CHAPTER V: DRUG REGISTRATION AND IMPORT

A. Overview

Getting approval for the import of drugs into India consists of up to three main phases. First, new drug approval must be received from the DCGI, not necessarily for new drugs only. Once the new drug registration has been obtained, or for drugs not needing it, an import registration certificate can be received from the DCGI. Finally, the importing party uses the import registration certificate to obtain an import license from the DCGI.

For a visual representation of the key steps, see Appendix I.

B. New Drug Registration

Under Indian law, many products which are not "new" by Western standards may still have to go through the new drug application process. The categories that require new drug registration are:

A. A drug which has not been marketed in India before.

B. A drug with a new therapeutic purpose or dosage that has not been marketed in India.

C. A new fixed-dose combination of two or more drugs, if they have not been approved in such a combination before.

D. A drug or formulation which received its first new drug approval (of any of the types listed above) less than four years ago. This does not apply if the drug has been included in the Indian Pharmacopoeia since then.

E. Any vaccine, unless certified otherwise by the DCGI.

The DCGI typically requires **phase III trials to be performed in India** before it will approve a foreign new drug for marketing. Other phases may be performed outside India. However, this only applies fully to category A ("true" new drugs).

New drug application content varies based on the category of new drug. For any category, **all new drug applications** must have the following information:

1. Drug name

2. Dosage form

3. Composition of formulation

4. Test specifications for:

a. Active ingredients
b. Inactive ingredients

5. Pharmacological classification

6. Indications

7. Manufacturer(s) of raw materials

8. Applicable patents, if any

To register new drugs for marketing which have **never been registered** before (type A above), the following items are required in addition to 1-8 above:

1. Introduction (brief description of drug and its therapeutic class)

2. Chemical and pharmaceutical information
    a. Active ingredient(s) (generic name, chemical name, or INN)
    b. Physiochemical data
    c. Analytical data
    d. Complete monograph specification
    e. Validations
    f. Stability studies
    g. Formulation data

3. Animal pharmacology data
    a. Summary
    b. Specific pharmacological actions
    c. General pharmacological actions
        i. Essential safety pharmacology
            1. Cardiovascular system
            2. Central nervous system
            3. Respiratory system
    d. Follow-up and supplemental safety pharmacology
        i. Follow-up essential safety
            1. Cardiovascular system
            2. Central nervous system
            3. Respiratory system
        ii. Supplemental safety
            1. Urinary system
            2. Autonomic nervous system
            3. Gastrointestinal system
            4. Other organ systems (where there is cause for concern)
    e. Pharmacokinetics
        i. Absorption
        ii. Distribution