PRESENTATION ON DRUG REGISTRATION IN INDIA

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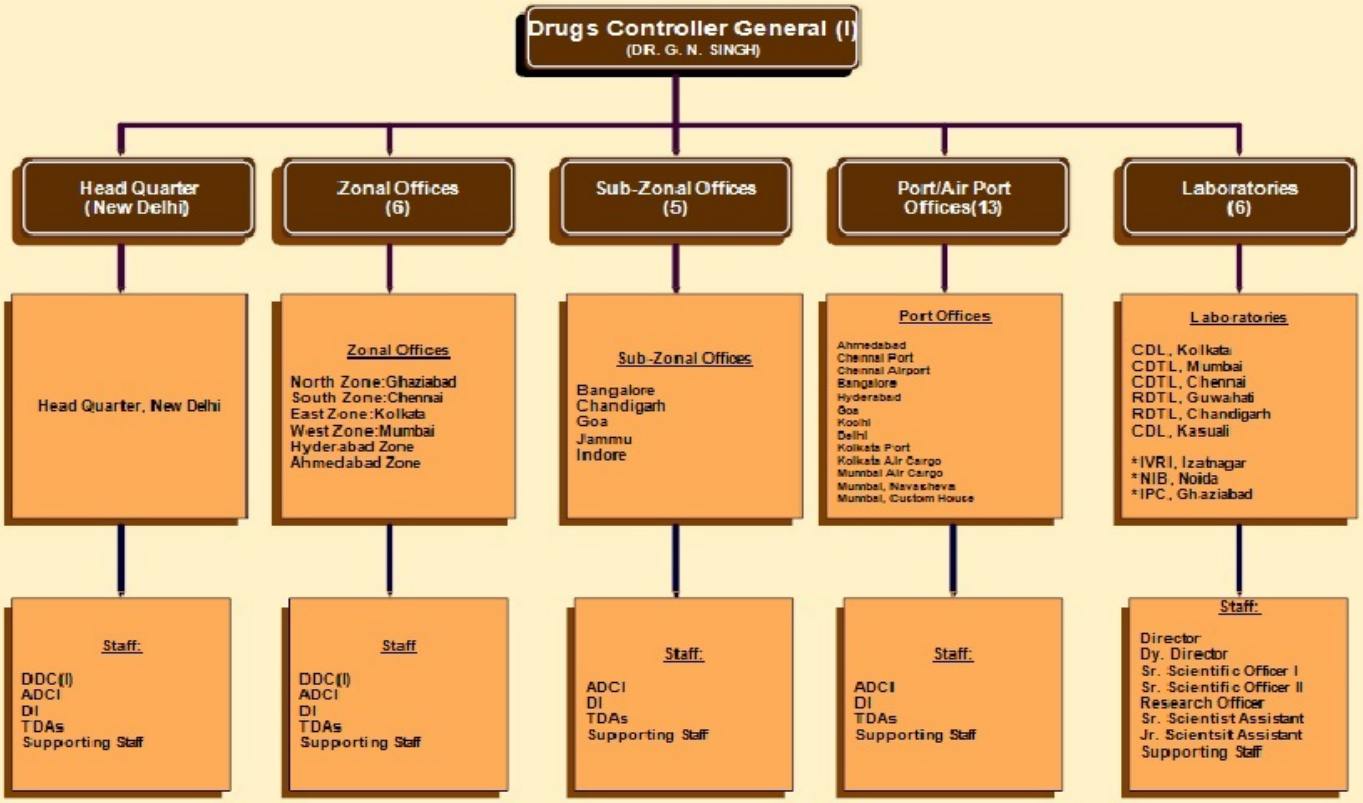
REGULATORY FRAMEWORK IN INDIA

- The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.
- CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control.
- Major functions of CDSCO:
  - Regulatory control over the import of drugs
  - Approval of new drugs and clinical trials
  - Meetings of Drugs Consultative Committee (DCC)
  - Meetings of Drugs Technical Advisory Board (DTAB)
  - Approval of certain licences as Central Licence Approving Authority is exercised by the CDSCO headquarters.

