

# New Drug Approval (1)

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- ❑ No new drug can be imported or manufactured for sale without the permission of the DCGI.
- ❑ Application in Form 44 with details as per Schedule Y and Appendix I/IA are required, with a fee of Rs. 50,000 (approx. US \$1,115).
- ❑ Data requirements are different for new drugs and for drugs that have already been approved (formulation, bulk drug substance, fixed dose combination, new indications/new dosage form).
- ❑ Information for new drug:
  - Particulars of new drug:
    - ❑ Name dosage form
    - ❑ Composition of formulation
    - ❑ Test specification for active and inactive ingredients
    - ❑ Pharmacological classification
    - ❑ Indications for which it is proposed to be used
    - ❑ Manufacturer of bulk drug substances
    - ❑ Patent status of the drug