *CMJ* titled 'All that glitters in glitazones' (1).

The authors are advocating that the Drug Regulatory Authority (DRA) be allowed to consider cost effectiveness in addition to efficacy, safety, and quality, when evaluating a new drug for registration. They are alluding to the present position in the National Health Service (NHS) of the UK as an example. However, their argument is not correct.

The Medicines Control Agency (MCA) is responsible for registration of drugs in the UK. It considers efficacy, safety and quality only. Whether a drug is cost effective and should be used in the NHS is now decided by the newly formed National Institute of Clinical Excellence (NICE).

The DRA is the parallel authority to the MCA of the UK. Therefore, like the MCA, it should continue to confine itself to evaluating efficacy, safety and quality. Whether a new drug is available for prescription in the government health service is decided by the government of Sri Lanka. The government does not include a drug in the government drug list until there is agitation for its inclusion by clinicians. Hence new drugs are not available for patients in the government health service for many years after they are available in the local private sector and internationally. In fact, the DRA is so cautious that most new drugs are registered in Sri Lanka few years later than in many other countries.

Zanamavir is available for prescription outside the NHS by private practitioners (though a few in number), by specialists and general practitioners. Then it has to be

purchased by patients. The position is similar in Sri Lanka. Of course, the private sector in Sri Lanka is much bigger than in the UK. Even in the UK the private sector is expanding. Today 850 000 people the UK receive treatment each year in private facilities, where about 20% of elective surgery is now performed (2) .

The range of drugs available for prescription in the NHS is much wider than in the government health service of Sri Lanka. This is especially so for new drugs.

If the situation today in Sri Lanka is: 'One who decides does not pay and the one who pays does not decide'(1), whose fault is it? It is obviously in the medical profession who have no time to communicate with patients. Medical teachers should also take at least part of the blame.

If Sri Lanka is to be a modern country, new drugs of proven efficacy, safety and quality should be available for prescription at least in the private sector. If not, a few will get them through special import license, a few will get them from abroad, but the many who can afford them will be deprived.

The DRA should play a role similar to the MCA and not combine the roles of MCA and NICE.

References

1. de Abrew K, Mylvaganam S, Samarasekera MS. All that glitters in glitazones. *Ceylon Medical Journal* 1999; **44**: 184-5. (Letter).
2. Editorial. Echoes across the Atlantic. *Lancet*, 1999; **354**: 351.

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