1. What are the accountability and oversight measures in the budgeting processing of the Central Government? Explain.
केंद्र सरकार के बजट प्रसंस्करण में जवाबदेही और निगरानी के उपाय क्या हैं? समझाएं।

Demand of the question:

It expects students to write about the accountability and oversight measures in the budgeting process of central government.

Introduction:

India has been placed at 53rd position among 117 nations in terms of budget transparency and accountability, according to the Open Budget Survey. The survey, conducted by International Budget Partnership (IBP), has provided India's Union Budget process a transparency score of 49 out of 100, which is higher than the global average of 45.

Body:

The expenditure of the central government has increased from Rs 3.3 lakh crore in 2000-01 to Rs 30 lakh crore in 2020-21. With the objective of improving the quality of life of citizens, these public funds are spent across various sectors such as defence, security, agriculture, health, social welfare, education, and infrastructure.

Members of Parliament (MPs) have a core role in examining how this money is being raised, how it is planned to be spent, and whether such spending would lead to desired outcomes.

Accountability and Oversight through the Union Budget:

- Parliamentary oversight of public funds broadly involves two functions, scrutinising and sanctioning the government's expenditure and taxation proposals through the Union Budget; and examining the utilisation of funds that have been allocated for various activities, through parliamentary committees.
- Legislative control over the budget can be exercised through the General discussion on the budget, after it is presented in the Parliament. Discussion at this stage is limited to general examination of the budget and proposals of the government. At the end of the discussion, the Finance Minister gives a reply.
- After which, parliamentary standing committees which has both members of Lok Sabha and Rajya Sabha a examine detailed estimates of expenditure of all ministries, called Demands for Grants.
- One of the functions of Standing Committees is to scrutinise the allocation of funds to the ministries under their supervision. At present, there are 24 Standing Committees that together oversee the work of all the ministries. For instance, the Standing Committee on Defence scrutinises the Demands for Grants of all departments under the Ministry of Defence. Budgeted

expenditure for defence stands at 4.71 lakh crore which is higher by 5% than revised estimates of 2019-20.

- These Committees examine the amount allocated to various programmes and schemes under the Ministry, and trends of utilisation of the money allocated to the Ministry.
- In doing so, officials of the Ministry are required to depose before the Committee to respond to queries and provide additional information in connection with the Demands for Grants being examined. While examining a ministry's expenditure, the Committees may consult or invite views from experts.
- Committee's report to parliament creates condition for informed debate on the budget involving Cut Motions and Voting on Demands for Grants, prior to the beginning of the next fiscal year.
- Passing of the Finance Bill and the Appropriation Bill without which the Government will not have the constitutional authority to collect tax revenue and to spend money from the Consolidated Fund.
- Parliamentary Committees dealing with the financial affairs of the government, viz. The Public Accounts Committee, the Estimates Committee, and the Committee on Public Undertakings.

However, Budget transparency and accountability assumes greater significance during the times of the COVID-19 pandemic,

- As a sizable chunk of public expenditure is likely to get financed by higher magnitudes of government borrowing not just in the current fiscal but in the subsequent couple of years too.
- Union Government should also publish a Pre-Budget Statement, which can be scrutinised by the legislators and the public at large before the annual budget is presented.
- Creating an integrated budget and expenditure information architecture at every district headquarter and enabling the District Development Coordination and Monitoring Committee to use this information to enforce accountability of the executive for budget implementation, will substantially improve budget transparency and accountability at the district level in the country.

Conclusion:

The Union Budget is perhaps the most important and comprehensive platform for the Central Government to implement its economic policies. It affects almost every sector of the economy as well as every section of the population. The policies driving the budget and implementation of the budget proposals are therefore of direct relevance to the entire population which needs to be reformed to bring accountability and stringent parliamentary oversight.

2. What do you understand by fiscal targeting? What is its significance for the economy in general? Illustrate.

राजकोषीय लक्ष्यीकरण से आप क्या समझते हैं? अर्थव्यवस्था के लिए इसका क्या महत्व है? उदाहरण देकर स्पष्ट करें।

Demand of the question:

It expects students to write about the concept of Fiscal targeting and its significance for the economy in general.

Introduction:

Fiscal targeting assumes more importance as many countries adopted stimulus measures to deal with economic slowdown. However, excess liquidity may carry a high social cost. Beyond the usual fears about debt and inflation, there is also good reason to worry that the excess cash in banks will be funnelled toward financial speculation, leading to still more precautionary behaviour, and discouraging both consumption and the investment needed to drive the recovery.