Organisation Chart
Central Drugs Standard Control Organisation



Abbreviations:CDSCO- Central Drugs Standard Control Organisation; CDL-Central Drug Laboratories ; CDTL-Central Drug Testing Laboratories; RDTL-Regional Drug Testing Laboratories; IVRI-Indian Veterinary Research Institute; NIB-National Institute of Biologicals; IPC-Indian Pharmacopoeia Commission; DDC(I) - Deputy Drugs Controller (I); ADC(I)- Assistant Drugs Controller; DIs-Drugs Inspectors; TDAs-Technical Data Associates

REGULATORY FRAMEWORK IN INDIA

Statutory Functions undertaken by Central Licensing Authority	Statutory Functions undertaken by State Licensing Authority
Laying down standards of drugs, cosmetics, diagnostics and devices	Licensing of drug manufacturing and sales establishments
Laying down regulatory measures, amendments to Acts and Rules	Licensing of drug testing laboratories
To regulate market authorization of new drugs	Approval of drug formulations for manufacture
To regulate clinical research in India (approval of clinical trials)	Monitoring of quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state
To approve licenses to manufacture certain categories of drugs as Central Licence approving Authority i.e. for Blood Banks, Large Volume Parenterals and Vaccines & Sera	Investigation and prosecution in respect of contravention of legal provisions

REGULATORY FRAMEWORK IN INDIA

Statutory Functions undertaken by Central Licensing Authority	Statutory Functions undertaken by State Licensing Authority
To regulate the standards of imported drugs	Administrative actions
Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC)	Pre- and post- licensing inspection
Testing of drugs by Central Drugs Labs Publication of Indian Pharmacopoeia (IP)	Recall of sub-standard drugs

FDC REGISTRATION PROCESS IN INDIA

Step 1
- Determine the classification of FDC
- Determine if the FDC requires registration in India

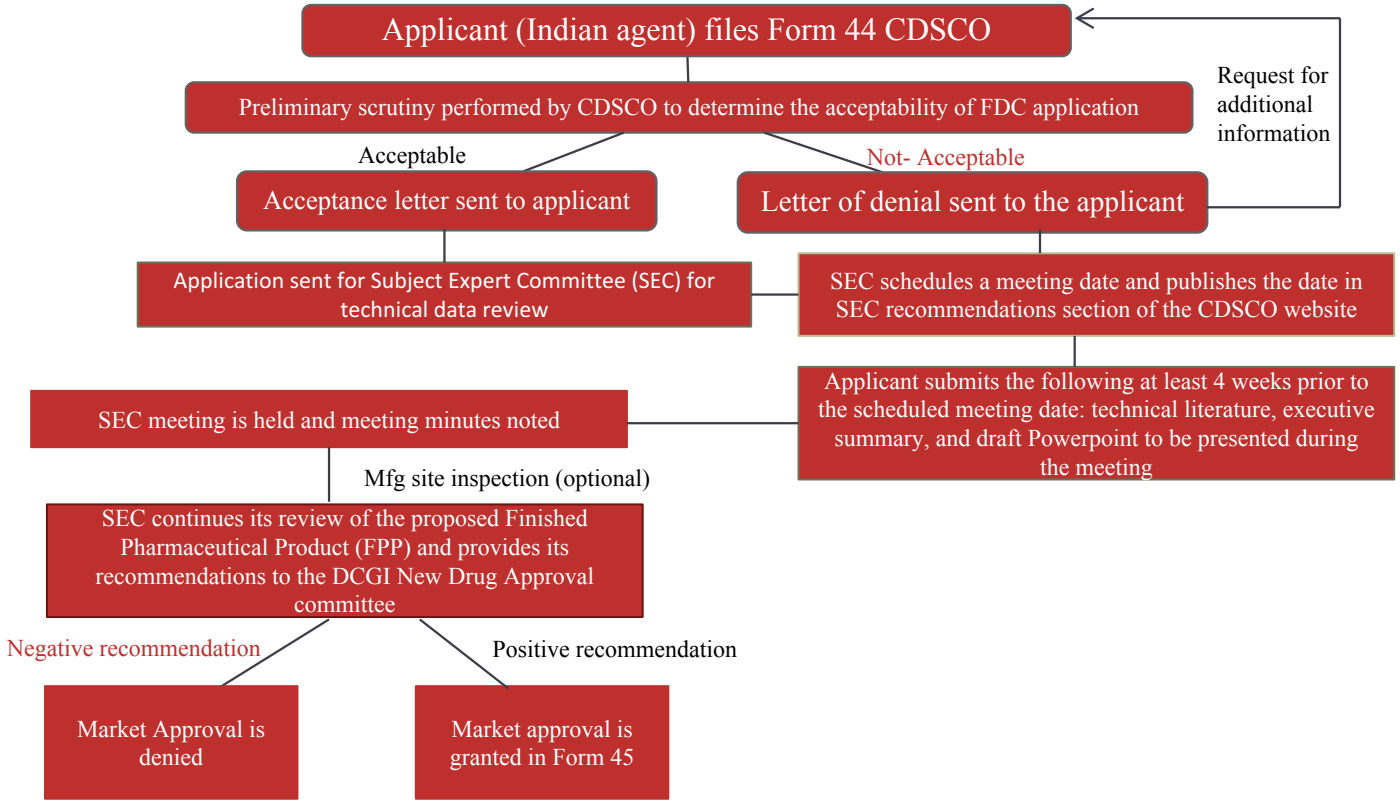
Step 2
- Appoint a Local Authorized Agent to represent the manufacturer in India
- Apply for Market Approval in Form 44
- Obtain the Market Registration Certificate in Form 45

