To the Editors:

In reply

Cost-effective drugs? It depends on what door is chosen

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This letter on the Drug Regulatory Authority (DRA) and what its function should be raises important questions. Quoting the examples of the Medicines Control Authority (MCA) in the UK as an example, Dr. Jayasuriya advocates that the Sri Lankan DRA too should not concern itself with cost-effectiveness.

I begin with a statement of fact – DRAs do concern themselves with cost-effectiveness; the "need clause" by the Norwegian DRA is the best known example, and Swedish, and Dutch DRAs too examine cost-effectiveness during registration. Therefore, some countries routinely examine cost-effectiveness during drug registration. Cost-effectiveness is not examined during registration in the UK for a simple non-medical reason, but the explanations are rather lengthy.

The Department of Health (DoH) in the UK (under whose umbrella the MCA functions) regulates as well as promotes the pharmaceutical industry. This results in the DoH having a schizophrenic attitude as both customer and sponsor of the industry. Last year the industry sold over 6 billion sterling pounds worth of drugs to the National Health Service (NHS), and also earned over 3 billion pounds in exports. This sponsor/customer relationship is well demonstrated by how benzodiazepines are handled; there are at least 13 registered in the UK but only 5 generic versions are made available in the NHS. Flunitrazepam is out, diazepam is in, Valium is not; nitrazepam too is in but not Mogadon (2). Cost-effectiveness has therefore been introduced by the "back door". However, because all the 13 benzodiazepines and the expensive brands of 5 are registered, they can be manufactured and exported legally through the "front door".

All the drugs that are registered in the UK are available in the private sector as stated by Dr. Jayasuriya, but the private sector is miniscule. By figures that he quotes it constitutes less than 2% of the health care provided. The DoH takes no action in this tiny market. However, it did react to the possibility of the NHS budget having to pay for new drugs that it considers ineffective. When the European Medicines Evaluation Agency (EMEA) was established, European Community countries were required to register any new product that the EMEA approved. The NHS would then have to make these drugs available too.

So DoH established the National Institute of Clinical Excellence (NICE), which would recommend on the basis of cost-effectiveness, what new drugs would become available in the NHS. This neatly side-stepped the effect of the EMEA approvals. Again cost-effectiveness has been intro-

duced into the NHS in the UK, this time through the "side door", but as previously, not through drug registration. All indications are that drugs considered unsuitable for the NHS by NICE will continue to be registered in the UK. Zanamavir, if rejected for the NHS, will be limited to the 2% of patients of the private sector of the UK, but presumably will be exported through the "front door" to Sri Lanka to be made available without limitations to 100% of the patients in Sri Lanka.

What are the consequences of not having cost-effectives as a criterion in drug registration in Sri Lanka? Two examples will suffice. Ranitidine was registered in Sri Lanka by the company which developed the drug, and the product made in the UK was sold at over Rs. 30 a tablet. However, this same company manufactured ranitidine in India and sold it for Rs. 3. The Indian product was not made available to the patients in Sri Lanka and attempts to import it by third parties were blocked (2). The only possible reason was a much bigger profit.

The second example is of ondansetron, undoubtedly the most effective anti-emetic for patients undergoing cancer chemotherapy. The company that discovered it has registered the drug, and post-registration there has been a steep increase in price far in excess of the depreciation of the rupee against sterling. Ondansetron is available in India by another manufacturer at one-sixth of the price in Sri Lanka, but as with the cheaper ranitidine mentioned above, it cannot be imported into Sri Lanka. Some patients who had cancer chemotherapy without the cover of ondansetron got intractable nausea. They did not return for subsequent treatment and presumably died prematurely.

Discovering new drugs is an expensive process and pharmaceutical companies cannot be expected to give away drugs. Nevertheless, there are schemes implemented in Sri Lanka where special drugs are made available at reasonable prices with controls to prevent abuse of the scheme (3). In the case of ondansetron no such schemes have been thought of, and the sole objective seems to be profit, some might even say greed.

How would cost-effectiveness as a criterion for registration in Sri Lanka have helped in these situations? The international treaties on Intellectual Property Rights allow governments to consider public health need which could include cost-effective drugs. If appropriate regulations were in place in Sri Lanka, it would have been possible for cost-effectiveness to be one of the criteria for registration.

The editor of the *British Medical Journal* recently commented on "power and responsibility" (4). It is well worth reading. The SL DRA appear to have the "responsibility without the power"; responsible to ensure relevant and affordable drugs but little or no power to achieve it. On the other hand, along with some other socially dubious groups, the pharmaceutical companies appear to have the "power without the responsibility", the power to sell drugs at whatever prices they want, but with no responsibility towards the patient.

References

1. Hypnotics and anxiolytics (Chapter 4.1). British National Formulary. Royal Pharmaceutical Society of Great Britain and British Medical Association. March 1990 issues onwards. (Note – NHS symbol crossed out).
2. Weerasuriya K, Goonaratna C. Rationing in developing countries. *British Medical Journal* 1992; **304**: 1440.
3. Eddleston M, Weerasuriya K, Olliaro P. Ethics review and clinical trials. *Lancet* 1998; **351:** 1066.
4. Smith R. Doctors and nurses: a new dance? *British Medical Journal* 2000; **320**: 0. (15 April) (Editor's choice).

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