Body:

Fiscal targeting:

- Fiscal deficit targeting is also known as fiscal targeting to achieve objective of fiscal consolidation. India follows obligation under FRBM act to limit its fiscal deficit in prescriptive manner and adopt various strategies to deal with fiscal deficit.
- The FRBM Act, aimed at establishing financial discipline, provides for a trigger mechanism for a deviation from the estimated fiscal deficit on account of structural reforms in the economy with unanticipated fiscal implications.
- Fiscal targeting resolves around judicious and balanced call keeping in mind the need to support the economy on one hand and the sustainable level of fiscal deficit that is consistent with macroeconomic and financial stability on the other.
- Centre's fiscal deficit in 2020-21, as things stand now, could be 1.7-1.8 percentage points higher than the 3.5% of GDP, which was targeted in the Budget, said Chief Economic Advisor Krishnamurthy Subramanian in June. Assumption of Fiscal deficit to be 5.2 -5.3% of GDP is based on 10% nominal GDP growth, which would have been tough without COVID-19 outbreak.

However, the Indian economy seems caught between tight fiscal targets prescribed under the FRBM (Fiscal Responsibility and Budget Management) review and a government which treats them as cast in stone, even at a time when the economy is reeling under the impact of the COVID-19 crisis.

Significance of fiscal targeting for economy:

- In the absence of fiscal targeting, higher fiscal deficit for an economy means increased government borrowing, which in turn implies higher interest

burden. India has a debt-to-GDP ratio of 70%, which is the highest among its emerging market peers.

- Even though, Most of India's government debt is internal (from domestic market), implying less external vulnerability. Nevertheless, high government debt implies high interest burden and the threat of economic instability.
- Many of the developed economies like the US and Japan have much higher debt-to-GDP ratio. However, their interest burden is much less as their governments are borrowing at much lower interest rates.
- The other disadvantage of a high debt-to-GDP ratio is that it has an impact on the country's credit ratings and investor sentiments.
- Higher government borrowing crowds out private investment in the economy.
- While there is no doubt that the government should be fiscally prudent, what is being increasingly debated is whether our fiscal management should be counter-cyclical. This means that when economic growth is above potential, policymakers should reduce fiscal deficit. Similarly, when economic growth is poor, fiscal deficit should be allowed to expand (within a ceiling) in order to support economic growth.
- While it is ideal to have a rule-based fiscal consolidation path, experience shows that there are threats of genuine disruptions. Like present COVID-19 pandemic recession following a fiscal deficit target under present circumstance could result in adverse impact on developmental expenditure.
- However there is need to be more prudent in not allowing unproductive expenditure on populist measure.

Conclusion:

In the present COVID-19 pandemic induced slowdown, governments have to consider paradox of thrift and spend more. However, all measures should be well targeted to optimise the outcome. There is need to maintain balance between expansionary austerity and fiscal slippage.

3. What are the risks associated with the development cycle of a medicine or vaccine? What are the regulatory provisions to ensure drug safety in India? Examine.
किसी दवा या वैक्सीन के विकास चक्र से जुड़े जोखिम क्या हैं? भारत में दवा सुरक्षा सुनिश्चित करने के लिए नियामक प्रावधान क्या हैं? जांच करें।

Demand of the question:

It expects students to write about the risk associated with the development of medicine or vaccine along with regulatory provisions to ensure drug safety in India.

Introduction:

The University of Oxford and AstraZeneca Plc.'s experimental vaccine is the first to enter the final stages of clinical trials to assess how well it works in protecting people

from becoming infected by the virus that causes the corona virus disease (Covid-19), which has infected 9.4 million and killed 480,000 globally since late December.

Body:

There were 13 experimental vaccines in clinical trials and another 129 in the preclinical evaluation stage on June 22, according to the World Health Organisation's draft landscape of Covid-19 vaccines.

