



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Emerging Opportunities for Indian Pharma Companies in the EU

EMA Perspective

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An agency of the European Union



EU-India and Medicines

➤ **Opportunities for Both sides:**

Already a big quantity
of active substances
and medicinal products
in the EU market are
manufactured in India






Marketing pharmaceutical products in the EU

EU Pharmaceutical Legislation:

- Marketing Authorisation
- Traditional Herbal Medicinal Products
- Manufacturing (Good Manufacturing Practice)
- Clinical Trials
- Pharmacovigilance
- ...



EU GMP (or equivalent) for manufacturing of medicines and active substances for the EU market

https://health.ec.europa.eu/medicinal-products/eudralex_en

Regulatory Standards



EU and India Regulatory Standards to be the same or equivalent:

- EMA ready to support
- Active participation of India in international regulators fora (ICH, IPRP, PIC/S, ICMRA)
- Same standards independently of the target market



Thank you for your attention

Further information

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