

# Twenty-five years of essential drugs: A panel disussion

*Following the presentation of papers at the Amsterdam symposium a panel discussion went further into the issues of Essential Drugs. Some of the ideas raised are presented in brief below*

## **The WHO Certification Scheme**

It is widely felt that the WHO Certification Scheme for pharmaceuticals moving in international commerce fails to provide the reliability which importing countries seek; in particular the fact that some exporting countries issue Certificates under the Scheme which are not based on proper regulation and inspection of manufacturing plants undermines the authority of the Scheme as a whole. One solution which has been mooted is that importing countries should band together, perhaps with donor support, to perform inspections of the plants in the countries from which they buy; another approach could be to publicize instances in which the Certificates issued by particular national authorities have been found untrustworthy. It is difficult for WHO – as an international but not supranational body – to impose proper standards of inspection on manufacturing countries.

## **Borrowing to finance drugs?**

The view advanced in Richard Laing's paper that in principle a poor country should not take up loans (e.g., from the World Bank) to buy consumable goods such as drugs proves to be widely shared. The World Bank itself initially viewed such loans as a means of creating a basic stock of drugs so that cost recovery systems have a starting point. It is evident however that in practice much of the funding acquired in this way soon evaporates, leaving only a burden of debt.

## **Decentralization and drug supply**

With a growing decentralization of government it is important to define those matters which cannot properly be decentralized – not because one is anxious to retain power at the centre but because they demand technical insight and experience which is in very short supply. International drug procurement, with all its complexities, is one such matter. For many African countries it is difficult enough to maintain a procurement staff even in the capital city to serve the entire nation; it proves impossible to establish expertise in procurement in regions and districts.

## **How much quality do we need?**

The dogma that all drugs must be manufactured to the highest standard of quality attainable (ICH, IF-PMA) is increasingly questioned. There are a very small number of drugs – such as digoxin and phenytoin, perhaps not more than 20 in all – which raise such delicate problems of bioequivalence and toxicity

that very stringent demands are justified. For the bulk of drugs – and certainly for such products as simply analgesics and antacids – manufacturing to these standards is unnecessary and raises costs to disproportionate levels. In addition, setting excessive demands of this type will disqualify many plants from manufacturing which are fully capable of making simple preparations to an acceptable standard. On the other hand this argument does not justify reducing the intensity of inspection or control which remain necessary at every stage.

### **Cost recovery and the poorest of the poor**

In theory rules can be drawn up to determine which members of the population can be excused from payment for drugs when cost recovery schemes are implemented. In practice, such rules are difficult to formulate and apply. Field experience seems to show that the question of exemption from payment is best handled at the village level, where the local community traditionally knows which of its members are indigent and in effect need to be supported by their fellow citizens.

### **Costs of HIV drugs**

In much of Africa, any attempt to provide causal treatment for HIV has been abandoned because of cost: treating a single patient may cost \$60,000; to treat half the cases of HIV in Uganda would remand funding in excess of the Gross Domestic Product. In view of the complexity of the manufacturing process, the costs of retrovirals are never likely to fall substantially, irrespective of the patent position. For the present the emphasis must be on prevention of HIV infection and on the treatment of secondary infections.

### **Donors and drug donations**

The WHO Guidelines on Drug Donations have met a long-felt need; a high proportion of drug donations have always proven to be inappropriate, often useless and even dangerous (e.g., provision of expired drugs). Among recipients it is an open secret that some donations represent no more than an empty political gesture, commonly intended to create goodwill at little expense and without regard for real needs. Where a donor indeed wishes to provide assistance it can best be given in the form of funding to existing activities. If drug donations in kind are contemplated, the recipient must approve them in advance as critically as if the drugs were to be purchased.