

IMPORTANT NEWS

Enhanced Good Manufacturing Practices Standards for Effective Governance

Inside Story of the News:

In recent times, the Indian government has instructed all pharmaceutical firms to **adopt the Revised Good Manufacturing Practices (GMP), aligning their procedures with international standards**. Larger companies with a turnover exceeding Rs 250 crore must incorporate these changes within six months, while smaller and medium-sized enterprises with turnovers under Rs 250 crore are given a year to do the same.

- GMP serves as a framework to ensure consistent production and control of products in accordance with quality criteria.
- Its **purpose is to reduce inherent risks in pharmaceutical manufacturing** that cannot be eliminated through final product testing.
- The introduction of the GMP system incorporated in India 1988 when it was included in **Schedule M of the Drugs and Cosmetics Rules, 1945**, with the most recent update in June 2005.
- The revised Schedule M now includes **WHO-GMP standards**.
- The World Health Organization (WHO) has established comprehensive GMP guidelines.
- Various nations have developed their own GMP requirements based on WHO GMP guidelines.
- Some have aligned their regulations, such as the **Association of South-East Asian Nations (ASEAN), the European Union, and the Pharmaceutical Inspection Convention**.

Key Revisions in Updated GMP Guidelines:

- The updated GMP focus on **enhancing quality control measures, precise documentation, and IT support to uphold the excellence of produced medicines**.
 - Companies are now obligated to integrate quality risk management practices to recognize potential threats to their product quality and take suitable preventive measures.
 - Routine quality assessments of all products are stipulated to ensure uniformity in quality and procedures.
- Accelerated stability tests might be conducted to appraise product stability under expedited conditions.
- This involves maintaining drugs in stability chambers at specified temperatures and humidity levels to assess their stability over time.
- Accelerated stability tests may be conducted to assess the product's stability under accelerated conditions.
- The novel guidelines underscore the utilization of computerized systems for overseeing GMP-associated processes.
 - These systems are tailored to deter data manipulation, unauthorized entry, and data omission.
 - They also automatically document all steps and verifications to guarantee conformity to procedures without any tampering.
- The fresh Schedule M outlines prerequisites for additional product types, encompassing biological products, substances with radioactive components, or plant-derived items.

- The new directives delineate prerequisites for investigational products manufactured for clinical trials.
 - This assures that products utilized in clinical trials satisfy the requisite quality and safety benchmarks.

Rationale Behind the Revised GMP Guidelines:

- Instances have arisen where nations have reported suspected contamination in syrups, eye-drops, and eye ointments manufactured in India.
 - To illustrate, the fatalities of 70 children in the Gambia, 18 children in Uzbekistan, and 3 individuals in the US have been associated with these products.
- Presently, out of the total 10,500 drug manufacturing facilities within the country, merely 2,000 are in alignment with global norms, carrying WHO-GMP certification.
- Through risk-based inspections, numerous shortcomings were identified in 162 manufacturing units across India.
 - These deficiencies encompass insufficient testing of raw materials, absence of product quality assessments, infrastructure challenges, and a scarcity of qualified professionals.
- The heightened standards will guarantee that pharmaceutical enterprises adhere to established procedures, quality control protocols, and abstain from taking shortcuts, ultimately enhancing the quality of medicines accessible both in India and on the global market.
- Furthermore, this will elevate the quality of medications in the domestic sector.
- The majority of the 8,500 manufacturing units without WHO-GMP certification currently supply medicines within India.

Bill to Amend the Government of National Capital Territory of Delhi Act, 2023

Inside Story of the News:

Recently, the central government has introduced **the Government of National Capital Territory of Delhi (Amendment) Bill, 2021, in the Lok Sabha**. This bill seeks to make amendments to the Government of National Capital Territory of Delhi Act, 1991, with the objective of "further defining the roles and responsibilities of the elected government and the Lieutenant Governor (LG) in Delhi."

- In 1991, the Constitution was amended **by adding Article 239 AA**.
- This amendment, in line with the recommendations of the **S Balakrishnan Committee (1987)**, conferred a special status upon Delhi.
- According to this provision, the National Capital Territory (NCT) of Delhi would have both an Administrator and a Legislative Assembly.
- Simultaneously, the Government of National Capital Territory of Delhi (GNCTD) Act was enacted to complement the constitutional provisions concerning the Assembly and the Council of Ministers in the national capital.
- **In practical terms, the GNCTD Act delineates the Assembly's powers, the discretionary authority held by the LG, and the Chief Minister's responsibilities, particularly in terms of providing information to the LG.**
- In a 2018 judgment, a five-judge Bench determined that the LG's consent is only necessary for matters pertaining to police, public order, and land.

