# COMPLIANCE

## DRUG SHORTAGE MANAGEMENT

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**PURPOSE**

This guide establishes Center procedures for the evaluation of drug shortage situations, so that appropriate actions may be taken promptly.[1]

**DEFINITIONS**

- **CDER Drug Shortage Coordinator** - designated by the Center's Deputy Director for Pharmaceutical Science to facilitate a determination by the appropriate Office Director(s) as to the medical necessity of the shortage product(s) as soon as practicable (see Responsibilities and Procedures, 1.a.).

- **Medically Necessary Product** - A product is considered to be medically necessary, or a medical necessity, if it is used to treat or prevent a serious disease or medical condition, and there is no other available source of that product or alternative drug that is judged by medical staff to be an adequate substitute. Patient "inconvenience" alone is an insufficient basis to classify a product as a medical necessity.

**BACKGROUND**

- It is Agency policy to attempt to prevent or alleviate shortages of medically necessary products. A drug shortage situation may involve an actual or potential shortage of a drug product. The Agency may be alerted to shortage situations by external sources such as health care professionals, industry, the press, and/or consumer groups, or through normal FDA surveillance and enforcement activities. Drug shortages may arise from varying causes, such as the unavailability of raw materials or packaging components, marketing decisions, and enforcement issues.

[1]This guide does not confer any rights or expectations on any person who may claim that the guidance was not followed or was implemented improperly.

- External reports of shortages are also received through the Drug Shortage system (DSs) operated by the Drug Quality Reporting System (DQRS). The DSs responds to questions from health professionals, consumers, and others regarding drug shortage issues. They then contact the involved manufacturer(s) or supplier(s), FDA's field organization, and appropriate Center staff to determine whether the shortage is caused by production or distribution problems. Each report is assigned an individual accession number and entered into the DQRS data base.

- In addition, FDA has requested that the industry report shortage situations involving medically necessary products.

**RESPONSIBILITIES AND PROCEDURES (See Attachment A)**

- **General Procedures**. All drug shortage situations will be reported promptly to CDER. Shortage situations involving FDA enforcement activities will be forwarded to the Office of Compliance (OC), while all other shortage situations will be forwarded to the Division of Pharmacovigilence and Epidemiology (DPE) (see Attachment B).

- All reports will be screened by OC and DPE to determine whether a real or potential shortage situation, in fact, exists. If a bona fide shortage situation is confirmed, the shortage issue will be brought to the attention of the CDER Drug Shortage Coordinator for a determination as to the medical necessity of that product(s) as soon as practicable.

- Special actions may range from discussions with the industry, acceleration of NDA/ANDA review activities, and/or, in extraordinary circumstances, enforcement discretion.

1. Center for Drug Evaluation and Research (CDER).

a. Office of Compliance

CDER's Office of Compliance monitors the resolution of all shortage situations involving compliance issues.

Depending on these issues, either the affected Compliance Division(s) or Recall Officer will have the lead. Responsibilities include:

(1) Receiving and monitoring reports of shortage situations involving compliance problems. Situations may result from voluntary actions by the manufacturer, e.g., recalls, cessation of distribution, contemplated/ongoing regulatory actions to correct violations.

(2) Screening the reports and forwarding to the CDER Drug Shortage Coordinator if a bona fide shortage situation exists.

This may involve coordination with various headquarters and Field offices to obtain information that more fully characterizes the nature and scope of the situation.

In all cases, the affected Compliance Division(s) coordinates with the CDER Recall Officer who represents the Director of the Office of Compliance.

(3) Participates in discussions to characterize the impact of the compliance issues on the overall quality of the product and to identify any precedent actions bearing upon the issue.

b. Division of Pharmacovigilence and Epidemiology (DPE)

DPE monitors the resolution of all reports or situations involving product shortages relating to non-compliance problems. Responsibilities include:

(1) Operating the Drug Shortage system (DSs).

(2) Receiving reports of shortages from FDA units, industry, and health professionals.

(3) Conducting an evaluation of the reported shortage, which includes:

(i) determining the cause of the reported shortage, e.g., production vs. distribution;

(ii) contacting the person who reported the shortage to obtain additional information, including actions taken to obtain the drug;

(iii) identifying proportional market share.

(4) Contacting the Office of Compliance to determine whether FDA compliance actions are related to the shortage. If so, forwarding a report to the Office of Compliance for resolution.

(5) Forwarding a confirmed drug shortage situation to the

CDER Drug Shortage Coordinator to determine whether the product is a medical necessity.

(6) Responding to Office of Compliance requests for market share information for use in resolving evaluations of situations involving compliance problems.

(7) Maintaining a computerized data base containing all drug shortage reports.

c. Office of the Director

The Deputy Director for Pharmaceutical Science's designees serve as the CDER Drug Shortage Coordinators for confirmed drug shortages. Responsibilities include:

(1) Requesting the Director(s) of the review office(s) to determine whether the product(s) is a medical necessity. If appropriate, convenes an ad hoc meeting with the appropriate Office Director(s) and review division personnel.

(2) When a medical necessity exists, coordinating an action plan to prevent or mitigate, whenever possible, a supply disruption.

