29 July 2023

FINANCE COMMISSION

GS 2 POLITY
SOURCE: TH

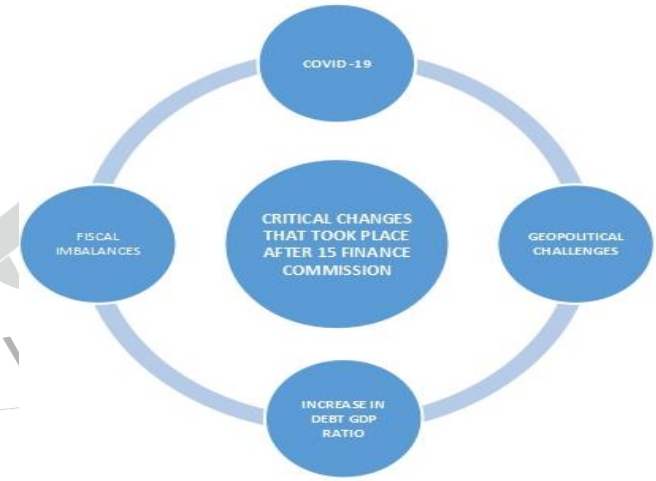
CONTEXT : CHARTING THE PATH FOR 16 FINANCE COMMISSION

The Union government is planning to set up the **16th Finance Commission** during the **fiscal year 2023-24.**

- The commission's main task is to suggest the ratio in which taxes should be divided between **the Centre and states for the five-year period starting from April 1, 2026.**
- The members of the commission and its Terms of Reference (ToR) are currently being determined.

FUNCTIONS OF FINANCE COMMISSION

1**. Division of Net Tax Proceeds**: The Commission recommends the distribution of net tax proceeds between the Centre and the states, and also allocates the same among the states. It determines the basis for sharing divisible taxes and formulates principles for grants-in-aid to the states every five years.



2. Principles for Grants-in-Aid: The Finance Commission defines the principles governing grants-in-aid to the states from the Consolidated Fund of India.

3. **Boosting Resources of Panchayats and Municipalities**: The Commission suggests steps to extend the consolidated fund of the state to enhance the resources of the panchayats and municipalities, based on the recommendations made by the state Finance Commission.

4**. Matters of Sound Finance**: The President can refer any matter related to sound finance to the Commission for consideration.

KEY ISSUES OF FINANCE COMMISSION

1**. Impact of Enhanced Tax Devolution**: The Commission analyses the impact on the fiscal situation of the Union Government due to substantially enhanced tax devolution to States following the 14th Finance Commission's recommendations, alongside national development programs **like New India-2022.**

2**. GST and Compensation**: The Commission assesses the impact of the Goods and Services Tax (GST), including compensation for possible loss of revenues for five years and the abolition of certain cesses.

3**. Progress in Population Growth and Revenues**: The Commission evaluates the efforts made in moving towards a replacement rate of population growth and the progress in increasing tax/non-tax revenues, promoting savings through Direct Benefit Transfers and Public Finance Management System, and fostering the digital economy.

PRELIMS SPECIFIC :

- **ARTICLES :** ARTICLE 280 AND 281
- **CONSTITUED BY**: President in every 5 years.
- **PART OF CONSTITUTION** : PART 12 OF CONSTITUTION
- **Finance Commission (Miscellaneous Provision) Act 1951:** The Act determines the qualifications requisite for appointment as members of the Finance Commission and the manner in which they shall be selected, and to prescribe their powers.
- **COMPOSITION:** composed of a total of five members of which one is the Chairman of the Finance Commission and the other four members of the Finance Commission who are appointed by the President of India**.**
- **ELIGIBLE FOR REAPPOINTMENT**

4. **Progress in Sanitation and Waste Management:**
The Commission reviews the progress made in sanitation, solid waste management, and efforts to end open defecation through behavioural change.

REFORMS WORTH PURSUING:

- Twelfth finance commission recommended for setting up a loan council.
- Sixteenth finance commission should examine subject of non-merit subsidies in detail.
- Finance commission should be strict about states maintaining fiscal deficit within limits.

WAY FORWARD:

Economist C. Rangarajan suggests a comprehensive equalization approach through:

