

## Who issues the Certificates?

- ☛ a *Certificate of a Pharmaceutical Product* or a *Statement of Licensing Status of a Pharmaceutical Product* is issued by the regulatory authority of the exporting country
- ☛ a *Batch Certificate of a Pharmaceutical Product* is usually issued by the manufacturer, but exceptionally, as in the case of biological products, by the regulatory authority of the exporting country
- ☛ WHO itself neither issues these Certificates nor regulates international trade in pharmaceutical products.

## What conditions should regulatory authorities issuing Certificates meet?

They should:

- ☛ have an effective licensing system for pharmaceutical products, manufacturers and distributors
- ☛ apply GMP requirements similar to those recommended by WHO
- ☛ have a technically competent pharmaceutical inspectorate to assess GMP implementation
- ☛ operate an effective post-marketing quality surveillance system
- ☛ have access to an independent quality control laboratory
- ☛ have sufficient administrative capacity to issue the required Certificates and to carry out enquiries in the case of complaint.

## How can importing countries use the Scheme effectively?

Importing countries should:

- ☛ make the Scheme mandatory
- ☛ request and accept only WHO-type Certificates
- ☛ ensure that the authority issuing a Certificate meets the required conditions

- ☛ check that Certificates have been signed by the competent authorities whose names are issued by WHO
- ☛ refuse to accept old Certificates or photocopies of Certificates.

## What are the Scheme's strengths and weaknesses?

Strengths:

- ☛ it uses a standard format that helps importing countries to obtain all the information needed about the pharmaceutical product they are importing: registration status, manufacturing conditions and quality of the batch
- ☛ use of a standard format obliges certifying authorities to disclose important information to the importing country
- ☛ it promotes information exchange between countries about pharmaceutical products and can lead to harmonization of product information.

Weaknesses:

- ☛ a Certificate is only as good as the certifying authority
- ☛ the Scheme relies on the honesty and competence of the issuing authorities
- ☛ the Scheme does not cover pharmaceutical products while they are in transit, during which time a product could be relabelled or mixed with other products.

## For further information, please contact:

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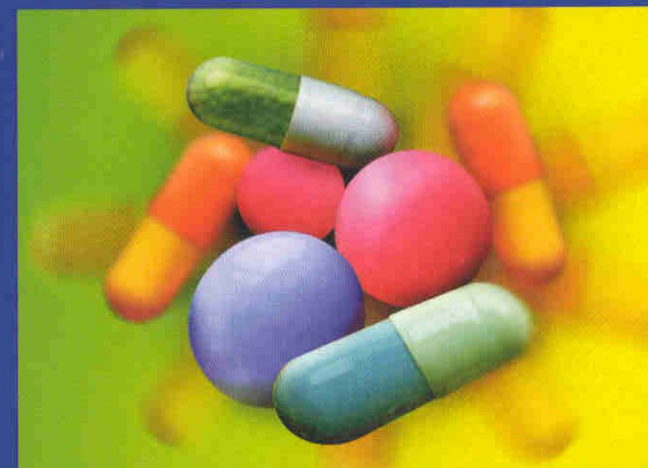


World Health Organization Geneva, 2000

WHO/EDM/QSM/2000.2

Original: English; Distribution: General

# WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce



What is it?

How does it function?

What are its strengths  
and weaknesses?

## Why worry about the quality of pharmaceutical products?

Pharmaceutical products can prevent or cure diseases but only if they are safe, effective, of acceptable quality, and used rationally. Ineffective, unsafe and poor-quality pharmaceutical products can prolong treatment periods and even worsen the conditions being treated. Indeed, they can harm the health of individual users and, in certain cases, the health of a country's entire population.



Photo: C. Gaggero

## Who is responsible for the quality of drugs?

Governments, manufacturers, distributors and patients are responsible for the quality of drugs.