**Note:** Enforcement discretion may be exercised where the shortage situation results from compliance issues. A decision to exercise such discretion as the option best meeting the public interest must be based on careful consideration of the impact of the violations on the quality of the product, the medical risks that would result from them, and any other factor that CDER deems relevant. The Office of Compliance (OC), Office of Enforcement (OE), Office of General Counsel (OGC), and the Field will participate in these discussions to describe the impact of the violations on the overall quality of the product.[2]

(3) Determining whether there are other sources, alternate products, routes, or dosages for the drug product(s) (the contractor for the Drug Quality Reporting System and the

[2]A decision to exercise or refrain from exercising enforcement discretion is not subject to judicial review.

field offices may be requested to assist in determining alternate sources and production capacity); and,

(4) Assuring that the Agency position is defensible and documented. This may require consultation and/or concurrence of the Director of CDER, OGC, or other Agency officials.

2. Office of Regulatory Affairs

a. District Offices

(1) The district will forward drug shortage situations that do not involve compliance issues directly to the Division of Pharmacovigilence and Epidemiology. Shortages can be reported to the Division of Emergency and Epidemiological Operations (DEEO), HFC-160, only for after-hour emergencies. DEEO will forward these reports to DPE.

(2) The district will alert and then forward directly to the Office of Compliance drug shortage situations involving compliance issues.

(3) District recommendations for regulatory actions will identify potential shortage situations warranting consideration by CDER.

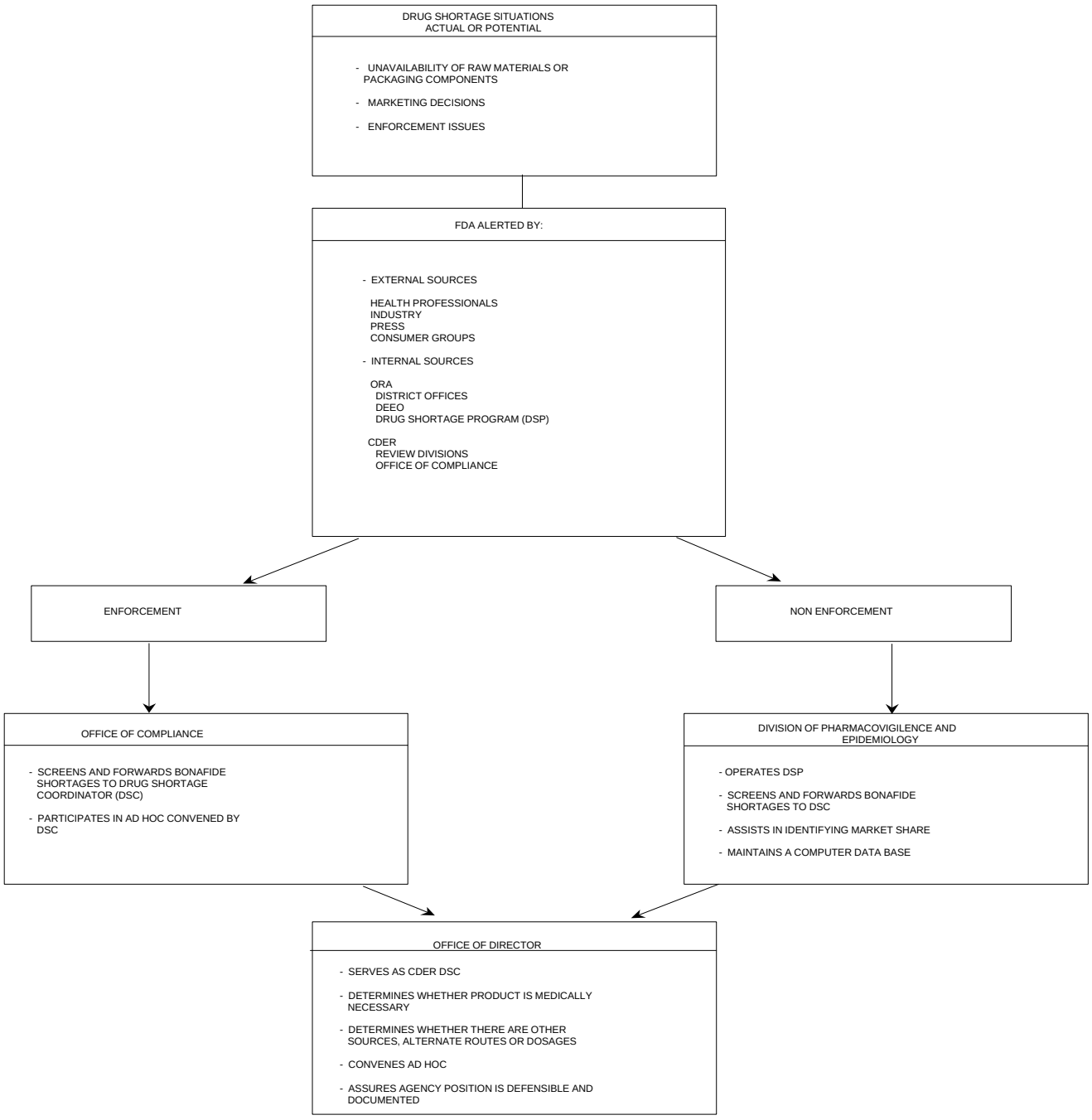
(4) For medical necessities, the district will work with CDER in determining the nature and scope of shortage situations.

b. Division of Emergency and Epidemiological Operations (DEEO)

(1) DEEO will promptly advise CDER of all shortage reports received. Reports related to Compliance issues are sent to OC. All other reports are sent to DPE.

**Attachment A**

DRUG SHORTAGE MANAGEMENT RESPONSIBILITIES



**Attachment B**

## HOW TO PROCESS A DRUG SHORTAGE REPORT