General Chapter Prospectus: Storage and Transportation of Investigational Drug Products (IDPs)

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Proposed Title: <1079.1> Storage and Transportation of Investigational Drug Products (IDPs)

Suggested audience: Clinical trial sponsors (Drug product manufacturers, Research Organizations, etc.) and clinical trial personnel

Estimated proposal PF: Pharmacopeial Forum 43(4) [Jul.–Aug. 2016]

Background and objective(s): Clinical trials are drug studies that are performed to determine if an investigational medicine meets the effectiveness and safety criteria as has been outlined in the protocol for the clinical trial. Investigational drug products (IDPs) are products not commercially available for the indication or dosage being tested; there may be situations when a commercially available product may be used in a clinical trial as a positive control (comparator), a new indication, or a rescue medication. The pre-commercial nature of IDPs means the manufacturing ingredients, including active pharmaceutical ingredients (APIs), excipients, the clinical trial dosage, and any associated stability and packaging components may not be as defined as they would for a final approved finished product.

IDP distribution differs from commercial distribution in that the quantities for IDPs are often small (e.g., as little one or two bottles or unit dose packages) and there are numerous final destinations for distribution, such as clinics and remote clinical settings. Another difference from

commercial drug product is the known stability of the IDP, which is often a new chemical/molecular entity and in early stages of clinical trials and has not been through the robust stability program of commercial products. The IDP also creates a different challenge when compared to a commercial product with ensuring the proper distribution of every container, because a temperature excursion of just a single container may jeopardize the entire clinical trial outcome. Thus, the objective of the chapter is to offer guidance on the distribution of IDPs.

Description of scope and application: This General Chapter will focus on aspects of storage and distribution that are unique to IDPs (e.g., unblinding, comparators, and academic studies).

Preliminary outline:

1. Introduction
2. Scope
3. Key Factors FOR IDP Distribution
    a. Number of Clinical Trial Sites
    b. Audits
        - clinical trial site
    c. Available Product Quantities
    d. Expiration/Retest Dates
    e. Qualification of Packaging for IDP and Track & Trace
    f. IDP Supply Chain Challenges
    g. Timing
    h. Key Global Challenges for IDPs
4. IDP Environmental Conditions
    a. Unblinding
    b. Comparators
    c. Returned IDPs
5. Assessing Risk Early in the Distribution Process
6. Terms & Acronyms

Anticipated implementation timing: Routine.

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