



Vaccine Self-Sufficiency in Developing Countries¹

AKIRA HOMMA²

OVERVIEW

The production of vaccines for basic immunization or against other diseases that particularly affect the Region is carried out in public laboratories in several countries. There are no private laboratories that produce vaccines in Latin America.

Many of the institutions that are involved in vaccine production were created around the turn of the century. Throughout the years, most of these institutions have maintained their activities without substantial staffing changes and without any consistent planning for modernization of facilities, equipment, or technology. The regular budget that these publicly owned institutions receive from their respective Ministries of Health can only support basic work. In turn, the Ministries do not question the results of their production activities. In general, these laboratories pay insufficient attention to issues of increased yield and productivity, since the cost-benefit ratio of production is not evaluated and preoccupation about accountability is not present. In some cases, production pat-

terns are inconsistent and some problems exist with assurance of vaccine quality.

The vaccine-producing laboratories in the Americas are usually part of larger national public health networks. They share the network's administrative procedures, which often are not adequate for optimum production. In fact, these institutions would benefit from adopting management procedures used in the private sector.

Despite the above-mentioned problems, some Latin American governments have made a formal commitment to acquiring self-sufficiency in vaccines and biologicals. At present, only Mexico produces all the vaccines for basic child immunization (Table 1). However, no laboratory in the Region is producing a sufficient quantity of vaccine to meet the country's own demand.

COUNTRY INITIATIVES

Mexico

Mexico is strongly committed to achieving national self-sufficiency in the essential vaccines needed for its national immunization program. To reach this objective and strengthen its vaccine and biological production activities, in 1981 the Mexican Government created a special institution called *Gerencia General de Biológicos y Reactivos* [General Management of Biologicals and Reagents] (GGByR). This institute coordi-

¹ Based on a presentation to the Study Group Meeting on Vaccine Self-Sufficiency, organized by the Agency for Cooperation in International Health, 14–15 December 1995, Tokyo.

² PAHO Special Program for Vaccines and Immunization.

Table 1. Countries producing vaccines in Latin America and quantities produced (x 1000 doses), 1994.

Country	DTP	DT	TT	BCG	Measles	OPV	Hepatitis B	Yellow fever
Argentina*	400	—	2 000	3 000	—	—	—	—
Brazil†	5 000	18 600	8 000	12 000	15 000	20 000‡	—	20 000
Chile	3 500	1 500	1 200	—	—	—	—	—
Colombia	2 650	550	4 000	2 500	—	—	—	5 000
Cuba§	—	500	2 500	—	—	—	10 000	—
Mexico	9 500	200	9 500	7 500	7 500	25 000	—	—
Ecuador	800	350	800	1 300	—	—	—	—
Uruguay	160	160	300	750	—	—	—	—
Venezuela	4 000	—	—	—	—	—	—	—
PAHO Revolving Fund pur- chases	20 000	5 000	21 000	11 000	12 000	50 000	—	—

— Does not produce the vaccine.

* Two vaccine producers.

† Three new DTP facilities, one starting operation; one new BCG facility.

‡ Formulation of imported bulk.

§ Starting operation of new facilities; many institutions involved in research and development.

Note: Several countries are producing rabies vaccine using the Fuenzalida and Palacios technology and are producing anti-rabies serum (snake, toxic, rabies).

nates the functions of three entities that existed prior to its creation: one producing bacterial vaccines, another involved in the production of viral vaccines, and a third dealing with the development and production of biological reagents for clinical diagnosis.

The GGByR has also recently organized a quality assurance department and has assigned a director to coordinate all activities related to the strengthening of good manufacturing practices at production institutes.

Particularly during the past five years, the Mexican Government has made a consistent and important investment in the modernization of facilities, equipment, and technologies at the National Institute of Hygiene, where bacterial vaccines are being produced. In November 1995 this institute celebrated its first 100 years. It marked the date with the inauguration of new facilities for the formulation and filling of vaccines, as well as a new fermentation laboratory. The next target is moderniza-

tion of the downstream processing of pertussis and diphtheria components. The Government has already allocated resources for this purpose.

Brazil

Some biomedical institutions in Brazil date from the beginning of this century. Noteworthy are the Oswaldo Cruz Foundation, which became famous working on the control of such public health threats as plague and yellow fever, and the Instituto Butantan, known for its development and production of anti-snake serum. More recently, Bio-Manguinhos/FIOCRUZ has established the complete cycle of measles vaccine production and a formulation and filling operation for oral poliomyelitis vaccine (OPV), with technical support from Japan and the financial support of both the Brazilian Government and the Japan International Cooperation Agency.

