EDITORIAL

Drug Development for Children

The issue of which medicines children need has been discussed in Europe and the United States of America[1,2]. Initiatives, such as the Food and Drug Administration Modernisation Act and the Pediatric Rule in the USA, have encouraged clinical trials of medicines in children and this is welcomed[3]. These clinical trials will increase the evidence base for the safe and effective use of medicines in children.

Concern, however, has been expressed that the medicines studied have been those where there is the greatest financial profit to be made rather than the medicines of greatest clinical need[4]. The European Union is currently considering introducing financial incentives to stimulate clinical trials of medicines in children and will hopefully learn from the American experience. Previous European guidance has emphasised the clinical relevance of the medicine, encouraging trials particularly in conditions affecting children where there is currently no treatment.

We need also to recognise the needs of children in relation to medicines throughout the whole world. The paper by Gabriel Anabwani therefore is a welcome contribution to the needs of children in poorer less developed countries[5].

Anabwani argues the case for a public private partnership to develop new drugs for tropical disease. He makes a strong argument for such a partnership in the case of trypanosomiasis and leishmaniasis - conditions which are prevalent in many African countries. Both conditions are the cause of much death and human suffering and yet safe and effective drugs are not available. There is currently little effort to develop new drugs, because markets in the developing world offer a poor return on investment by the pharmaceutical industry.

However, developing new drugs for the diseases that afflict Africa is only part of the solution. The majority of people living with HIV in African countries do not have access to highly active anti-retroviral treatment. This is not because the drugs have not been developed but because their cost is prohibitive and the facilities for counselling, and testing for HIV are often rudimentary. The incidence of polio is currently at its lowest point in history and almost universal vaccine coverage has been achieved. However the eradication of the disease is threatened by the difficulties of reaching children who live in areas affected by military conflict and areas with poor infrastructure[6]. There is little point in developing new drugs, unless there is the infrastructure to deliver them to those in greatest need.

It is of concern, therefore, that countries in the developing world will be required to open their health care systems to market forces under agreements with the World Trade Organisation and the European Community[7]. This will erode the principal of ensuring access to health services in these countries by means of sharing costs and risks across the community (the "risk pool"). If these agreements are enacted, there is a very real risk that access to treatment for infections such as HIV, malaria, tuberculosis will become more difficult for Africa's poor.

Furthermore, moves by the International Committee for Harmonisation to strengthen the regulatory framework for drugs may deny useful drugs to people in the developing

world[8]. Some drugs carry risks which may be unacceptable to those fortunate enough to live in countries with a low prevalence of infectious disease and who have a choice of expensive alternatives. An example might be the use of oral chloramphenicol in the developing world for a wide range of infections in the knowledge that there is a small but important risk of fatal aplastic anaemia.

However there have been some positive developments and Anabwani cites some examples of good practice. Merck Sharp & Dohme's Ivermectin donation programme, for West African River Blindness has led to a global strategy for control of onchocerciasis. The development of Artesunate, for malaria, has been through public-private partnership. An initiative for developing new drugs for neglected diseases, such as that proposed by Anabwani, has been launched at a recent conference organised by *Medecins sans Frontieres*, in New York[8]. It has been suggested that "Africa can cure its own health problems" but this depends on countries in Africa achieving "distributive justice[9]." This will be a great deal more difficult if the dogma of global trade is allowed to distort the health priorities of these countries. Infectious diseases do not respect national boundaries. Controlling infectious disease, through partnership, is in the interests of both the rich developed countries and the children of the underdeveloped world who experience significant morbidity and mortality from infectious diseases[5].

Alan Smyth
Department of Paediatrics, Nottingham City Hospital, Nottingham, UK

Imti Choonara
Academic Division of Child Health, Derbyshire Children's Hospital, Derby, UK

References

1. Choonara I. Essential drugs for infants and children: European perspective. Pediatrics 1999;104:606
2. Kauffman RE. Essential drugs for infants and children: North American perspective. Pediatrics 1999;104:603-5
3. Spielberg SP. Pediatric therapeutics in the USA and internationally, an unparalleled opportunity. Paed Perinat Drug Ther 2000;4:71-4
4. Jong GW, van den Anker J, Choonara I. FDAMA's written request list: medicines for children. Lancet 2001;357:398
5. Anabwani GM. Drug development: a perspective form Africa. Paed Perinat Drug Ther 2002;5:4-11.
6. Anonymous. Global instability threatens polio eradication. *Lancet* 2002;**359**:1414
7. Pollock AM, Price D. Market forces in public health. *Lancet* 2002;**359**:1363-1364.
8. Medecins San Frontieres. The Crisis of Neglected Diseases: Developing Treatments and Ensuring Access. March 12-14 2002, Workshop and Conference, New York City. (http://www.neglecteddiseases.org/summary.pdf)
9. Ncayiyana DJ. Africa can solve its own health problems. *BMJ* 2002;**324**:688-689.