- The court further clarified that decisions made by the Council of Ministers must be communicated to the LG.
- However, the LG's decisions were to be based on the guidance and recommendations of the council of ministers.
- The court also emphasized that the LG of Delhi does not hold the same status as a State Governor but functions as an Administrator, albeit with the title of Lieutenant Governor, and within specific boundaries.
- Bolstered by the Supreme Court's ruling, the elected government ceased forwarding executive matter files to the LG prior to executing decisions.
- The elected government has maintained the LG informed about administrative developments but not necessarily before carrying out or implementing decisions.
- However, if approved, the amendment will compel the elected government to seek the LG's counsel before acting on any cabinet decision.

Contents of the Legislation:

- **National Capital Civil Services Authority:**
 - The introduced Bill establishes **the National Capital Civil Services Authority, which is designed to provide recommendations to the LG concerning specific matters pertaining to services.**
 - These matters encompass:
 - (i) transfers and appointments,
 - (ii) issues linked to vigilance,
 - (iii) procedures for disciplinary actions, and
 - (iv) sanctions for prosecution of Group A of All India Services (excluding the Indian Police Service) and DANICS.
 - The composition of the Authority will comprise:
 - (i) the Chief Minister of Delhi in the capacity of Chairperson,
 - (ii) the Principal Home Secretary of the Delhi government as the Member Secretary, and
 - (iii) the Chief Secretary of the Delhi government as a member.
 - The appointment of both the Principal Home Secretary and Chief Secretary will be carried out by the central government.
- **Powers of the Lieutenant Governor:**
 - According to the Act, situations in which the LG may exercise his own judgment encompass:
 - (i) matters falling outside the legislative authority of the Delhi Legislative Assembly but assigned to the LG, or
 - (ii) situations where he is legally obligated to make decisions based on his own judgment or perform any judicial or quasi-judicial tasks.
 - The Bill specifically **stipulates that in such circumstances, the LG will make decisions solely at his own discretion.**
 - This legislation broadens the discretionary role of the LG by conferring upon him the authority to endorse the recommendations made by the authority or send them back for further review.
 - In scenarios where a divergence of opinions arises between the LG and the Authority, the verdict of the former will ultimately prevail.

- **Disposal of matters by Ministers:**
 - A minister within the Delhi government holds the authority to establish standing directives for the resolution of issues brought to their notice.
 - These directives must be formulated in collaboration with the relevant Department Secretary.
 - Specific matters necessitate submission to the LG, facilitated through the Chief Minister and the Chief Secretary, for his input before any directive is issued.
- **Duties of Secretaries:**
 - Furthermore, the pertinent Department Secretary is obligated to bring specific issues to the attention of the LG, the Chief Minister, and the Chief Secretary.
 - These matters encompass situations that could potentially lead to disputes between the Delhi Government and the central or any state government, as well as the Supreme Court or the High Court of Delhi.

Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY): Overview and Significance

Inside Story of the News:

Recently, a performance audit report from **the Comptroller and Auditor-General of India (CAG)** has **raised concerns about irregularities in the Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (PMJAY)**. The CAG's audit report on the Performance Audit of AB-PMJAY, which was presented in the Lok Sabha, **indicated that a total of 7,49,820 beneficiaries were linked to a single mobile number in the scheme's Beneficiary Identification System (BIS)**.

- PJ-MAY stands as **the world's largest government-funded health insurance initiative**.
- Introduced in February 2018, it provides a coverage of Rs.5 lakh per family for both secondary and tertiary care.
- The program operates on an entitlement basis, targeting beneficiaries as identified by the most recent Socio-Economic Caste Census (SECC) data.
- The National Health Authority (NHA) has granted states and union territories the flexibility to use non-SECC beneficiary family databases with comparable socio-economic profiles to tag against the remaining (unverified) SECC families.
- The scheme aims **to extend coverage to 10.74 crore underprivileged rural families and identified categories of urban workers' families**.
- An examination of data revealed that in 43,197 households, family sizes were unrealistically high, ranging from 11 to 201 members.
- Within the treatment specified by the Scheme, 88,760 patients lost their lives.
- A total of 2,14,923 claims registered as paid in the system were associated with new treatment for these patients.
- Some retirees in certain states possessed PMJAY cards and were utilizing the scheme for medical treatment.
- Lapses in promptly removing ineligible beneficiaries from the scheme resulted in ineligible individuals receiving benefits under PMJAY.
- The National Anti-Fraud Unit sent periodic reminders to the States/UTs highlighting disparities in validated data.

- Instances were found where pensioners in Chandigarh, Haryana, Himachal Pradesh, Karnataka, Maharashtra, and Tamil Nadu held PMJAY cards and were availing treatment under the program.
- The audit revealed that delayed actions to eliminate ineligible beneficiaries led to ineligible persons taking advantage of the Scheme and excessive premiums being paid to insurance companies.

