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CERTIFICATION OF IMPORTED PHARMACEUTICAL PREPARATIONS

by

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In its resolution WHA22.50 the World Health Assembly recommended that Member States adopt and apply a certification system for pharmaceutical products moving in international commerce. As the full text is available in Annex 12 of the Official Records of the World Health Organization No.176, this paper will be restricted to giving some background information on how this scheme was developed.

Various aspects of quality control of drugs moving in international trade have been extensively discussed by the Executive Board of WHO and the World Health Assembly between 1963 and 1969. The main points discussed have been:

a) quality control exercised by public health authorities;
b) quality control exercised by the manufacturer;
c) the possibilities of supplementing the quality control of imported drugs by a system of certification.

During the discussions at the Executive Board and the World Health Assembly, three possible approaches to certification were considered:

1. Certification by WHO that drugs for export comply with established international standards.

2. Certification that drugs intended for export comply with standards not less than those required for consumption in the country of origin.

3. Certification that the exporting firm fulfils certain minimum requirements for production control, supplemented, if requested, by certificates for individual batches of drugs.

As for suggestion 1, it emerged during the discussions that the technical and financial implications of such a centralized certification system would exceed the capacity of any existing international organization.

Suggestion 2 would require that national legislative systems be harmonized to a much higher degree than is now the case.

The third suggestion is, to a certain extent, based on already existing practices in the international trade of drugs, and it also forms the basis of the recommendation of the World Health Assembly.

It should, however, be pointed out that in its resolution WHA22.50 the Assembly requests a report "on further progress with regard to the certification scheme and the implementation thereof".

Harmonization of legislation, even between closely related countries, is a very lengthy and complicated procedure, to a great extent depending on historical and local traditions.

The approach adopted towards application of these recommendations may vary from country to country, owing to, for example, differences in materia medica used and variations in the legislation necessary for the endorsement of these requirements by the national authorities.

As more information becomes available on how such a certification system can be applied in various countries, it will certainly be necessary to propose improvements to the recommended certification scheme.