Office of Generic Drugs

Handling of Adverse Experience Reports and Other Generic Drug Postmarketing Reports

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PURPOSE

- This MAPP defines the procedure for handling any adverse experience report (AER) or other postmarketing reports received by the Office of Generic Drugs (OGD) concerning the use of a generic drug product.

BACKGROUND

- The monitoring of postmarketing adverse events seen with the use of all drug products, including generic drug products, is one aspect of the overall Center for Drug Evaluation and Research (CDER) effort to evaluate the safety of drug products after approval.

- Generally, OGD receives few AERs or similar reports since the reports may not specify a generic manufacturer for the drug product. Furthermore, the safety profile of a particular drug is usually well-known before generic versions are approved. Therefore, AERs associated with a generic drug are less likely to be reported.

- OGD also receives reports through the Drug Product Quality Report System (DQRS), Field Alert Reports (FARs), and anecdotal reports of poor product performance or potential evidence of inequivalence.

REFERENCES

- 21 CFR 314.98
- 21 CFR 314.81 (b)(1)(i) and (ii)

POLICY

- The Associate Director for Medical Affairs in OGD will triage all reports of any adverse experience with, or non-optimum performance of, a generic drug product.

- All adverse experience reports will be forwarded to the Office of Drug Safety to ensure that the information is in the CDER AERs database.

- DQRS reports and FARs will be directed to the Associate Director for Medical Affairs if there are potential clinical implications.

RESPONSIBILITIES

- Any OGD staff that receives a report of any kind about the postapproval performance of a generic drug product will forward that report to the Associate Director for Medical Affairs. Such reports might include formal postmarketing adverse event reports, DQRS reports, or anecdotal reports of less than optimal generic product performance.

- The Associate Director for Medical Affairs will read the reports and take one or more of the following actions:

    1. Review the report in depth if there are clinical concerns.

    2. Forward a copy to the Office of Drug Safety, if appropriate.

    3. Refer the matter to the Associate Director for Chemistry if the matter appears to be solely a manufacturing product quality issue.

    4. Refer the report to the Therapeutic Inequivalence Action Coordinating Committee (TIACC) if the report presents evidence of the generic drug product not being equivalent to the reference listed drug or if it reports lack of effect of the generic drug.

    5. Determine that no action is indicated and document that fact.

PROCEDURES

- Accepted OGD review procedures will be followed.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.