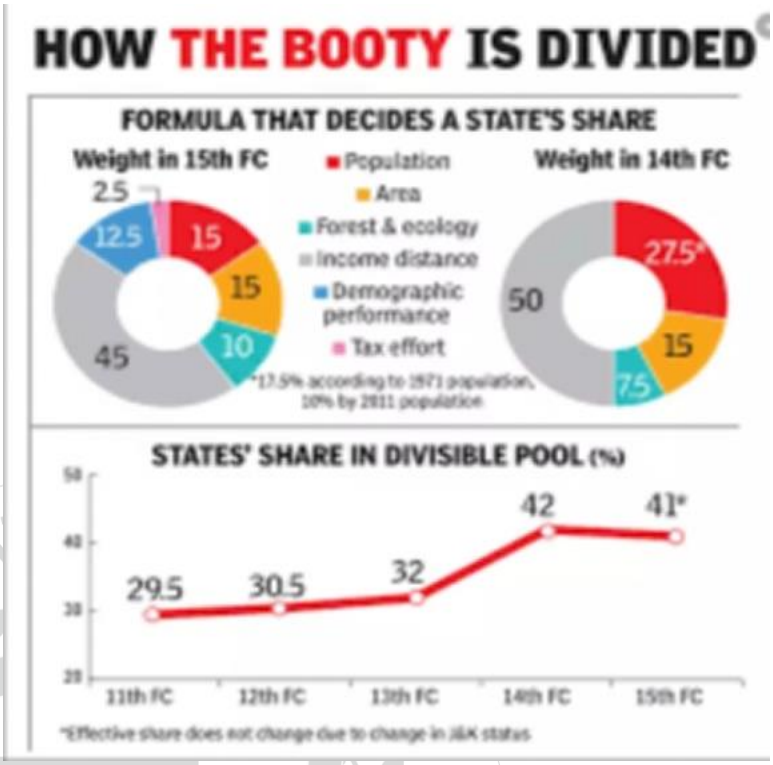
1. Proper estimation of States' fiscal capacities, considering both GST and non-GST taxes.

2. Accurate assessment of expenditure needs, incorporating needs, cost and special requirements of states.

3. Efficient fiscal transfers to ensure equity, balanced regional development, stability, and cooperative federalism.

4. Ensuring adequate resources for socio-economic development, critical infrastructure, and balanced regional development in poorer states.

5. It is important to address the developmental gap among states while providing economic and social services to the population. The central government's role remains crucial in handling issues related to industrial growth, inter-generational concerns, and environmental matters.



BIOSIMILARS

GS 3 SCIENCE AND TECHNOLOGY

SOURCE: TH

Biosimilars are novel versions of original biologic drugs that receive approval after **the patent of the original drug expires.**

Essentially, a biosimilar is a biological medicine that closely resembles another biological medicine that has already been approved (known as the 'reference medicine'). These biosimilars go through **the same rigorous standards of pharmaceutical quality**, safety, and effectiveness that are applicable to all biological medicines.

PRELIMS SPECIFIC :

FEATURES	GENERIC DRUGS	BIOSIMILARS
Composition	Small molecules that are chemically synthesized	Large molecules that are produced from living organisms
Similarity to Reference Drug	Identical	Not identical
Regulatory Approval Proces	Abbreviated New Drug Application (ANDA)	Biologics License Application (BLA)
Cost	Typically 40-50% less than the brand-name drug	Typically 15-20% less than the reference biologic
Availability	Widely available	limited availability

FEATURES OF BIOSIMILAR DRUGS

- **Structure:** Biosimilars are made using the same manufacturing process as the reference biologic, so they have the same overall structure.
- **Function:** Biosimilars have the same biological function as the reference biologic, meaning that they work in the same way to treat the same medical conditions.
- **Clinical safety and efficacy**: Biosimilars have been shown to be safe and effective in clinical trials, with no clinically meaningful differences from the reference biologic.
- **Approval:** Biosimilars are approved by the FDA after rigorous evaluation and testing. This process includes comparing the biosimilar to the reference biologic in terms of structure, function, safety, and efficacy.
- **Cost**: Biosimilars can be a cost-effective alternative to the reference biologic. This is because biosimilars are typically priced lower than the reference biologic, and they can be used to treat the same medical conditions.

ISSUES FACED BY BIOSIMILARS :

- **Regulatory challenges**: The regulatory approval process for biosimilars is complex and time-consuming.
    - For example, the FDA approval process for biosimilars typically takes several years, and the cost of development can reach up to $100 million.
- **Acceptance by healthcare providers**: Some healthcare providers may be hesitant to prescribe biosimilars, even though they have been shown to be safe and effective.
    - For example, a study published in the journal JAMA found that only 38% of physicians were willing to prescribe a biosimilar instead of the reference biologic.
- **Pricing:** Biosimilars are typically priced lower than the reference biologic, but they may not be as affordable as generic drugs.
- **Immunogenicity**: There is a small risk that biosimilars may cause an immune response in some patients. This is because biosimilars are not identical to the reference.
    - For example, a study published in the journal Nature Medicine found that a small number of patients who were treated with a biosimilar to infliximab developed an immune response.

WAY FORWARD

- **Address concerns about safety and efficacy**: These concerns can be addressed through education and outreach, as well as by conducting additional clinical trials.
- **Reduce regulatory barriers**: . Regulatory barriers can be reduced by harmonizing global regulatory standards, as well as by streamlining the approval process.
- **Improve patient access:** These barriers can be addressed by increasing awareness of biosimilars among healthcare providers and patients, as well as by expanding insurance coverage for biosimilars.

VALUE ADDED:

- **The World Health Organization (WHO) has developed a set of guidelines for the development and regulation of biosimilars. These guidelines have helped to harmonize global regulatory standards for biosimilars.**
- Biosimilar medicines in India are regulated by the **Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare (MoHFW).** The CDSCO is responsible for the approval of all drugs in India, including biosimilars.

PESA ACT :

GS 2 POLITY

SOURCE: IE

WHY IN NEWS: The Jharkhand government has released draft rules for public consultation to implement The Provisions of the PESA ACT 1996.