Step 3
- Apply for Import Registration in Form 40
- Obtain Import Registration Certificate in Form 41

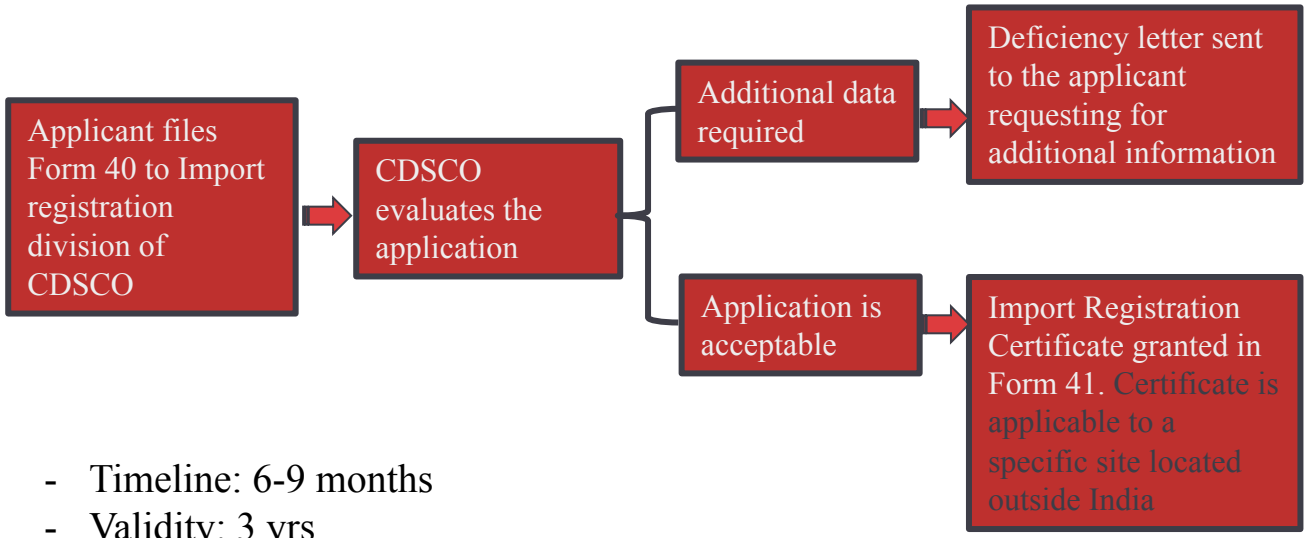
Step 4
- Apply for Import License in Form 8 and 9
- Obtain Import Licence Certificate in Form 10

