EDITORIAL

WORLD HEALTH CERTIFICATION SCHEME ON DRUGS.

A former Director – General, World Health Organization, Dr. Halfadan Mahler once wrote, "There are certain human values that are or should be sacred in all cultures; social justice is one of them"(Afro Technical Papers No. 18, 1981, page 7, WHO publications). Health care provision to the marginalized population of any society is a cornerstone of this social justice and was highlighted in the Alma-Ata declaration of 1978.

The Alma-Ata meeting set a target of year 2000 by which every woman and man would be expected to enjoy a level of health that would permit her or him to lead a socially and economically productive life. Availability of quality Essential Drugs (ED) was considered critical to success of this long-term objective. In this context, ED refer to a core of approximately 120 drugs which must be available at all times in the health centers and dispensaries, the first point of contact for the poor rural populations. The ED concept found a practical expression in WHO model Essential Drug List published about that time. Other countries published their National Essential Drug Lists borrowing heavily from WHO Model.

Since many of the drugs in National Essential Drug Lists are imported to the recipient countries, it became necessary to consider how quality assurance could be guaranteed before the drugs could leave the country of origin. Several legal technicalities were evident since the importing countries had obvious vested interest. The problem was partly addressed by introduction of WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. Details of this scheme are readily available in WHO Technical Report No. 823, 1992.

The certificate which is in a standard format recommended by WHO comments on the suitability of manufacturing facility for a specific product. A Certifying Authority, usually an official in the Ministry of Health, is nominated by the exporting country and gazetted by the WHO, such information being made available to other countries who are signatory to this Certification Scheme. The Certifying Authority is obliged to state the basis on which the product has been licensed in the country of origin. Permission for issuing the certificate to the applicant is required from the product license holder. Furthermore, a product may be manufactured in a country other than that issuing the product certificate and inspection conducted under the aegis of the country of manufacture. No adverse comment can be included in the certificate without the consent of the manufacturer. Often the Certifying Authority will be content to write, "Information not given".

A pertinent question is whether the WHO Certification Scheme has served the intended purpose. The Scheme alone is inadequate and needs to be complemented by other measures such as quality assurance by National Quality Control Laboratories in the recipient countries. It should also be mandatory for the drugs to be registered in the recipient country. All countries promote their exports, drugs included, to earn foreign currency and it is unlikely that the Certifying Authority would be non-partisan where national interests are at play. When a drug product is found to be substandard, the Certifying Authority cannot be held accountable and the importer has no course for legal redress. Indeed, it can be argued that such deterioration occurred during storage and transport as it moves along supply system. Most problems are detected several months later after the importation. A case in point is paracetamol tablets imported to Kenya and which were found to turn grey (fungal contamination) several months later. Needless to say the importer was held accountable and taken to court.

Editorial–in-Chief.