Risk associated with development cycle of a medicine or vaccine:

- There are two kinds of risk associated with the development of medicine or vaccine. First is associated with the developer of drug or vaccine whereas second associated with the process of development and use of medicine or vaccine.
- Risks to developer: Cost of research and development (R&D), biological and technical challenges associated with targeting more complex diseases, competition with better standards of care, larger scale of clinical studies to prove safety and efficacy and last but not least an increasingly stringent regulatory environment.
- There is chance of too many resources of pharmaceutical companies might get wasted in development of one particular drug or vaccine in competition with others.
- Vaccine development, on average, takes 10.71 years from the preclinical phase, and has a success rate of 6%, according to a study in the science journal, PLOS One. Some remain elusive for decades despite massive investments, like for vaccines against HIV, the virus that causes AIDS.
- There is always chance of retreat of disease even before the development of medicine or vaccine dedicated for that disease which might led to financial disaster.
- Risks associated with processes and use: Scientists and medical experts are concerned that rushing a vaccine could end up worsening the infection in some patients rather than preventing it.
- Risk of vaccine enhancement, where instead of protecting against infection, the vaccine can actually make the disease worse when a vaccinated person is infected with the virus. The mechanism that causes that risk is not fully understood and is one of the stumbling blocks that has prevented the successful development of many vaccines
- Researchers would take months to test for the possibility of vaccine enhancement in animals. Given the urgency to stem the spread of the new corona virus, some drug makers are moving straight into small-scale human tests, without waiting for the completion of such animal tests.
- There is a risk of immune enhancement: Some vaccinated animals developed more severe disease compared with unvaccinated animals when they were exposed to the virus during previous SARS outbreak trials.
- The best-known example occurred in a U.S. trial in the 1960s of a vaccine created by the NIH and licensed to Pfizer Inc to fight respiratory syncytial virus

(RSV), which causes pneumonia in infants. The vast majority of babies who received the vaccine developed more severe disease, and two toddlers died.

- A more recent example occurred in the Philippines, where some 800,000 children were vaccinated with Sanofi's dengue vaccine, Dengvaxia. Only afterward did the company learn that it could increase the risk of more severe disease in a small percentage of individuals.
- Study of side effects: It might take long time to gauge side effects among vaccinated set and genetic susceptibility of drug or vaccine.
- Vaccine derived virus: Example of vaccine derived polio virus, on rare occasions, if a population is seriously under-immunized, an excreted vaccine-virus can continue to circulate for an extended period of time. The longer it is allowed to survive, the more genetic changes it undergoes. In very rare instances, the vaccine-virus can genetically change into a form that can paralyse known as a circulating vaccine-derived poliovirus (cVDPV).
- Ethical challenge: If we could develop a drug or an antibody that would be able to mitigate the disease, we would still need to think about the ethical concerns of a human challenge. There's also the question of who volunteers for such a challenge. There's been a whole history extremely fraught where minorities were used as experimental subjects without their understanding or consent.

Regulatory provisions for drug safety in India:

- Under the Drug and Cosmetics Act, 1940 (latest amendment in 1995) subsequent Drugs and Cosmetic Rules, 1945 the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities.
- While the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
- Drug Controller General of India is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.
- Demonstration of safety and efficacy of the drug product for use in humans is essential before the drug product can be approved for import or manufacturing and marketing in the country.
- After preliminary evaluation of application(if goes well), regulatory evaluation starts with the permission to conduct BE-Bioequivalence and Permission to conduct CT-chemical trial, then SEC-Subject expert committee reviews it and give NOC certificate then again review of BE/CT report.
- Simultaneously, after review of CMC-Chemistry and manufacturing control data; if satisfactory IPC-Indian Pharmacopeia commission testing NOC to applicant. After completion on both front DCGI can inspect on-site facility.
- DCGI instituted a system of review by a Subject Expert Committee (SEC) in 2012 to decide whether a new drug should be approved for the Indian market. The SEC was meant to have external experts who were specialists in the field of

therapy being considered. After a SEC approval, the DCGI is required to take the final call on whether to approve a drug.

- All clinical trials conducted in India to be prospectively registered, i.e. before the enrolment of the first participant to Clinical Trail Registry of India.
- The Clinical Trials Registry- India hosted at the ICMR's National Institute of Medical Statistics is a free and online public record system for registration of clinical trials being conducted in India. Initiated as a voluntary measure later trial registration in the CTRI has been made mandatory by the Drugs Controller General India (DCGI).
- An Ethics Committee is a committee comprising of medical, scientific, non-medical and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial and it shall be responsible for reviewing and approving the protocol, the suitability of the investigators, facilities, methods and adequacy of information to be used for obtaining and documenting informed consent of the study subjects and adequacy of confidentiality safeguards.

Conclusion:

All the forces of medical and pharmaceutical fraternity are working together against the common enemy- corona virus. Unprecedented collaboration at world level will certainly reduce the time of medicine or vaccine development however utmost care and caution necessary to mitigate humanitarian and financial risks associated with development of medicine and vaccine.