- **Governments** – for formulating drug policy, drug laws and regulations, defining norms and standards, establishing regulatory authorities with appropriate structure, power and resources, and enforcing drug laws.
- **Manufacturers** – for producing and distributing pharmaceutical products in accordance with internationally-accepted good manufacturing practices (GMP).
- **Distributors** – for purchasing from reliable and legitimate sources, undertaking inspection when goods are received, ensuring proper storage, transportation and distribution conditions, keeping records of the products purchased and distributed

to ensure traceability, monitoring the quality and expiry dates of products throughout the supply system, and reporting suspected quality defects to drug regulatory authorities.

- **Patients** – for following the advice they are given on how to store any pharmaceutical products they have been prescribed.

Some countries, however, lack the capacity to ensure the quality of imported pharmaceutical products. The WHO Certification Scheme can assist them.

## What is the WHO Certification Scheme?

The WHO Certification Scheme is an international voluntary agreement, devised to enable countries with limited drug regulatory capacity to obtain partial assurance from exporting countries concerning the safety, quality and efficacy of the products they plan to import.

## How does the Scheme function?

The voluntary agreement requires that the regulatory authorities of exporting countries issue Certificates when requested by importing countries. Three types of Certificate are issued under the Scheme:

### Certificate of a Pharmaceutical Product:

- is used when a product is being considered for a product licence (marketing authorization)
- attests whether a specified product is approved for use in the exporting country, or if not, why not
- certifies whether the premises where the product is manufactured are inspected regularly and meet GMP requirements
- attests that the product information attached to the Certificate is that approved for use in the exporting country.

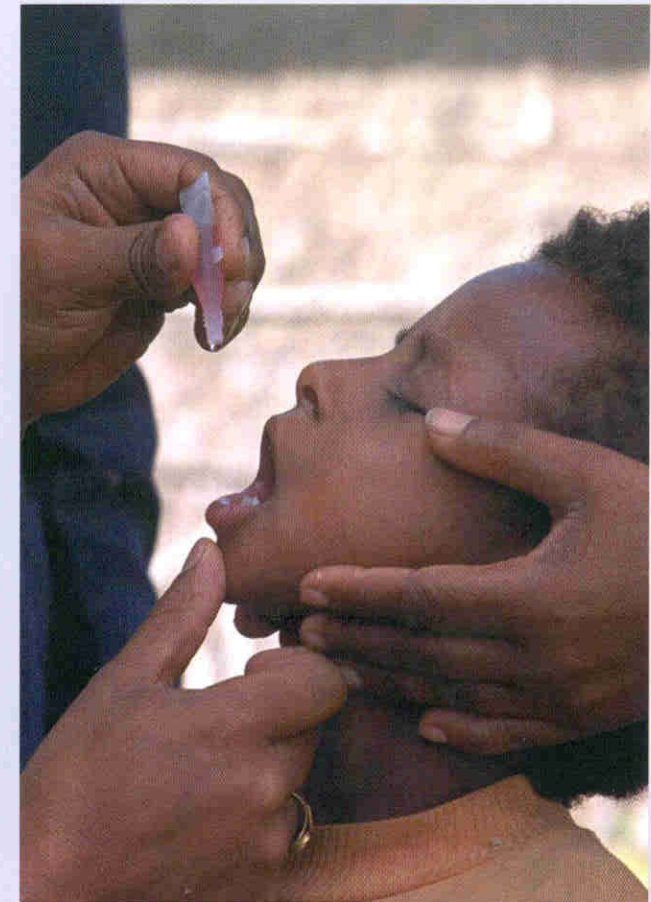


Photo: H. Anenden

### Statement of Licensing Status of a Pharmaceutical Product:

- certifies that a licence has been issued for a specified product, or products, for use in the exporting country
- is used by importing agents when considering bids in an international tender, and to facilitate screening and preparation of information.

### Batch Certificate of a Pharmaceutical Product:

- accompanies and attests to the quality and expiry date of a specific batch or consignment that has already been licensed in the importing country
- is useful in drug procurement.