

ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers

Pharmacists are responsible for selecting, from hundreds of manufacturers and suppliers of drugs, those that will enable them to fulfill an important obligation: ensuring that patients receive pharmaceuticals and related supplies of the highest quality and at the lowest cost. These guidelines are offered as an aid to the pharmacist in achieving this goal.

Obligations of the Supplier

Pharmacists may purchase with confidence the products of those suppliers meeting the criteria presented here. Other factors such as credit policies, delivery times, and the breadth of a supplier's product line also must be considered when selecting a supplier.

Technical Considerations

1. On request of the pharmacist, the supplier should furnish
 - a. Analytical control data.
 - b. Sterility testing data.
 - c. Bioavailability data.
 - d. Bioequivalency data.
 - e. Descriptions of testing procedures for raw materials and finished products.
 - f. Any other information that may be indicative of the quality of a given finished drug product.

Testing data developed by independent laboratories should be identified by the supplier. All information should be supplied at no charge.
2. There should be no history of recurring product recalls indicative of deficient quality control procedures.
3. The supplier should permit visits (during normal business hours) by the pharmacist to inspect its manufacturing and control procedures.
4. All drug products should conform to the requirements of *The United States Pharmacopeia—The National Formulary (USP—NF)* (the most recent edition) unless otherwise specified by the pharmacist. Items not recognized by *USP—NF* should meet the specifications set forth by the pharmacist.
5. To the extent possible, all products should be available in single unit or unit dose packages. These packages should conform to the "ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs."¹
6. The name and address of the manufacturer of the final dosage form and the packager or distributor should be present on the product labeling.
7. Expiration dates should be clearly indicated on the package label and, unless stability properties warrant otherwise, should occur in January or July.
8. Therapeutic, biopharmaceutical, and toxicologic information should be available to the pharmacist on request. Toxicity information should be available around the clock.
9. Patient/staff educational materials that are important for proper use of the product should be routinely available.

10. On request, the supplier should furnish proof of any claims made with respect to the efficacy, safety, and superiority of its products.
11. On request, the supplier should furnish, at no charge, a reasonable quantity of its products to enable the pharmacist to evaluate the products' physical traits, including pharmaceutical elegance (appearance and absence of physical deterioration or flaws), packaging, and labeling.

Distribution Policies

1. Whenever possible, delivery of a drug product should be confined to a single lot number.
2. Unless otherwise specified or required by stability considerations, not less than a 12-month interval between a product's time of delivery and its expiration date should be present.
3. The supplier should accept for full credit (based on purchase price), without prior authorization, any unopened packages of goods returned within 12 months of the expiration date. Credits should be in cash or applied to the institution's account.
4. The supplier should ship all goods in a timely manner, freight prepaid, and enclose a packing list with each shipment. All items "out of stock" should be noted, and the anticipated availability of the item should be clearly indicated. There should be no extensive recurrence of back orders.
5. The supplier should warrant title to commodities supplied, warrant them to be free from defects and imperfections and fit for any rational use of the product, and indemnify and hold the purchaser harmless against any and all suits, claims, and expenses, including attorneys' fees, damages, and injuries or any claims by third parties relating to the products.

Marketing and Sales Policies

1. The supplier should not, without written consent, use the pharmacist's or his or her organization's name in any advertising or other promotional materials or activities.
2. The supplier should honor formulary decisions made by the organization's pharmacy and therapeutics committee, and the supplier's sales representatives should comply with the organization's regulations governing their activities.
3. The supplier should not offer cash, equipment, or merchandise to the organization or its staff as an inducement to purchase its products.
4. Discounts should be in cash or cash credit, not merchandise, and should be clearly indicated on invoices and bills rather than consisting of end-of-year rebates or similar discount practices.
5. In entering into a contract to supply goods, the supplier should guarantee to furnish, at the price specified, any minimum amount of products so stated. If the supplier

is unable to meet the supply commitment, the supplier should reimburse the organization for any excess costs incurred in obtaining the product from other sources. If, during the life of the contract, a price reduction occurs, the lower price should prevail.

6. All parties to the bidding process should respect the integrity of the process and the contracts awarded thereby.

Responsibilities of the Purchaser

It may be desirable to purchase drugs or other commodities on a competitive bid basis. The pharmacist should ensure that competitive bidding procedures conform to the guidelines below:

1. Invitations to bid should be mailed to the suppliers' home offices with copies to their local representatives (if any), unless suppliers specify otherwise.
2. Potential bidders should be given no less than 3 weeks to submit a bid.
3. The opening date for bids should be specified and honored by the purchaser.
4. The language of the invitation to bid should be clear and should indicate the person (and organization address and telephone number) the bidder should contact in the event of questions or problems. Specifications should be complete with respect to products, packagings, and quantities desired.
5. If bidding forms are used, they should contain adequate space for the bidder to enter the information requested.
6. The winning bidder should be notified in writing. Unsuccessful bidders may be informed of who won the award at what price, if they so request.

7. The quantities specified in the invitation to bid should be a reasonable estimate of requirements.
8. If the invitation to bid is offered on behalf of a group of purchasers, the individual members of the group should not engage in bidding procedures of their own and should purchase the goods in question from the winning bidder.

Reference

1. American Society of Hospital Pharmacists. ASHP technical assistance bulletin on single unit and unit dose packages of drugs. *Am J Hosp Pharm.* 1985; 42:378–9.

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