A crisis to be overcome

Isao Arita

The Expanded Programme on Immunization (EPI) has developed an excellent vaccine delivery system at country level. In 1974, the vaccination coverage with six antigens was less than 5% in most developing countries, whereas today the coverage has reached some 80%. This achievement has resulted in a substantial reduction of the incidence of EPI diseases. However, three major problems - coping with increased demand, ensuring quality control, and introducing new vaccines - pose what amounts to a vaccine crisis.

Firstly, although the demands for vaccine have considerably increased, a global system to meet them has not been developed or is not yet well coordinated among multilateral and bilateral agencies, nongovernmental organizations, and producers in private and public sectors. World production capacity actually exceeds the demand, but it is not possible to make the vaccines fully available to the global programme except in the industrialized countries.

A good example is the current shortfall of oral poliovaccine for the global poliomyelitis eradication programme. This is caused by the change in immunization strategy, as a result of the need to cover older age groups than previously (under 12 months only) in order to stop transmission. Recent estimates show that about 1650 million doses are required each year for the global programme. This is three times higher than previous estimates. Efforts are being made to cover this increased demand, but at present we have no definite solution.

EPI has now set up time-limited programmes for the elimination of neonatal tetanus by 1995 and a 95% reduction in measles deaths, also by 1995. There is concern whether the global vaccine supply system will meet the demands required to attain these goals.

Secondly, in recent years national production lines have been increased in many developing countries, but regulatory control of the vaccines' quality has not been adequately developed. For example, among some 60 producers of tetanus toxoid throughout the world, the quality of 40 products is not known. Roughly half of the vaccines in EPI use have not been assured for quality by the independent regulatory authorities.

Thirdly, it has proved difficult to introduce new vaccines since the inception of the programme in 1974, despite great developments in vaccine research leading to, for example, hepatitis B vaccine. Even now, the latter is available in only limited quantities in the developing countries where it is most needed.

Towards self-sufficiency

The Children's Vaccine Initiative (CVI) should now seek solutions to these three important problems. Solving the first two will, I believe, pave the way for solving the last one, namely, the introduction of new vaccines, because introducing any...
new vaccine requires an efficient mechanism for vaccine supply and quality control.

In the last two decades, several countries with a population over 50 million have initiated vaccine self-sufficiency programmes. CVI has decided to promote this through its Vaccine Independence Initiative. The plan includes: full production of EPI vaccines; production sharing; quality-control sharing; and a revolving fund and other support for vaccine procurement. Production sharing means sharing the bulk of output with partner laboratories. Quality-control sharing means sharing complicated tests with a partner laboratory.

Some 11 countries were tentatively selected for initial feasibility studies in the development of full production and quality control of six antigens and/or production sharing. They are— in order of infant population size of individual countries— India, China, Indonesia, Pakistan, Brazil, Bangladesh, Mexico, Iran, Viet Nam, Egypt and Thailand. These eleven countries easily account for more than half of the world total of 140 million infants. Hence, if the initiative succeeds, the problem of vaccine supply should be much reduced.

The feasibility studies will be based on criteria such as reasonably developed infrastructure of related industries, large market size, production experience, possible quality control, possible availability of donors, and political commitment. That last criterion, namely political commitment on the part of recipient and donor countries, is of particular importance.

Other countries may be added and some may drop out in the course of this investigation. The whole undertaking requires a great deal of funding, particularly from bilateral donors, as well as expertise from producers in industrialized countries. Therefore, it is important to involve the possible donor’s participation during the earliest phase of feasibility studies.

CVI teams have already visited China and Viet Nam to review their poliovaccine quality, and joint teams are being sent to Bangladesh, Brazil, Egypt, Mexico, Viet Nam (a second visit), and elsewhere to make a preliminary assessment of feasibility according to the established criteria. The Pan American Health Organization (PAHO) has already put into effect this vaccine independence initiative, including the use of revolving funds.

### Ensuring quality and supplies

To put the problems in perspective, I can compare the situation of the EPI vaccine programme to that of WHO’s Smallpox Eradication Programme, with which I was involved. In the smallpox programme, the assurance of vaccine supply in quantity and quality was the most critical problem during the first four years of the programme (1967–70).

The first development was the introduction of international quality control. Initially only 30% of the smallpox vaccine batches met WHO requirements. The system finally ensured that more than 80% of the production batches met WHO requirements. The second development was the establishment of a global vaccine supply system whereby smallpox-endemic countries with large populations became self-sufficient, with vaccine supply meeting their national vaccine demand. At least two-thirds of the vaccines were met by local production lines.

Thus, it was possible for the Smallpox Eradication Programme to establish a worldwide supply mechanism of the vaccine with strong international quality control because of full support from the international community as well as from national health authorities. Although concerned with only one freeze-dried vaccine, we have this past experience to show that our aims with EPI vaccines can be achieved.

There will be a great deal of work still to do. Technology transfer, for instance, will pose many problems and it is urgent to attract the interest of donors. Above all, it is of vital importance to have firm leadership with an effective structure in order to proceed with the plan.