



Pan American Health Organization

Regional Office of the
World Health Organization

<http://www.paho.org>

*Quality of vaccines to be
purchased by the
PAHO/Revolving Fund
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Vaccine of quality

- Vaccines that are safe, effective and pure and show consistency in production between batches.



- First requirement for the acquisition of a vaccine through the Revolving Fund is: the vaccine must be pre-qualified by the World Health Organization as a supplier of the United Nations Agencies
(PAHO/ BID Solicitation. Art II, Document B, page 2)



What is the prequalification procedure?

- A procedure to assess the acceptability, in principle, of vaccines to be purchased by UN Agencies



OBJECTIVE

- The purpose of the assessment is to verify that the vaccines
 - a) meet the specifications of the relevant UN Agencies
 - b) are produced and overseen in accordance with the principles recommended by WHO, including those for good manufacturing practices (GMP). This is intended to ensure that vaccines used in national immunization services in different countries are safe and effective and that they meet particular operational specifications for packaging and presentation



Principles of the prequalification procedure

- Reliance on the national regulatory authority (NRA) of the country of manufacture;
- General understanding of the product and presentations offered, production process, quality control methods and relevance for the target population of available clinical data;
- Assessment of production consistency through compliance with GMP specifications;
- Random checking-testing of vaccines to monitor compliance with tender specifications on a continuing basis;

Monitoring of complaints from the field.



Introduction of new vaccines

- For the introduction of new vaccines, the prequalification procedure will require the implementation of postmarketing surveillance programs by the manufacturer, under the supervision of the NRA in the country where the vaccine is going to be introduced



- For vaccines that are not included in the prequalification system (vaccines outside of EPI) the license from other international regulatory agencies such as FDA and EMEA is acceptable to facilitate purchasing by the Revolving Fund.



Summary

- The prequalification procedure has been effective in promoting confidence in the quality of the vaccines shipped to countries through UN purchasing agencies (such as PAHO). In recent years it has been recognized that the system should be expanded to include other vaccines that are or could be used by countries. Currently this is under discussions by the WHO prequalification team.

