The OIG Applauds FDA's Progress in Inspections of Generic Drug Manufacturers but Recommends More to be Done

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The Department of Health and Human Services' Office of Inspector General (OIG) has recently recommended that the Food and Drug Administration (FDA) continue to increase its pre-approval inspections of generic drug companies.[1] The OIG noted that, in 2012, nearly 80% of prescriptions filled in the U.S. were for generic drugs.

Here are some highlights of the OIG report.

- FDA has improved its oversight and inspection of generic drug manufacturers:
  - The OIG reviewed FDA data on inspections of generic drug manufacturers from 2011-2013;
  - Pre-approval inspections of generic drug facilities increased by 60% during the three-year period, due in part, from increased funds provided by the Generic Drug User Fee Act of 2012;
  - Pre-approval inspections of foreign drug companies increased; there has been public concern expressed about the quality of generic drugs made at ex-U.S. sites.
- The OIG recommended that FDA establish a formal plan to review facility records in advance of inspections or, perhaps, even in lieu of conducting a pre-approval inspection (as permitted under the Food and Drug Administration Safety and Innovation Act).
- The OIG report said that FDA should "develop an appropriate timeline to reduce the backlog of preapproval inspections."
  - FDA's Office of Regulatory Affairs did not conduct all of the pre-approval inspections requested by the Office of Generic Drugs' application reviewers.
- In FY 2013, FDA conducted post-approval surveillance inspections of all generic drug manufacturing facilities that it identified as "high risk" facilities (approximately 65% of those inspected were ex-U.S. firms).
- In FY 2013, the agency conducted 589 surveillance inspections of generic firms:
  - 57% were foreign inspection:
    - 31% occurred in Asia;
    - 21% occurred in Europe;
    - 3% occurred in Canada;
    - 2% occurred elsewhere.
- On the basis of the high-priority inspections, FDA required corrective action for 11 generic manufacturers, 2 of which were foreign.
- FDA has set a goal that, by FY 2017, it will achieve domestic and foreign inspection parity, with "comparable depth and rigor."
  - Parity is defined as within 20% of equal frequency of foreign and domestic inspections.
- The OIG recommended that FDA cross-check its registration records with the names of manufacturers listed, for example, on approved abbreviated new drug applications and, if appropriate, issue Warning Letters if the companies are not complying with registration requirements.

1 OIG Report, "FDA Has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs," available at http://oig.hhs.gov/oei/reports/oei-01-13-00600.pdf.

AGG Observations

- Expect more foreign inspections of generic drug manufacturers, including an increase of domestic sites so that FDA can achieve its goal of parity.
- Expect FDA to request, in advance, facility records to expedite, if not forego, inspections.
- Poor inspections can lead to delays in generic drug application approvals and, for marketed products, enforcement actions, including the issuance of Warning Letters or imposition of Import Alerts.

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