Role of PSUs in Drug Accessibility

What is the issue?

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- The WHO has invited expressions of interest to produce generic versions of an anti-tubercular drugs.
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- India need to use this opportunity to shore up public sector capacity for making medicines.
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What is international convention for drug accessibility?

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- Compulsory licensing (CL) is a mechanism permitted by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.
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- This enable countries to issue licences to domestic drug manufacturers to produce and market affordable generic versions of life-saving drugs.
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- This allows countries to overcome patent restrictions to assure availability of such drugs when the situation demands.
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- Drugs effective against multi-drug resistant tuberculosis and anti-cancer drugs are clear examples of such a need, which should be addressed through compulsory licensing.
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What is the significant role of India in pharma sector?

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- India is rightly acclaimed to be the pharmacy of the world, with its huge

private sector capacity for producing branded and unbranded generic drugs.
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- India opted for process patenting over product patenting in 1970, this changed to a product patent regime in 2005.
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- This has provided a sufficient time for growth of the generic drug industry in the private sector.
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- India has used the CL route previously to permit two Indian companies, to produce a potent anti-cancer drug nexavar, this enabled a 32-fold reduction in the cost of the drug.
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What are practical concerns with Indian drug industry?

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- **Growth of Private sector -** The growth of Private drug industry has led to the decline and near disappearance of public sector capacity for manufacture of drugs and vaccines.
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- Similarly, drugs for neglected tropical diseases are of little interest to the commercially driven private drug industry.
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- **Patent regulations -** In India the experience of price negotiation with the patent-holding companies is not encouraging, if they do not see evidence of a government’s intent to use the CL route as an imminent possibility.
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- If the domestic private sector drug manufacturers are not ready to apply for CL, public sector capacity to seek and utilise such licences becomes indispensable.
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- **Import of raw materials -** Active pharmaceutical ingredients (APIs), which are needed for drug manufacture (formulation), are now mostly imported from China.
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- This makes India highly vulnerable to disruptions in supply and cost escalations in import.

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What is the role of PSUs in universal drug accessibility?

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- Compulsory licences need to be issued by the government for patent protected drugs or even off-patent drugs which are commercially unattractive to private manufacturers.
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- The role of PSUs will offer an opportunity to produce drug volumes for use in primary and secondary care facilities as well as help in ‘benchmarking’ drug costs.
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- The existence of PSUs would also provide an opportunity to utilise the provision of Compulsory Licensing under TRIPS.
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- Effective implementation of the Ayushman Bharat initiative calls for investment in expanding public sector capacity for producing essential drugs.
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- National security demands with suitable government support and incentives, to ensure uninterrupted and inexpensive availability of APIs is need of the hour.
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- Thus active public sector capacity is needed to ensure that Indians are not denied access to essential drugs.
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Source: The Hindu

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