



EIA Not Needed for Bulk Drug Makers

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Why in News

Recently, the **Ministry of Environment, Forest and Climate Change** has exempted manufacturers of bulk drugs and intermediates from **Environment Impact Assessment** (EIA) till 30th September as an interim measure.

It was done to **expedite clearances** to such manufacturers and intermediaries which are making medicines related to **Covid-19**.

Environment Impact Assessment

- It is a process of **evaluating the likely environmental impacts** of a proposed project or development, taking into account inter-related socio-economic, cultural and human-health impacts, both beneficial and adverse.
- **The United Nations Environment Programme (UNEP)** defines EIA as a tool used to identify the environmental, social and economic impacts of a project prior to decision-making.
- It **aims** to predict environmental impacts at an early stage in project planning and design, find ways and means to reduce adverse impacts, shape projects to suit the local environment and present the predictions and options to decision-makers.
- Environment Impact Assessment in India is **statutorily backed** by the **Environment Protection Act, 1986** which contains various provisions on its methodology and process.

Key Points

- All proposals for projects or activities in respect of **Active Pharmaceutical Ingredients** (API, also called **Bulk Drugs**), received up to the 30th September 2020, shall be appraised as **Category B2 projects**, provided that any subsequent amendment or expansion or change in product mix, after the 30th September 2020, shall be considered as per the provisions in force at that time.

- Rules notified under the **Environment Protection Act, 1986** classify projects into **three categories**:
 - **Category A Projects**- These are appraised by the Union Ministry.
 - **Category B Projects**- These are appraised by the states.
 - **Category B2 Projects**- These are projects which are exempted from EIA and public hearings.
- The drug production and availability to reduce the impact of the **Novel CoronaVirus** are to be ensured as part of a **comprehensive and robust system to handle** the outbreak.

Active Pharmaceutical Ingredients

- These are **significant ingredients** in the manufacture of drugs.
- The **Hubei province of China** is the hub of the API manufacturing industry.
- India is **heavily import-dependent for APIs from China**.
- Recently, the Union Cabinet has approved **two schemes**, namely the scheme on **Promotion of Bulk Drug Parks and Production Linked Incentive (PLI)** Scheme to promote domestic manufacturing of critical Key Starting Materials/Drug Intermediates and Active Pharmaceutical Ingredients in the country.

Source: FE