Improving access to essential drugs for people living with HIV/AIDS

K Balasubramaniam

There is an ongoing global debate on improving access to essential drugs for people living with HIV/AIDS (PLWA). Treatment activists need objective and factual information on the relevant aspects of HIV/AIDS drugs to enable them to fully participate in the debate, organise campaigns to increase awareness among the general public and to lobby national governments to introduce public policy measures to ensure regular availability of essential HIV/AIDS drugs at affordable prices.

Many PLWA living in most developed countries are now able to live relatively healthy and productive lives. They have regular access to the drugs they need. Universal social health insurance in all developed countries (except the US) ensures that the burden of drug costs is not borne by any individual. On the other hand, PLWA in developing countries have to pay for their drugs; there is no social health insurance in these countries.

HIV/AIDS is a relatively new infection. The specific drugs to treat it have been recently introduced into the market by multinational drug companies. They own patents on the drugs, enjoy a monopoly market and fix very high prices arguing that they need the profits to recover the enormous costs incurred in research and development (R & D) of the drugs.

This paper describes two strategies to reduce the cost of HIV/AIDS drugs and also shows evidence to contradict the industry's justification for the high prices. The two strategies are compulsory licensing and parallel importing.

Compulsory licensing

Compulsory licensing involves a government giving a manufacturer a licence to produce a drug for which another company holds a patent, in exchange for the payment of a reasonable royalty to the patent holder.

Dr K Balasubramaniam,
Pharmaceutical Adviser, Consumers International Regional Office for Asia and the Pacific, PO Box 1045, 10830 Penang, Malaysia.

The manufacturer who gets a compulsory licence will put into the market the same drug at a much lower price. There will be price competition and the original producer of the patented drug will be forced to bring his price down.

India offers the best example of this type of competition, where the originator of the branded product lowers his price. But this was not by compulsory licensing. The Indian patent law of 1970 did not provide patent protection for pharmaceutical products; protection was given to processes only. When a new drug would be introduced into the world market, Indian scientists and research workers would develop a new process - different from that used by the originator and patented in India.

This is called reverse engineering. For example, ranitidine is a common anti-ulcer drug introduced into the world market in the early 1980s. Glaxo marketed it as Zantac in all Asian countries and as Zinetac in India. Indian manufacturers produced the drug and competed with Glaxo who, in 1998, sold 100 tablets of Zinetac (150 mg) at a price equivalent to US$2.00 in India. However, in other Asian countries where there was no competition, prices were much higher - $61 in Sri Lanka, $55 in Malaysia, $61 in the Philippines and $183 in Mongolia. Similar competition has brought down the price of drugs for HIV/AIDS. The Washington-based Consumer Project on Technology estimates that prices for HIV/AIDS drugs can be reduced by up to 90 per cent of the prices charged by the originators if compulsory licensing is allowed. With the new national legislation on patents to be introduced, India will have to provide patent protection to products and processes. Indian manufacturers cannot produce new drugs by reverse engineering. But the government can give compulsory licensing to an Indian manufacturer to produce a generic version of the branded drug. The TRIPs Agreement allows compulsory licensing.

Parallel importing

Parallel importing involves a government or an importer in a country shopping around in the world market for lower-priced equivalents, importing them and not accepting the higher-priced drugs in the domestic market.

Prices of the same product manufactured by the same company can vary widely among countries, as in example of prices of the drug Zantac referred to earlier. In the European Union (EU), parallel importing of patented products is widely used. It is an effective method to lower prices to consumers. The European Commission encourages parallel imports. Multinational drug firms, which had obstructed parallel importing within the EU, have been fined by the European Commission. Parallel importing of generic drugs is also possible.

According to the United Nations Industrial Development Organization, approximately 90 developing countries in the world have no capacity to manufacture drugs. They import 100 per cent of their requirements as finished products. For these countries, parallel importing is one of the best ways to improve access to essential drug. The TRIPs Agreement allows parallel importing. The TRIPs Agreement allows compulsory licensing and parallel imports, two very effective strategies to reduce drug prices and improve access to essential drugs for PLWA.

Unfortunately since the creation of the World Trade Organization, the United States government, through its trade representative, continues to exert strong pressure on developing countries, particularly those with a viable pharmaceutical industry, to adopt national legislation on intellectual property rights which will provide a higher level of patent protection than is required by the TRIPs Agreement. A number of developing countries have adopted, or are considering, national legislation which is far more restrictive, including not allowing compulsory licensing and parallel importing. It is indeed ironical that parallel imports of a range of goods routinely flow into the United States itself; compulsory licenses for certain patented technologies are given in the US.

Developing countries should not be in a rush to initiate the complex process of reform of national legislation on intellectual property rights and provide for strong patent protection before the end of the transitional period in 2005 without studying the short- and long-term implications of the reform.

