

GPV POLICY STATEMENT

Ensuring the quality of locally produced vaccines and the viability of local production

The mission of the Vaccine Supply and Quality (VSQ) Unit in the Global Programme for Vaccines and Immunization is to ensure high quality, reliable and affordable vaccines against priority diseases today and for the future. To meet this goal, the strategies below are directed to assure the quality of vaccines supplied through local production.

Strengthening National Control Authorities (NCAs)

What is needed? All countries need some sort of NCA, but the governments of countries in which vaccine production takes place need to exercise six critical control functions, and they need to exercise them in a competent and independent manner, backed up with enforcement power. These six functions are:

- A published set of requirements for licensing
- Surveillance of vaccine field performance
- System of lot release
- Use of laboratory when needed
- Regular inspections for Good Manufacturing Practice (GMP) compliance
- Evaluation of clinical performance



© World Health Organization 1998

This document is not a formal publication of the World Health Organization (WHO), and all rights are reserved by the Organization. The document may, however be freely reviewed, abstracted, reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes. The views expressed in documents by named authors are solely the responsibility of those authors.



Global Programme for Vaccines and Immunization
Vaccine Supply and Quality
World Health Organization, 1211 Geneva 27

Fax: 022 791 4193; E-mail: gpv@who.ch

The documented performance of these functions according to established indicators will be essential to guarantee vaccine quality.

Which of these critical control functions is needed in a country depends on vaccine source, as shown below.

Critical control functions depending on vaccine source

Vaccine source	Licensing	Surveillance	Lot release	Laboratory access	GMP inspections	Clinical evaluation
UN agency	✓	✓				
Procure	✓	✓	✓	✓		
Produce	✓	✓	✓	✓	✓	✓

What is the current situation? An inventory of performance of national control functions in 53 vaccine-producing countries in the world has shown that many of these countries are not fulfilling the necessary role in assurance of vaccine quality. In 1996, only 34 of 53 producing countries (64%) were exercising the necessary six critical control functions. Furthermore, in-depth assessment of some countries, according to indicators established by the countries themselves, shows that even these functions may not be performed to a depth sufficient to assure vaccine quality.

What must countries do? As a first step, countries must commit resources, both human and financial, to the assurance of vaccine quality. Second, they must critically assess the functioning of their NCAs, and develop systematic plans which will indicate how identified gaps will be filled, including targets, goals, milestones, and the costs for each step. These plans should include blueprints for staff training and accessing needed technical and financial inputs. They must implement these plans and monitor their impact.

What can WHO and other agencies do? WHO can and is providing technical assistance for the development and implementation of these plans. Support to countries for assessment of their NCA functions is ongoing. Moreover, VSQ's Global Training Network is available to provide support in accordance with identified gaps and national plans. Other agencies have indicated their willingness to support these efforts, including, in particular, the Asian Development Bank, the World Bank, and a number of bilateral aid agencies. WHO policy is that no technical nor financial support to vaccine production will be provided to facilities unless they have a functional NCA and have developed a strategic plan to achieve viability.

Viability study for local production

What is needed? The VSQ unit has developed criteria for assessing the viability of local production. These criteria are designed to objectively evaluate a manufacturer's performance in seven key areas, which are outlined in the box below. The criteria address the potential sustainability of the production facility, the quality and reliability of the products, and the likelihood that the facility will be a relevant resource in the country, not only for its

