



Vaccine Research, Development and Production in Brazil

COHRED's Working Group on Research to Action and Policy tries to make a specific contribution to the global discussions on the research/policy nexus by commissioning studies that highlight country experiences in this regard. Case studies have been conducted in Brazil, Burkina Faso, Indonesia, South Africa and Uruguay.

In this learning brief, the main lessons learned from the Brazilian case study are highlighted. The case study aimed to contribute to thinking about the links between research and health policy in the light of Brazil's experience in vaccine research, development, production and utilisation by the health system. The vaccines field comprises a strong research component, and at the same time constitutes one of the most important modalities of government action in the health field. Brazil's experience over recent decades appears to be a relatively successful case of a country in the South engaging in vaccine production and progressively making headway in incorporating the research results into its health policies.

The study involved a literature review and a field survey among some of the leading agents in the fields of health science and technology, and health policy. Emphasis was given to the analysis of two successful cases (vaccines against Hepatitis B and *Haemophilus influenzae* Type B) that illustrate the link between research and policy in the vaccine field in Brazil.

Study context

In the early 1970s, the Brazilian government extended its national vaccination programs, resulting in the creation of the National Immunisation Program (PNI). In the 80s, when the demand for vaccines expanded acutely as a result of the success of the PNI, and a national health quality control system was set up, it became evident that vaccine production capacity

was inadequate and locally produced vaccines were of poor quality. The supply of essential immunobiologicals reached a crisis point, and jeopardised the entire immunisation strategy. To meet this challenge the Immunobiologicals Self-sufficiency Program was formulated in 1986, to encourage national production by public institutions, primarily the Oswaldo Cruz Foundation and the Butantan Institute. The Government channelled a total of approximately US\$ 150 million, during the years 1986-1998, for these producers to invest in production capacity and quality. Although the goals of self-sufficiency have not yet been attained, Brazil now has the highest vaccine production capability in South America, with the capacity to produce a number of traditional vaccines (DTP, BCG, measles) routinely. The country has also organised a mass immunisation and vaccine production structure that has had considerable impact on the health conditions of the population.

Lessons learned

The case study revealed a number of issues that had an impact on the link between research and policy in the field of vaccine development in Brazil:

- ◆ Research initiatives towards generating new vaccines or processes should occur in synergy with the development of production capacity for these vaccines. Whenever research initiatives took place in isolation from the production structure and capacities, the results were confined to scientific publications and to increase knowledge, but were not put to use in vaccination programmes.
- ◆ Health policies for the control of diseases which are preventable by immunisation should guide research efforts into new health products and processes. The dichotomy

between health policy and science and technology policy has to be overcome in order to enable the public to make wider use of product and process research.

- ◆ The experience in Brazil showed that the lack of interest from the private sector in carrying out research and development activities, finally forced the direct involvement of the State in the vaccine production. This proved to be the only possible way to directly respond to the health need formulated in policies.
- ◆ The two success stories presented reveal a dynamic interaction between setting up a domestic Research and Development base and the ability to select and absorb knowledge generated internationally as a short cut to the acceleration of the introduction of new vaccines into national programs.
- ◆ In addition to technical and scientific proficiency, the leaders of health product research and development programs must act as veritable entrepreneurs to link up the world of science with those of industrial production and health policy.
- ◆ In countries the size and economic proportions of Brazil, the existence of a local health products research base proves essential for two reasons:
 - the impact of health product research and production on quality of life will be greater the more these activities relate to local epidemiological needs

- in less-developed countries, the development process itself, and thus overall health conditions, are closely tied up with the constitution of an endogenous capability for research and innovation. There is no developed country without an advanced S&T base in high technology sectors.

Further Reading

- ➔ Gadelha, CAG (2000) *Incorporating Biotechnology Research into Health Policy: The Case of Vaccine Development and Production in Brazil*, Report for COHRED's Working Group on Research to Action and Policy.
- ➔ Gadelha, CAG & Temporão, JG (1999) *A Indústria de Vacinas no Brasil: Desafios e Perspectivas*. BNDES publication.
- ➔ Homma, A (ed) (1999) *Vaccine Development: New Challenges*. Proceedings of the international workshop on vaccine development & production. Fundação Oswaldo Cruz: Rio de Janeiro.

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