Vaccine producers in the developing countries have an important role to play in supplying high-quality products, and their efforts need to be supported by both the public and private sectors.

Vaccination is undoubtedly the most effective measure against infectious diseases, particularly if we consider its cost against the cost of treating the clinical case, not to mention the loss through death of the patient.

The increasing commitment of the international health community to extend vaccination to all the babies born in the world each year (currently 140 million) has been remarkable during the last decade. This trend underlines the responsibility of governments and the need for international support to the developing countries, where about 95% of the newborn babies are found, and indeed where important improvements in vaccine development have been discovered.

Ever since the last century, the public sector has been involved in the production of vaccines, starting with smallpox and rabies, then followed by the development and production of DPT (diphtheria – pertussis – tetanus) vaccine and BCG (for preventing tuberculosis). Today, government production is responsible for at least 60% of the DPT vaccine available (although quality standards may vary) as well as significant amounts of BCG and yellow fever vaccines. The public sector often produces vaccines by traditional methods, and clearly the introduction of modern techniques is essential.

As for the price of vaccines, at present the private sector sells them at higher prices to industrialized countries and lower prices to developing countries (through such international bodies as UNICEF and WHO). This mechanism might be difficult to maintain over a long time considering the increased demand for vaccines in the developing countries and the rising costs of production.

All these facts point to the need to strengthen the public sector as a world vaccine producer, in both industrialized and developing countries, with the former acting mainly as technology donors to the less developed areas.

Quality control
To ensure the production of good quality vaccines in non-industrialized areas on a regional basis, the following aspects are crucial.

- Definition by national authorities of the vaccination goals to be achieved, in order to guarantee a market for the products.
- Concentration of the production in a few larger countries, or in those with most experience in vaccine preparation. The existence of a large number of producers around the world, as we observe now with DPT vaccine, entails difficulties in quality control, which is an essential step towards improving the protection of the vaccinated population.
- Close interaction of the public institutions involved in the project, in each of the developing countries which are able to produce vaccines. This is to avoid duplication of activities and ensure that the best possible technologies are being used and are adapted, when necessary, to local conditions.
- Establishment of a national laboratory to control the quality of the vaccines, supported by national authorities and international institutions.
The control of vaccines may be a difficult task, and is normally achieved only after years of preparation of human resources and investments in building construction and purchase of equipment. Whenever possible, the expertise of one country in vaccine control should be shared by others that are geographically close or share common cultural links.

The existence of more than one laboratory for quality control in the same country should be strictly avoided, since any conflicting results which might arise could destroy the mutual confidence between producers and controllers. International laboratories responsible for vaccine control should be able to collaborate with the regional control laboratories, through exchange of information and experts, training courses and similar activities. The control laboratories should be regularly visited by international experts in order to maintain high standards of control procedures.

The transfer to developing countries of technology in the production of biologicals needs to be stimulated by both government and private organizations. Outstanding technologies are available from public institutions in various developed countries, and have already been made available to less-industrialized regions. Expanding these activities is likely to prove both possible and highly effective.

Contracts for vaccine production have been signed between private companies in the developed world and institutions outside those regions. These mechanisms too should be stimulated, and more experience is needed in the developing countries in drawing up such contracts, especially when the public sector is involved as a recipient of the technology.

**Private expertise**

The private sector has been responsible for developing new vaccines such as hepatitis B recombinant vaccine, using molecular biology. Under this technology the same organism used for beer production (S. cerevisiae) is induced to produce in large tanks those parts of the virus necessary for immunization. The private sector has much more experience in the large-scale production of biologicals, including rapid response to emergency situations, than the public sector. Consequently, the expertise of the private sector, as owners of the new and indispensable technologies, is an essential part of the whole system of vaccine supply for the world.

However, there is a clear tendency for producers in the private sector to decline in numbers. In the USA, for instance, only three vaccine producers out of the 20 existing in the 1960s are still operating. This decline has been due to different factors; essentially the high industrial costs and legal problems deterred many from continuing their activities.

Efforts are being made at present to give each child as many different vaccines as possible at the time of each vaccination intervention in the health care centres. This can be achieved by combining various products in the same syringe, but it calls for a lot of effort and much cooperative research between the producers in the private sector and the health authorities.

In summary, vaccine producers in developing countries have an important role to play in supplying high-quality products, and they need to be supported in their efforts by the mechanisms suggested here. If the world's children are to receive all the vaccines they need in the coming years, an adequate balance will have to be struck between the improved participation of the public sector in developing countries, the participation of government institutions in the industrialized areas, and the industrial capacity of the private sector.

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