

# Import: Registration (1)

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- ❑ All imported regulated devices must be registered by the manufacturer; i.e. registration of both the product and each facility that produces the product.
- ❑ “Manufacturer” is a company, unit or facility that manufactures drugs in a facility outside India, such facility being approved by the national regulatory authority of the country concerned, and with approval by the regulatory authority for free sale of the item within and/or outside the country.
- ❑ Manufacturer must either have a license to manufacture or sell drugs in India **OR** have an agent or importer who has a license.
- ❑ Agent or importer must be a legal entity in India.
- ❑ Application for registration must be submitted by agent/importer duly authorized to do so by power of attorney.