National Social Assistance Programme (NSAP)

Inside Story of the News:

The Ministry of Rural Development (MoRD) redirected funds from the National Social Assistance Programme (NSAP) to promote some of its other initiatives. This observation was brought to light in the Comptroller and Auditor General of India's (CAG) performance audit report on NSAP spanning from 2017-18 to 2020-21, which was recently presented in the Lok Sabha.

- Initiated in 1995 as a Centrally Sponsored Scheme by the MoRD, Government of India.
- It extends financial aid to elderly individuals, widows, persons with disabilities, and families who have lost their primary breadwinner, all falling under the Below Poverty Line (BPL) category.
- This assistance is provided in the form of social pensions.
- The program aligns with Article 41 of the Indian Constitution, a significant stride towards fulfilling Directive Principles.
- It stipulate the State's duty to provide public support to citizens facing unemployment, old age, illness, disability, etc., considering the limits of economic capacity and development.
- The Ministry of Rural Development (MoRD) diverted funds intended for NSAP, allocated for pension disbursement, towards promotional campaigns for other schemes managed by the ministry.
- The funds assigned for NSAP were earmarked for pension distribution and administrative costs, with 3% reserved for the latter.
- Starting in 2017, the MoRD initiated an advertising campaign through billboards to raise awareness about various ministry programs.
- A budget of Rs 39.15 lakh was sanctioned for billboards, and an amount of Rs 2.44 crore was sanctioned for campaigns spanning multiple states.
- The CAG's findings indicated that the advertising work orders did not encompass NSAP schemes, focusing instead on initiatives like Pradhan Mantri Awaas Yojana - Gramin (PMAY-G) and Deen Dayal Upadhyaya Grameen Kaushalya Yojana (DDU-GKY).
- The funds for this campaign were stated to be accessible through the National Rural Employment Guarantee Scheme and were authorized by competent authorities for expenditure under the same category.
- However, the audit identified that the funds were drawn from social security welfare-NSAP schemes.
- Consequently, intended Information, Education, and Communication (IEC) activities under NSAP were not executed as planned, and a sum of Rs 2.83 crore was diverted to promote other schemes under the ministry's purview.
- The MoRD, in its response, stated that the issue had been taken up with the department's IEC division.

- The CAG also reported the redirection of Rs 57.45 crore across six states/union territories, namely Rajasthan, Chhattisgarh, Jammu and Kashmir, Odisha, Goa, and Bihar.
- For example, in Rajasthan, NFBS funds were rerouted to cover insurance premiums with LIC for BPL and Aastha Card holders under the Pannadhay Jeevan Amrit Yojana (Aam Aadmi Beema Yojana).

Inter-Services Organization Bill Gets Approval from Rajya Sabha

Inside Story of the News:

The Inter-Services Organisation (Command, Control & Discipline) Bill – 2023 has been approved by the Rajya Sabha. This bill had already been endorsed by the Lok Sabha on August 4. This legislation bestows disciplinary and administrative authority upon the commander-in-chief and the officer-in-command of inter-services organizations concerning personnel from other services who are serving within these organizations.

- The framework is anticipated to encompass five joint services commands, specifically the western, eastern, northern, maritime, and air defence commands.
- The central government possesses the authority to establish an Inter-Services Organisation, which might incorporate a Joint Services Command.
- This measure will authorize the Commander-in-Chief/Officer-in-Command of Inter-Services Organizations to uphold discipline and ensure the appropriate fulfilment of responsibilities by personnel from the army, navy, and IAF who serve under their command.
- The Commander-in-Chief or Officer-in-Command of an Inter-Services Organisation will assume leadership of the said organization.
- Presently, soldiers from distinct services are governed by separate Acts of Parliament, namely the Navy Act of 1957, the Air Force Act of 1950, and the Army Act of 1950.
- The first Tri-Service theatre command of the Indian Armed Forces is located in Andaman and Nicobar Islands, specifically at Port Blair. It functions as a joint command.
- As a result, any disciplinary or administrative measures concerning personnel attached to these establishments necessitate reference to their respective services.
- The enactment of this Bill will secure effective discipline within inter-services establishments through the leadership of their heads.
- There will no longer be a necessity to refer personnel undergoing disciplinary proceedings to their parent services.
- Moreover, this measure will expedite the resolution of cases involving misconduct or indiscipline.

Introduction of Three New Bills in Lok Sabha for Criminal Law Reforms

Inside Story of the News:

The Centre has introduced **three new Bills in the Lok Sabha that propose a complete overhaul of the country's criminal justice system.** The three Bills are set to replace the Indian Penal Code (IPC), 1860; the Code of Criminal Procedure (CrPC), 1973 and the Indian Evidence Act, 1872. **IPC is set to be replaced by the Bharatiya Nyaya Sanhita, 2023. The CrPC will be replaced by the Bharatiya Nagarik Suraksha Sanhita, 2023. The Indian Evidence Act will be replaced by the Bharatiya Sakshya Bill, 2023.**

- The Indian Penal Code (IPC) is India's official criminal code, originally drafted in 1860 following the establishment of the first law commission in 1834 under the Charter Act of 1833.
- The Code of Criminal Procedure (CrPC) outlines the procedures for administering criminal law in India.
- It was enacted in 1973 and took effect on April 1, 1974.