Following the closing of an important private laboratory that owned a major

market share of the DTP, DT, and TT vaccines and the anti-snake serum, the Government decided to establish a National Program for Self-Sufficiency in Immunobiologicals in 1985. Through this program, the Brazilian Government has invested approximately US\$ 100 million over the last 10 years in three major laboratories (Instituto Butantan, Bio-Manguinhos/FIOCRUZ, and TECPAR) for DTP, DT, and TT vaccines, and in a fourth laboratory for BCG vaccine.

At the time the Brazilian self-sufficiency program was started, priority was given to the production of anti-snake and anti-toxin serums. For that reason, resources for the self-sufficient production of essential vaccines were allocated only after modernization of laboratories involved in producing the serums was completed.

Currently, only one laboratory (Instituto Butantan in São Paulo) is producing DTP, DT, and TT, and it is working hard to optimize these procedures at its new facilities. The other two institutions will need more time to become fully operational. However, once that happens, Brazil will have more than enough capacity to meet its own needs for all essential bacterial vaccines. In fact, the goal of Brazil's self-sufficiency program, like that of Mexico's, is to fulfill its national demand for essential vaccines; production of vaccines for export from both these countries remains a distant possibility.

Cuba

Cuba has invested strongly in several institutions involved in research, development, and production of biologicals. Cuban biotechnology infrastructure is well developed and is already supplying two vaccines to other countries: recombinant hepatitis B vaccine and *N. meningitidis* serogroup B vaccine derived from outer membrane protein. The facilities for vaccine production are very modern and fulfill good manufacturing practices (GMP) norms. Further-

more, the Finlay Institute houses the best group for validation procedures.

Although the Government is socialist, Cuba's management of vaccine production is "entrepreneurial" and market-oriented. The country is preparing not only to provide all the biologicals needed for its domestic immunization program but also to supply vaccines to other countries.

Elsewhere

Venezuela and Chile are also committed to enhancing their vaccine production, but the investments made so far have not allowed the creation of modern production facilities that meet GMP requirements.

PAHO'S ROLE IN THE IMPROVEMENT OF VACCINE PRODUCTION

In September 1993, a Strategic Plan for the Development of Improved DTP and DTP-based Combination Vaccines for Latin America and Caribbean Countries was discussed with all laboratories involved in the production of DTP vaccine and its components. Among the recommendations of the plan was the "improvement and expansion of the production capabilities of current DTP vaccine to satisfy the demand of the Region through the establishment and development of a program for certification of vaccine production laboratories in the Region, in order to facilitate the shared production and interregional distribution of vaccines."

To ensure the implementation of that recommendation, PAHO has been strongly advocating the enforcement of good manufacturing practices by vaccine-producing countries.

Accomplishments and Ongoing Activities

1. GMP workshops have been conducted in Mexico (twice), Brazil (three times),

Venezuela, and Argentina, with the collaboration of experts from the Salk Institute (California, U.S.A.). Approximately 200 people participated in these workshops, including professionals from all Latin American laboratories producing vaccines.

2. During 1995, two validation workshops were conducted, in Brazil and Mexico, the latter with the support of the U.S. Food and Drug Administration (FDA). All the DTP-producing laboratories in the Region were represented, as were professionals from the Mexican National Control Authority.
3. A Regional Workshop on Management of the Vaccine Production Laboratory was held in Venezuela. Management is one of the most important deficiencies among public laboratories, and special attention must be paid to improving this aspect.
4. An Expert Group for the Certification Program was organized. In November

1995, it made its first technical visit to the Instituto Nacional de Higiene/GGBYR of Mexico and to the Instituto de Salud Pública of Chile. Certification is an essential step toward the organization of a technical cooperation agreement among DTP vaccine producers.

During 1996 PAHO's Special Program for Vaccines and Immunization (SVI) will continue to conduct GMP workshops in the Region. An additional activity, which has been targeted as very important, is the development of specific and detailed manuals on GMP and the preparation of validation, auditing, and standard operational procedures.

In conclusion, the prospects for some Latin American countries to establish national self-sufficiency in essential vaccines are encouraging. It is quite possible that regional self-sufficiency will be achieved in five years.



World Health Day 1996: Healthy Communities

The theme of this year's celebration of World Health Day was creating healthy communities. Worldwide, activities were carried out in commemoration of the day¹ with the goal of stimulating the launch of healthy communities programs and celebrating the achievements of those already under way.

HISTORY AND STATUS OF THE MOVEMENT

The healthy communities movement got its start at a landmark 1984 conference in Toronto, Canada — "Beyond Health Care" — which explored the idea of health promotion at the local level.² Inspired by the

¹ World Health Day is observed annually on 7 April, the date the constitution of the World Health Organization was formally adopted in 1948.

² For more information, see the report "Healthy Municipios in Latin America," *Bulletin of PAHO* 29(3), 1995, pp. 272–275.