In this context, it is relevant that in May 1999, after more than a year of debate, the World Health Assembly unanimously adopted resolution WHA 52.19 on the Revised Drug Strategy, calling upon member states to ensure that public health interests are paramount in pharmaceutical and health policies; and to explore and review their options under the relevant international agreements, including trade agreements, to safeguard access to essential drugs.

This resolution gives the World Health Organization (WHO) a new mandate to monitor the health implications of trade agreements and provide assistance to countries in implementing trade resolutions while protecting public health. Over the past six months high officials from the WHO, the World Bank and UNAIDS and several national governments have expressed support for the use of compulsory licensing of patents to address the global HIV/AIDS crisis.

Compulsory licensing and parallel importing are, therefore, not issues for academic discussions; they are strategies that can and should be written into national legislations on intellectual property system of developing countries.

Having put compulsory licensing and parallel importing in their proper perspectives, it is relevant to critically examine the arguments put forward by the research-based multinational industry that the high prices for new and innovative drugs are necessary to recover the enormous capital investment on R&D which made introduction of the drugs possible, and also to put in capital to continue R & D for yet more new drugs.

As mentioned earlier, HIV/AIDS is a relatively new infection and the specific drugs frequently needed by PLWA are new, protected by patents and enjoy a monopoly market. Prices are determined by manufacturers who fix very high prices.

There is some evidence that the high prices have no relation to the cost of research and development that preceded the introduction of the drug. The best example is pentamidine, a very cheap drug developed to treat sleeping sickness in Africa. However, when it was found to be effective in the treatment of an HIV/AIDS related infection – PCP (pneumocystitis carinii Pneumonia) - the price of pentamidine increased 500 per cent. A recent survey of 20 African and South-East Asian countries conducted by UNAIDS found that pentamidine is available in only one of these countries.

Secondly, it has been shown that the industry has not carried out the original research and development for all the drugs they patent, market and enjoy monopoly pricing. The industry's efforts for some drugs were the development of alternative copycat drugs to government-produced drugs (e.g. the protease inhibitors, new nucleoside analogues).

Every class of drug for HIV/AIDS was discovered, tested and developed by government agencies. Among these drugs are ddI, AZT, d4t, Ritonavir and T-20. The drug industry's argument that the high prices have been fixed to recover the enormous cost of research and development is, therefore, not at all valid.

In conclusion, there is certainly a need for transparency. Consumers need to know the real costs of development and introduction of new drugs and the basis on which their prices are fixed.

Secondly consumers agree that effective patent protection is essential for innovation. But patent legislation should protect both the innovator and the consumer.

The present WTO international trade agreements provide a very sensible way of balancing the interests of the patent holders and public health through compulsory licensing and parallel importing – two strategies that will lower the cost of essential drugs for HIV/AIDS.

This report draws substantially on material prepared and distributed by Consumer Project on Technology and postings on Treatment Access Forum, an electronic list serve discussion group.

Pharmaceutical industry

Pharmaceutical industry; one of the flourishing industries; as the shares are floated everywhere, and priced all-time elsewhere.

Also contribute for research and science, find out new drugs, and conduct new trials; for health and welfare.

In addition, introduce wonder drugs, in developing countries, and abuse promotional privileges
All were highlighted many times.

Despite huge profits, industries feel beleaguered
As attacked by consumers, for high prices and large profits.

True, heavy blow to the industries, in view of awareness among public, carers and care providers, as well, introduction of essential drugs.

Also, cost-effective procedures, cost containment measures, health reform measures; all, likely to cap drug prices.

Cost consciousness among doctors, restriction from reimbursing agencies, questioning from the patients or consumers, have influenced the prescribing practrices.

Free market policy has threatened the pharmaceutical industry
Some collaborate with foreigners, or with other multinational companies.

To provide quality drugs, compete in the markets, and to introduce newer molecules.
Let them fix an acceptable price.

Pharmaceutical organisations conduct company sponsored education programmes, request physicians' participation, for the time spared, provides compensation in various forms; compliments, lunches, dinners, family tours, and at times cash incentives.

The programme is mostly educational
Consultative and promotional
Following participation, practitioners are deviated to compulsive prescription.

Pharmaceutical promotion not only towards doctors, but also, to pharmacists on OTC formulations and generics, by offering awards in various forms, let us all avoid unethical practices.

Intense price competition, indigenous preparation, and reduced taxation, certainly, will bring down prices.

Sufferers are neither supported, nor insured (mostly)
Let them not be fleeced, as their financial status is awkward.

Hence, industry should take measures
To curb theinflated costs, also reduce middleman profits, and make the sick to enjoy the benefits.

P Thirumalaikolundasubramanian *and* ***A Uma****, Madurai Medical College, Madurai.*