This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

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Twenty-fourth Report

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Geneva, 3–9 November 1971

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WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Twenty-fourth Report

The WHO Expert Committee on Biological Standardization met in Geneva from 3 to 9 November 1971. Dr V. Fattorusso, Director, Division of Pharmacology and Toxicology, opened the meeting on behalf of the Director-General. He welcomed the members of the Committee and emphasized that its work was of great value for the control of particular biological substances. He was sure that the decisions taken and the recommendations made would be fully in keeping with the high standard and traditions maintained over the years.

GENERAL

International Units for Biological Products

Many biological products used in medicine cannot be adequately characterized by chemical and physical means alone. However, the activity of a biological substance may be evaluated by a biological assay, preferably by comparison with a characterized sample of the substance called a biological standard. International biological standards are preparations intended to serve throughout the world as sources of defined biological activity quantitatively expressed as international units. International units provide a convenient means of expressing in uniform terms the results of biological assays obtained by laboratories in different parts of the world. The wide use of these standards and the corresponding international units in calibrating national standards reflects the value placed on them by national regulatory agencies responsible for the control of biological products. National standards are thus linked to the relevant international standards.

The Third World Health Assembly, in 1950, adopted a resolution [1] recommending that Member States of the Organization recognize officially the then current international standards and units, which were listed in the resolution. It also recommended that the standards and units be introduced into national pharmacopoeias and indicated that, where national authorities did not have their own pharmacopoeias, the potency of biological products be expressed in international units. The Eighteenth World Health Assembly,

[1] Resolution WHA3.8 (*Off. Rec. Wld Hlth Org.*, 1950, **28**, 17).

in 1965, adopted a similar resolution [1] and listed the international standards and units current at that time. This resolution additionally recommended that international standards and units (or their equivalents) be cited in national pharmacopoeias and be recognized in the national regulations that relate to the control of biological products.

Attention should be drawn at this point to another category of reference substances established by the WHO Expert Committee on Biological Standardization and known as international reference preparations. International reference preparations are, in many instances, similar in nature and function to international standards but have not been established as international standards on account of various considerations, which may be technical, scientific, or procedural.[2] Their official status for national control of biological products is different from that of international standards since they have not been included in resolutions of the World Health Assembly. Consequently, acceptance by Member States throughout the world of any international unit that might have been defined for these preparations is not implied. Nevertheless, national control authorities, recognizing the value and utility of these international units, often use them in their control measures.

Essentially, therefore, an international standard is for the specific purpose of providing an international unit to serve in the control of potency of the corresponding biological products and its acceptance as such by Member States is implied by virtue of the resolutions referred to above.

Thus, when an international standard is established by the WHO Expert Committee on Biological Standardization there may be important implications for national authorities. Implementation of the recommendations of the World Health Assembly on international biological standards would mean that national control authorities would themselves adopt the international unit (or its national equivalent) and use it in their control of the corresponding biological products.

However, when chemical and physical methods become available that are adequate for the characterization of a particular biological product, there is no longer a need for the international biological standard or reference preparation, which may then be discontinued. When an international standard (or international reference preparation) is discontinued the international unit automatically ceases to exist and national authorities may have to make changes in their specifications and methods for the control of the relevant biological products. It is desirable therefore that national control authorities should be given due notice of the intended discontinuation of any international unit so that any changes that may be required can be effected.

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[1] Resolution WHA18.7 (*Off. Rec. Wld Hlth Org.*, 1965, **143**, 5).