Proposed Amendments in the Bhartiya Nyay Sanhita Bill, 2023: An Overview

- The presented legislation outlines the definition of terrorism and encompasses activities like separatism, armed rebellion against the government, and challenging the nation's sovereignty.
- These were previously addressed through various legal provisions.
- In a move that has garnered widespread approval, the bill abolishes the offense of sedition, which had been widely criticized for its association with colonial times and its potential to stifle freedom of expression and dissent.
- Within the bill, there is a provision for imposing a 10-year prison sentence for engaging in sexual intercourse with women under false promises of marriage. This addresses a prevalent form of deceit and exploitation.
- The bill incorporates community service as an alternative for certain crimes.
- This innovation not only offers an opportunity for the reformation of offenders but also contributes to alleviating the issue of prison overcrowding.
- One significant inclusion in the bill is the establishment of a 180-day time limit for filing a charge sheet.
- This provision is aimed at expediting the trial process and preventing undue delays.

Proposed Amendments in the Bhartiya Nagrik Suraksha Sanhita Bill, 2023: An Overview

- As per the provisions of the Code, if an individual who is accused of a crime has been detained for less than half of the maximum imprisonment term specified for that offense, during either the investigation or trial, they must be released upon furnishing a personal bond.
- The presented Bill establishes that all legal proceedings, inquiries, and trials can be conducted using electronic means.
- The Code permits the medical examination of the accused in specific instances, including cases of rape. This examination is performed by a registered medical practitioner upon the request of a police officer of at least the sub-inspector rank. The newly proposed Bill, however, grants any police officer the authority to make such a request.
- The Bill mandates forensic investigation for offenses that are punishable by a minimum of seven years of imprisonment.
- Under the Code, a Metropolitan/Judicial Magistrate is granted the power to direct any individual to provide samples of their signatures or handwriting.
- Incorporating clear timelines for various procedures, the Bill demands that medical practitioners who conduct examinations on rape victims submit their reports to the investigating officer within a span of seven days.
- The Bill introduces provisions for the conduct of trials and the issuance of judgments in cases where a person has been declared a proclaimed offender but is absent during the proceedings.

Proposed Amendments in the Bhartiya Nagrik Suraksha Sanhita Bill, 2023: An Overview

- The upcoming Bill is covered to replace the Indian Evidence Act and entails modifications to 23 existing provisions while introducing one new provision.
- The comprehensive Bill encompasses a total of 170 sections.
- Within the scope of this Bill, electronic or digital records will be recognized as admissible evidence, carrying legal weight akin to that of documentary evidence.
- The definition of secondary evidence has been broadened to encompass various forms, including copies generated via mechanical processes from the original, copies derived from or compared against the original, document counterparts relative to parties who did not sign them, and verbal depictions of document contents provided by an individual who has directly witnessed them.

India's Foreign Exchange Reserves Decline by USD 2.42 Billion to USD 601.45 Billion

Inside Story of the News:

India's foreign exchange reserves have experienced **a decline for the third consecutive week, contracting by USD 2.417 billion to reach a total of USD 601.453 billion as of August 4**. This information has been reported in the Weekly Statistical Supplement released by the RBI. In the preceding week of reporting, the overall reserves witnessed a reduction of USD 3.165 billion, bringing the total to USD 603.87 billion.

- Foreign exchange reserves, also known as forex reserves, encompass assets like **foreign currencies, gold reserves, treasury bills, etc., held by a central bank or another monetary authority**.
- The RBI holds the responsibility of safeguarding India's foreign exchange reserves.
- The RBI monitors balance of payments and exerts influence on the foreign exchange rate of the country's currency, thereby ensuring stability in financial markets.
- One of its pivotal roles is to guarantee that the RBI possesses backup funds in the event of rapid devaluation or insolvency of the national currency.
- The reserves' key component, foreign currency assets, recorded a decline of USD 1.937 billion, marking a total of USD 533.40 billion.
- These foreign currency assets, expressed in terms of dollars, take into account the impact of appreciation or depreciation of non-US currencies like the euro, pound, and yen held within the foreign exchange reserves.
- During the reported week, gold reserves experienced a decrease of USD 224 million, settling at USD 44.68 billion.
- Special Drawing Rights (SDRs) saw a decrease of USD 171 million, leading to a total of USD 18.274 billion.
- The country's reserve position with the IMF dropped by USD 86 million, bringing the total to USD 5.099 billion.