Step 5
- Marketing in India

1. THE MARKET APPLICATION REVIEW PROCESS



2. IMPORT REGISTRATION PROCESS

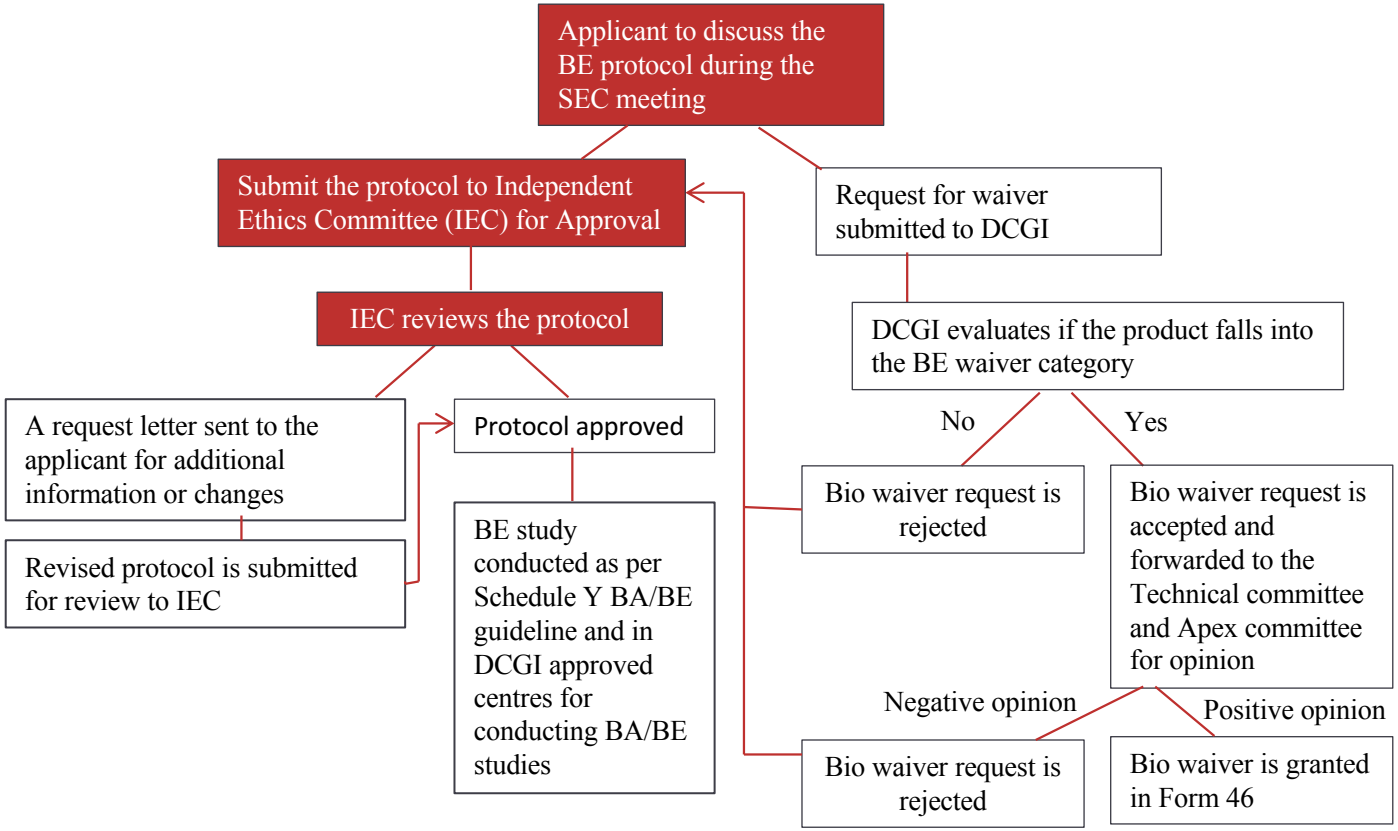


- Timeline: 6-9 months
- Validity: 3 yrs

BE STUDY IN INDIA

- Applicable guideline - “Guideline for Bioavailability and Bioequivalence studies” mentioned in Schedule Y of Drugs and Cosmetics Act (IInd Amendment), 2005.
- Related guidelines available on the CDSCO website for industry
  - Revised Checklist for Pre-screening of BA/BE Applications (Draft 2014) effective from 1st Feb 2014
  - Neutral Code - labelling
  - List of Approved BA/BE Centres

BE STUDY OPTIONS IN INDIA



BE WAIVER POSSIBILITY

In India, a biowaiver is granted based on two categories –

1. Finished Pharmaceutical Product (FPP) formulation:
   - parenteral products, solution for oral use, is a gas, powder for reconstitution as a solution, otic, opthalmic or topical solution, inhalation product or nasal spray.
2. Marketing status:
   - Approved in India for more than 4 years except for modified release dosage form [old drugs].

CDSCO INSPECTIONS

- CDSCO inspections may be conducted during review of application.
- For Indian manufacturing units the inspection is conducted on-site.
- For manufacturing sites located abroad, CDSCO may request for recent inspection/audit report performed by respective regulatory authority of the country where site is located.
- If deemed necessary, CDSCO may perform inspection of the FPP manufacturing site or BE study site.
- Manufacturing site is notified 1 month prior to the inspection date.
- CDSCO Inspection fees: FPP Manufacturer is liable to pay USD 5,000 (or its equivalent in Indian rupees) for Expenditure - Inspection fees + travel expenses for inspection that is to be borned by company, as may be required for inspection or visit of manufacturing premises.

PHARMACOVIGILANCE PLAN

- To be submitted at the time of initial marketing approval.
- Plan should mention:
  - Safety data from clinical development
  - Potential risks of the FDC
  - Population at risk
  - Situations not adequately studied
  - Drug-drug, drug-food interaction information
- Commitment to active surveillance.
- Protocols for any observational studies planned – these will need separate approvals.
- Safety signals obtained from other countries where product is approved must be reported.

DRUG PRICING AND REIMBURSEMENT

- The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (separate office from CDSCO) enforces price control regulations as per Drug Price Control Order (DPCO) 2013.
- DPCO applies to 509 medicines on the National List of Essential Medicines.
- Using a market-based approach, a price ceiling is set for essential medicines in order to ensure affordability.
- The maximum retail price is fixed based on the API, route of administration, dosage form and strength.
- Prices of drugs in India are generally low due to indigenous manufacturing capability and low cost base.
- For imported value-added products and new drugs, patients are willing to pay higher prices that for domestically-made products.

THANK YOU

FOR YOUR PARTICIPATION AND ATTENTION

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