

Force and the item was standardized. These reviews include consideration of such data as local purchase statistics, professional needs and uses, patient acceptance, comparison with items already stock listed, and an evaluation of known sources of supply.

ESSENTIAL CHARACTERISTICS

Since the Air Force request named only the one commercial product, it was necessary for DMMB to request Riker Laboratories for detailed information on Titalac. Riker advised that the product was patented, but agreed to provide that information—physical and chemical characteristics, test protocols, clinical and stability studies—which specifically identify the item produced by that manufacturer.

The Board used these data in the preparation of tentative essential characteristics for calcium carbonate and aminoacetic acid tablets. The essential characteristics (or EC's) are defined as those mandatory qualities required of an item to accomplish a specific professional, therapeutic, technical, or military purpose. For drugs, they include, but are not limited to—

A description of the item, and its application or use. Components of the formula, when appropriate.

Quantification, as required.

Unit of issue, type of container, package size, and any special packaging instructions.

Labeling requirements, identification data, and necessary instructions for use.

Initial proposals for type classification on an item are recorded on a "coordination worksheet for medical items pending adoption" (DMMB form 1, exhibit 1). DMMB distributed this form 1 concurrently to the services and to DPSC. Comments were solicited from all addressees. The services annotated the form 1 with their initial, and 12 months replenishment requirements.

Within DPSC, the form was reviewed in the Technical and Supply Operations Divisions of the Medical Directorate to hasten availability of the drug through the DOD wholesale distribution depots. Having determined that the EC's were adequate for preparation of a competitive specification or purchase description, DPSC returned the form 1 to the Board.

Had it been determined that no further data could be acquired, and that total available information was inadequate for preparation of a competitive specification, the case would have been returned to the services. Upon their recommendations, a determination would have been made to discontinue action, or to process the item indicating a limited source of supply.

Parenthetically, a recommendation for a limited source of supply may originate with a service, DPSC or DMMB. This action may be taken only in those instances where it has been professionally determined that the product of a specified supplier or suppliers is required to provide for the health and welfare of Armed Forces personnel or their dependents. The decision must be concurred in by all three military medical services. Such determinations normally derive from an accumulation of clinical experience, and may relate to experience prior to type classification of the drugs, or to those in the system which have accumulated a significant complaint history. I shall speak again of limited source items when I reach the statistical portion of my presentation.

Had DPSC or the services submitted conflicting recommendations regarding this particular standardization action, it would have been DMMB's responsibility to resolve them. There being none, comments were reviewed, data was finalized, and the results transcribed to an item review report (DMMB form 5, exhibit 2). Distribution follows that of the form 1, but the form 5 is an action document. It authorizes cataloging, preparation of specifications, procurement, and distribution. (This same form is used for any directed change in status, such as revised EC's or reclassification to limited standard or deleted.)

I will not describe in general terms the responsibilities and actions taken by personnel of the Technical and Supply Operations Divisions of the Medical Directorate upon receipt of an item review report.

SUPPLY OPERATIONS

A supply control study (DPSC form 2340) is developed by a supply operations commodity (item) manager to portray all data relevant to an appropriate