The Panchayats Extension to Scheduled Areas (PESA) Act of 1996 is an Act of the Parliament of India

that extends the provisions of Part IX of the Constitution of India relating to Panchayats to the Scheduled Areas. The Act was enacted to provide for self-governance through Gram Sabhas (village assemblies) for people living in Scheduled Areas.

KEY PROVISIONS OF PESA ACT

Gram Sabha's: The Gram Sabha is the highest decision-making body in a Scheduled Area. It is made up of all adult members of the village. The Gram Sabha has the right to manage natural resources, prevent alienation of land, restore alienated land, establish institutions of self-government, and participate in planning and implementation of development programmes.

Panchayats: Panchayats are local government bodies that are elected by the people of a Scheduled Area. Panchayats have the power to make laws and regulations, collect taxes, and provide services to the people.

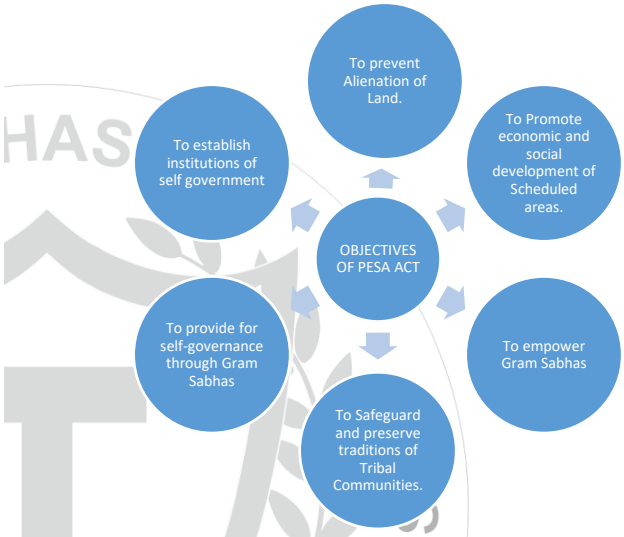
State Governments: State Governments have the responsibility to implement the PESA Act. They must ensure that Gram Sabhas and Panchayats are able to exercise their powers and functions effectively.

PRELIMS SPECIFIC :

1. The PESA Act, passed in 1996, aims to extend the regulations stated in Part IX of the Constitution, which pertain to Panchayats, to the Scheduled Areas.
2. According to the PESA Act, Scheduled Areas are defined as per **Article 244(1),** where the application of the
3. . Part IX of the Constitution, which consists of Articles 243 - **Fifth Schedule is extended to the Scheduled Areas and Scheduled Tribes in states excluding Assam, Meghalaya, Tripura, and Mizoram.**243 ZT, covers legislation related to municipalities and cooperative societies in addition to Panchayats
4. Scheduled Areas are areas identified by **the Fifth Schedule of the Constitution of India.** Scheduled Areas are found in ten states of India which have predominant population of tribal communities.
5. PESA was enacted **on 24th December, 1996** to extend the provisions of Part IX of the Constitution to Scheduled Areas, with certain exceptions and modifications

ISSUES FACED BY PESA ACT

- **Lack of awareness**: Many tribal communities are not aware of their rights under the PESA Act. This can make it difficult for them to exercise their rights and can lead to exploitation by others.
- **Lack of capacity**: Many Gram Sabhas lack the capacity to effectively exercise their powers and functions under the PESA Act. This is due to a lack of resources, training, and support.
    - In 2022, a report by the National Foundation for India found that only 20% of Gram Sabhas in Scheduled Areas have been able to exercise their rights under the PESA Act.
- **Lack of political will**: Some state governments have been reluctant to implement the PESA Act fully. This is due to a number of factors, including vested interests and a lack of understanding of the Act.
- **Land alienation:** There have been reports of land alienation in Scheduled Areas, even in areas where the PESA Act is in force. This is due to a number of factors, including poverty, ignorance, and the influence of non-tribals.
- **EG:** In 2020, a report by the National Commission for Scheduled Tribes found that there have been reports of land alienation in Scheduled Areas, even in areas where the PESA Act is in force.



Resource extraction: There have been reports of resource extraction in Scheduled Areas without the consent of the Gram Sabhas. This is due to a number of factors, including the lack of monitoring and enforcement of the PESA Act.

EG: In 2019, a study by the Centre for Policy Research found that there have been reports of resource extraction in Scheduled Areas without the consent of the Gram Sabhas.

WAY FORWARD

1. **The Bhuria Committee**: Constituted in 1994 to review the implementation of the PESA Act. The Committee recommended that the Act be amended to clarify the powers and functions of Gram Sabhas, and to strengthen the role of the State Governments in implementing the Act.
2. **The Soni Sori Committee:** Constituted in 2011 to investigate the alleged violation of the PESA Act in Chhattisgarh. The Committee found that the Act was not being implemented effectively in Chhattisgarh, and recommended that the State Government take steps to ensure that the Act is implemented in letter and spirit.
3. **The National Advisory Council**: The NAC has recommended that the Act be amended to include provisions for the protection of the rights of women and children in Scheduled Areas.