Republic of the Philippines
Department Of Health
OFFICE OF THE SECRETARY
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April 23, 2002

Administrative Order
No. 103 series of 2002

Subject: **BATCH CERTIFICATION OF ANTIBIOTICS**

I. Background / Rationale

In line with current trends and consistent with the policy of the Bureau of Food and Drugs (BFAD) to speed up the delivery of its services, these guidelines are issued to reinforce the principle that the ultimate responsibility of ensuring the quality, safety and efficacy of pharmaceutical products rests with the manufacturers, traders, distributors and/or product owner.

Consequently, upon the effectivity of this Order, all kinds of antibiotic and antibiotic containing products, whether in bulk, semi-finished or finished form and whether imported or domestically produced are no longer subject to batch certification subject to certain exceptions provided hereunder before it can enter the country or can be released for sale.

In lieu of the batch certification, the following guidelines will have to be observed to ensure the safety and effectiveness of antibiotic containing pharmaceutical products.

II. Definition of Terms

1. *Batch certification* – is a certification issued after a batch of antibiotics has been found to comply with the characteristics of identity, strength, quality and purity.

2. *Raw material* – All substances whether active or excipients that are employed in the processing of a finished product.

3. *Finished product* – a product that has undergone all stages of manufacturing operation.

4. *CGMP* – it is the current system of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate for intended use. It is thus concerned with both manufacturing and quality control process and procedures.

5. *Locally produced/manufactured* – Those produced/manufactured by a licensed producer or manufacturer within the country.

6. *Imported Finished Products* – A finished drug product importer/sourced from foreign suppliers.

III. Policies and Guidelines

A. For Importer Raw Materials

1. All importations of raw materials must be covered by an Imported Permit which the BFAD will issue only upon submission of the following documents and information:

    1. Valid LTO of Importer

    2. The type or kind of antibiotic to be imported, the size or quantities of the batch including the number of containers

    3. The source of the raw materials including the origin, name, address of suppliers/manufacturers

    4. CGMP Certification for manufacturers of imported raw materials issued by the regulatory authority of the country of manufacture/origin.

    5. Manufacturer's Certificate of Analysis of the raw materials (validated original copies only)

    6. Pro forma invoice and packing list.

2. Import Permit will be valid only for a period of three (3) months from date of issue, is non-transferable and good only for a single entry or importations.

3. The importer is mandatorily required to file with the Bureau within thirty (30) days from arrival date of Usage/Distribution Report for every batch of importation containing the following information:
    a. Date of Arrival of the Raw Materials
    b. Bills of Lading
    c. Name, address of the user/buyer
    d. Delivery Receipts indicating date, quantity of raw materials
    e. Sales Invoices

4. No succeeding request for an Import Permit will be issued unless the Usage Report set forth above is submitted and complied with.

B. For Locally Produced/Manufactured Raw Materials

1. The following information shall be required from the producer/manufacture:
    a. Valid LTO
    b. CGMP Certification from BFAD
    c. The batch identification mark of the specific product produced or manufactured, i.e. amoxicillin, ampicillin, etc.
    d. The size of the batch, including the number of containers of each size in the batch, the batch number and date of production.
    e. Certification of Analysis.

2. The local producer or manufacturer shall file with the Bureau within thirty (30) days from production date a usage/distribution report for every batch of production containing the following information.
    a. Name, address of the user/buyer of the raw materials
    b. Delivery receipt indicating date, quantity of raw materials delivered including the number of containers.
    c. Sales invoices

C. Locally Manufactured Finished Products

For locally manufactured antibiotics in finished dosage form using imported or locally produced raw materials, no batch certification will be required for the finished pharmaceutical products provided that:

a. The manufacture has a valid LTO
b. CGMP Certification from BFAD
c. The antibiotic containing pharmaceutical product in finished dosage form has a valid CPR with no reported adverse finding or violation.
d. The manufacturer submits to the Bureau prior to the distribution of a specific batch produced:

    i. The size of the batch including the number of containers of each size in the batch'
    ii. The results of the tests and assay of the batch of raw materials used in the manufacture of the finished dosage forms including documentary proofs as to source of raw materials such as Import Permit, Sales Invoices and Delivery Receipts; Provided however, that the raw materials are used within six (6) months from production date otherwise a new test and assay will have to made of the raw materials;
    iii. The result of the tests and assay of the batch of the finished pharmaceutical products.

D. For Imported Finished Products

The requirement on batch certification provided in A.O. 151 s. 1971 will be observed.

IV. Statutory Authority and Effectivity

The provisions set forth above notwithstanding, the statutory authority (R.A. 3720 as amended) remains, and batch certification can be resumed should the need arise.

This order supersedes other administrative issuances inconsistent herewith and shall take effect fifteen (15) days after publication in newspapers of general circulation.

Approved By:

(Sgd) MANUEL M. DAYRIT, MD, MSc
Secretary