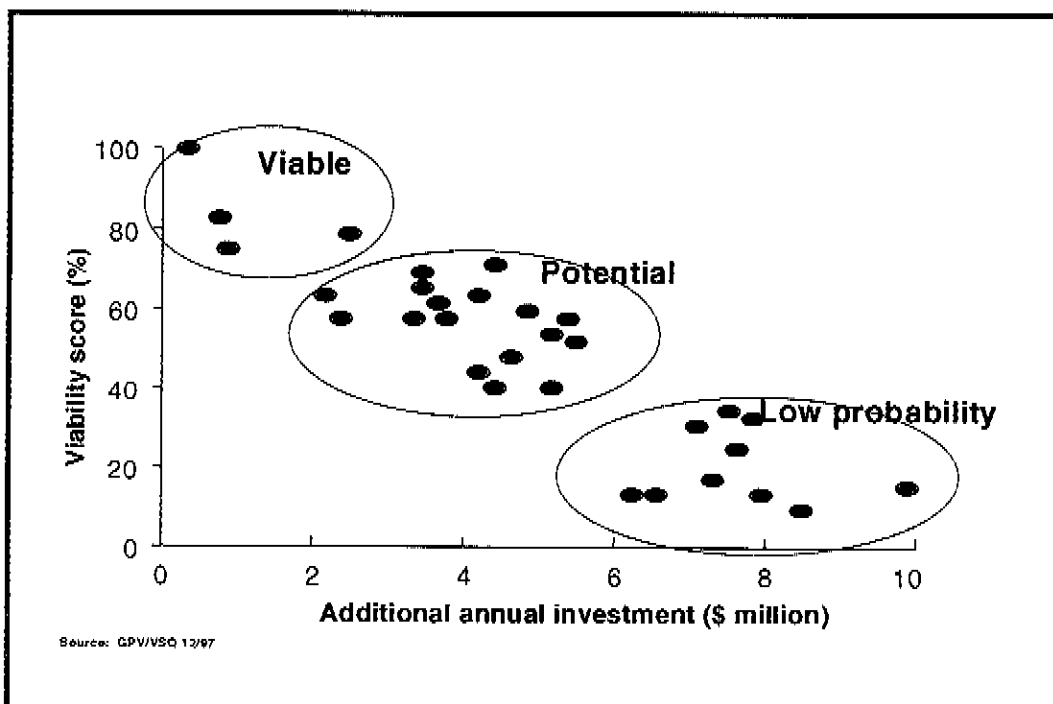
present vaccine needs, but also for future vaccines, which will depend on more sophisticated technologies.

Elements of viable production

- Economies of scale
- Consistency of production/GMP
- Access to new technology
- Historical ability to meet national needs
- Credibility of quality
- Management structure
- Legal status

What is the current situation? As the figure below shows, of 31 public sector vaccine production facilities in developing countries analysed using this method, only a handful are viable. Many have a low probability of becoming viable, and the rest are potentially viable, but need to address attention to quality, reliable, affordable vaccine production, especially for future vaccines, which will involve new technologies.

Viability of vaccine manufacturers



What must countries do? Local vaccine production cannot succeed unless there is government commitment at the highest level. The figure above shows that the cost commitment in terms of annual investment (even after the facility is built and equipped) is considerable. Once governments have demonstrated commitment to vaccine production, they need to understand the implications of their present situation. For some countries, whose local production facility is in the low probability viability category, the first step should be the establishment of an independent and competent National Control Authority, as defined above. Until the basic needs in management and quality are addressed, past experience shows that investment in vaccine production yields no sustainable results. For facilities which are potentially viable, the next step is a viability study to understand where they are, where they want to be, and how to get there. The outcome of such a study will be a strategic plan. For those facilities which are already viable, and which have already developed a strategic plan, they should specifically address the question of access to new technologies. There are five ways this can be approached.

- Developing strong research and development capacity
- Bulk filling arrangements
- Licensing technology
- Negotiating partnerships for specific products
- Entering into joint venture agreements with a research-based manufacturer

What can WHO and other agencies do? WHO policy is that technical and financial support for vaccine production will not be available for those countries without a functional NCA, and where the facilities have not developed a strategic plan for production viability. WHO will provide advice and support to develop the terms of reference of a viability study, and to implement it. It is currently providing this to several countries. The Asian Development Bank, International Finance Corporation and the World Bank, among other agencies, have expressed interest in support for viability studies and implementation of their recommendations.

Copies and information may be requested from:

World Health Organization, Global Programme for Vaccines and Immunization
20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Phone: +41 22 791 4373; Fax: +41 22 791 4193; E-mail: gpv@who.ch

This and other documents are available on the GPV Document Centre website at:
<http://www.who.ch/gpv-documents/>

Ordering code: WHO/VSQ/98.03; Printed: July 1998
© World Health Organization 1998

This document is not a formal publication of the World Health Organization (WHO), and all rights are reserved by the Organization. The document may, however, be freely reviewed, abstracted, reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.

The views expressed in documents by named authors are solely the responsibility of those authors.