

12034 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Reimbursable Cost List Price (RCLP) for a number of generic drugs and certain other products was established. The RCLP was based on cost data published in the pharmaceutical industries' "Red Book" and "Blue Book". To be placed on the RCLP a product had to be produced by a number of manufacturers or distributors, the list price had to vary considerably, the product had to be widely used, and the product had to be generally available throughout the State.

To determine whether a drug product had been demonstrated to be safe and effective the Department relied on the Federal Food and Drug Administration, and also on the manufacturer's guarantee that his drug product met all provisions of the Federal Food, Drug and Cosmetic Act or the California Sherman Food, Drug and Cosmetic Act. Other requirements included that the drug meet the requirements of the United States Pharmacopoeia (U.S.P.) or National Formulary (N.F.), and that the drug had been reviewed by the National Academy of Science-National Research Council, if applicable.

In the establishment of RCLPs only multisource generic drug types, those drugs produced or marketed by more than one manufacturer, were considered. Of the approximate 600 drugs listed in the Medi-Cal Drug Formulary 35 percent are multisource and 65 percent are single source. RCLPs were established originally for 196 generic drug types and medical supplies (see attached list) which the Department had determined met the criteria described above. These drugs potentially represented the greatest possible dollar savings due to their high utilization and price range differentials.